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Transcript of Proceedings

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

- - -

Twenty-seventh Meeting

of the

NATIONAL ADVISORY COUNCIL ON REGIONAL MEDICAL PROGRAMS

Rockville, Maryland
Monday, 5 June 1972

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Parklawn Building
Conference Room "M"
Rockville, Maryland

Monday, 5 June 1972

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P R O C E E D I N G S

DR. MARGULIES: If we can all have our seats, the
meeting will come to order.

I would like to call your attention to the agenda
book which is the basic text that we will follow during the
course of the next two days and particularly ask you to note
the statements on confidentiality of meetings and the conflict
of interest statement which are in there so that these instruc-
tions will be preserved during the course of the meeting and
thereafter.

Before beginning the main part of the discussion for
the day, there are some people I would like to introduce if you
have not already met them because we do have some new members
of the National Advisory Council and I will list them not in
order of importance but in alphabetical order.

First, Susan Curry on my right. She is a second
year medical student at the University of Florida in Gainesville.
Mr. Edwin C. Hiritto from Los Angeles who is to her right with
one chair inbetween.

Dr. Gerhard Meyer on my left over here who is a
practicing physician and associate clinical professor in San
Antonio. And Mrs. Mariel S. Morgan from Albuquerque.

I also should announce to you that Harold Hines has
resigned because he found that the pressure of business didn't
allow him to be here to regular -- on a regular basis and so

nb-2

1 he has resigned which means that we will have a new --

2 I would particularly like to welcome the four new
3 members to this council. Ordinarily we would have had a
4 period of orientation for you but as you know the time involved
5 is too limited.

6 We do have some new members of the National Review
7 Committee also who we will talk about in a few minutes. What
8 we will do is set up a period of orientation as soon as we can
9 so you can get accustomed to the usual procedures of the National
10 Advisory Council.

11 I think it is fair to tell you, however, that no
12 member of the council has felt constrained by his newness. This
13 council is in many ways the most effective -- well, I think
14 probably the most effective of the National Advisory Councils.
15 It has never acted in an inhibited fashion. It is made up of
16 people who are willing to say what they think. It has been
17 flexible and has changed with the times. It has continued
18 to change. I think that you need feel no hesitation in enter-
19 ing in at any point that you think you should, say what you
20 think, and don't be surprised if you disagree or agree with
21 half, less, or all of the rest of the members of the council.
22 It is that kind of a group.

23 I would also like to recognize the fact that
24 Dr. Chase is here representin- Dr. Musser for the Veterans
25 Administration. You all know John Chase. Dr. Ogden will not

nb-3

1 be here at all for the meeting. I understand that neither
2 Dr. DeBakey nor Dr. Roth can be here tomorrow so we will cover
3 as much ground today as we possibly can.

4 Dr. Wilson will address the meeting tomorrow morning
5 rather than today and we had thought that Jerry Riso would be
6 here but he will not be.

7 There are just a few details involving the meeting --
8 this meeting of the council, an explanation of why we are in
9 this room and some things which you need to know about the course
10 of the activities in general.

11 I would ask Ken Baum to acquaint you with them. Ken,
12 I think you remember, is the person who makes the council
13 function, prepares agenda books, gets people where they need to
14 get and does most of our thinking for us.

15 Ken?

16 MR. BAUM: Let me take a half minute here with a
17 couple of announcements. I think Parkinsons Third Law says
18 the amount of discussion is inversely proportional to the
19 subject.

20 First, about coffee breaks. We are going to have
21 the usual coffee breaks at about 10:15 and 2:15 in the
22 afternoon. On the other hand, because this room is small,
23 it is the only one we could get this time because we moved the
24 meeting up a month, coffee is going to be served in what is
25 called the Charcoal Room of the cafeteria.

nb-4

1 I think we have provided everybody with a little
2 map in your books. If not, we have more on the back that
3 shows you how to get to the Charcoal Room. At coffee break
4 time just go out the door, turn right, walk to the end of the
5 hall, the cafeteria is on the left. And if you walk all the
6 way through the cafeteria, it is the last bay on the left and
7 will be set up with pots of coffee and so forth. It is the
8 usual dime for coffee and 15 cents for doughnuts and things
9 like that.

10 Could we please have a show of hands on how many
11 people are going to require transportation to the Washingtonian
12 for the dinner this evening, council members?

13 (Show of hands.)

14 If the people who need transportation would please
15 see Mrs. Handal at the back of the room sometime during the
16 meeting we will get whatever arrangements have to be made.

17 Incidentally, Mrs. Handal was the one that sees to it
18 that things work smoothly not me really.

19 (Laughter.)

20 For the dinner arrangements this evening, the happy
21 hour will begin around 6:00. Anybody who doesn't know how
22 to get to the Washingtonian, we prepared a route map so you
23 can all get lost. Just don't take the wrong turn which gets
24 you back to Washington. Anything else, ask Mrs. Handal and
25 me and we will try to help you.

nb-5

1 The dinner tonight is going to be through the Washing-
2 tonian's buffet line. We have a private room. There will be
3 a private room for happy hour, but everybody will go through
4 the buffet line for dinner. I thought I would explain that
5 first.

6 Dr. Wilson and Dr. Stone, as far as we know, are
7 planning to attend the dinner tonight, too.

8 Because this room is so small, anybody who is going
9 to be leaving the meeting permanently, that is particularly
10 the guests around the room, if you are going -- if your part
11 of the meeting that you are interested in is finished and you
12 are leaving, if you would please advise Mrs. Handal or the
13 secretary at the door, we can use your seat for some of our
14 own staff. We have had to be very careful to control attendance
15 at the meeting because there isn't enough room for everybody
16 who would like to be here.

17 We will have a few seats that we are going to be
18 rotating people through and we hope it causes as little
19 inconvenience as possible.

20 When we get to certain places one group will shift
21 in and another group will shift out so there will be a little
22 bit of shuffling back and forth.

23 The only other thing is that there are a couple of
24 unfamiliar looking folders perhaps on the desk. In addition
25 to the council agend, books which are black and the binders

nb-6

1 with the rings in them which are all colors of the rainbow,
2 you have an additional two books. One is this blue folder
3 which contains some information about the review of emergency
4 medical services applications and there is this brown cover
5 folder with information about the review processes for manpower
6 programs.

7 When we get to the RMP application review, there is
8 an additional folder which we will be passing out to you in
9 a black envelope with management information system tabulations
10 but we didn't want to overload the desk. I thought we would
11 mention what you have in front of you. I think that is all.

12 Thank you.

13 DR. MARGULIES: You had mailed to you the minutes
14 for the February 8th and 9th meeting. If there are any
15 additions, corrections, or comments to be made on them, I
16 would appreciate hearing them at this time.

17 DR. DE BAKEY: I move they be approved.

18 MRS. MARS: Second.

19 DR. MARGULIES: All in favor?

20 (Chorus of ayes.)

21 DR. MARGULIES: Opposed?

22 (No response.)

23 DR. MARGULIES: There are some guests here, some
24 of whom are going to participate actively in the council and
agenda during the course of the day and I would like to

1 introduce them to you.

nb-7

2 I don't think Fred Stone is here yet but he will be.
3 Dr. Van Hoake is on my left over here. He is the new director
4 of the National Center for Health Services Research and
5 Development and we are going to ask him to talk to us during the
6 course of the morning about some of the tighter relationships
7 which we are looking forward to having here.

8 Dr. Gordon MakLeod is over here on the left. He is
9 the director of the Health Maintenance Organization Service
10 and will be involved with our review of the HMO applications.

11 Dr. Margaret Edwards from the National Cancer
12 Institute is here, I think. Here she is right over on my
13 right.

14 Dr. McFinleave from the National Heart and
15 Lung Institute, next to her over here on the right, Arthur
16 Broug from the National Library of Medicine. They cluster
17 together rather effectively.

18 Mr. John Corn, Smoking and Health Program, way over
19 on the left. Mr. Elmer Olexa of HEW audit agency. We have
20 to be careful of him.

21 There are some special consultants who are here.
22 I don't believe that Scherlis is here yet. He will be later
23 on in the morning. Warren Perry a member of the RMPS review
24 committee is here. He was chairman of the review committee
25 for supplementary grants which we considered about ten days

nb-8

1 a little over, whatever the time was, about eight days ago and
2 he will be presenting the review of those supplementary
3 grant applications.

4 There are some new members of the staff also whom
5 you will have an immediate reason to know and work with. One
6 is Dr. Larry Rose of the Professional Technical Development
7 staff who is right here on my right. He is in charge of the
8 emergency medical activities here.

9 Bob Walkington chief of the evaluation branch over
10 there on your right in the office of Program Planning and
11 Evaluation.

12 One other bit of business to get out of the way to
13 get confirmation therefore, is the consideration of future
14 meeting dates which are scheduled now on the new three a year
15 on October 16 and 17, February 7 and 8, and June 5 and 6.
16 The last two dates in 1973.

17 Any problems with those, any reasons of major impor-
18 tance why we can't schedule them then?

19 All right. We will go on. If there is anything
20 we have overlooked, I would appreciate hearing about it.

End #1

#2-ter-1

1 I would like to spend a few minutes with you now
2 considering some of the major issues which includes policy ques-
3 tions which I am sure you are going to be interested in. I
4 consider this an opportunity to discuss some of the subjects
5 which we are going to bring up.

6 The first of these has to do with budget, and just
7 by way of review, I think you do recall that we had last year --
8 some money which was held back, some \$44.5 million, which was
9 available for release during the current fiscal year. Also,
10 a reminder that our appropriations now, one year appropriations
11 and this makes a considerable difference in reviewing.

12 As a consequence, '69 funds held over from the past
13 year and the new appropriations, when there was a release of
14 funds we were restored to active level of about \$145 million
15 for the total RMPS program. The amount which was available
16 for grants and contracts was actually \$135 million, and there
17 were certain funds earmarked which you will hear more about
18 during the course of our discussion, some 16.2 million, maximum,
19 for health maintenance organization activities.

20 These will require only a part of the RMPS funds so
21 that we will have a remnant of the 16.2 million, which will
22 probably be in the range of \$7 million, which will be available
23 for regular RMP activities. It was \$8 million which was ear-
24 marked for emergency medical systems. I will describe that a
25 little more fully in a moment.

1 That was set aside for a contract activity conducted
2 out of the Office of the Administrator which is now at the
3 point of completion of review of the contract. There was \$7.5
4 million set aside for area health education centers. That
5 has not been released.

6 It is not certain whether it will, and if released,
7 what the character of the restrictions, if any, will be, and we
8 will talk about that in a moment.

9 I think you recall that there was \$5 million set
10 aside for a Cancer Center to be constructed in the Northwestern
11 part of the United States, and we will have an updating of that
12 request.

13 That left -- and that is the basis upon which we have
14 been functioning. Ninety-eight point three million dollars for
15 the regular RMP grant activities. If the -- if we have about
16 \$7 million left from the HMO activities, and if the 7.5 million
17 is released from OMB that will mean that our level of funds
18 available for regular grant activities would -- and that is the
19 key figure -- is a 112.0 million. Of that, all but 7.5 million
20 is definite, but the 112 million is the maximum we would have
21 available between now and July 1, for use in RMP supported
22 activities.

23 We are prepared to utilize that full amount with no
24 difficulty because of the variety of activities which we have
25 developed.

1 Now, there is, of course, the next fiscal year to
2 consider, beginning July 1. This year Congress has moved quite
3 rapidly. There has been early action in the House, early action
4 in the Senate, and they are now at the point of reviewing the
5 individual House and Senate recommendations and subsequently
6 reaching some kind of a conclusion.

7 The figures which are under consideration range widely
8 and I think it would be impossible to predict at this time
9 what the final outcome will be. I think that it is of great
10 importance that the total request to Congress by the Adminis-
11 tration was one hundred and -- was over \$131 million this year,
12 which is in contrast with the request of a year ago, which was
13 about 52.5, recognizing a rising interest in what the regional
14 medical programs does.

15 Customarily, Congress accepts the administration's
16 request, and adds to it. Whether it will this year, and whether
17 that will actually survive the appropriations process is specu-
18 lative, and I am not very interested in speculating with you.

19 There have been a series of suggested amendments.
20 One for a life plan for dialysis and transplant for kidneys.
21 There has been a very large suggested amendment which would deal
22 with categorical diseases among other things so that the
23 figures range all the way from 131 million to 229 million;
24 meaning that my reasons for not speculating are fairly obvious.

 The House and Senate Committees are scheduled to

1 consider the appropriations bill this week and it is possible
 2 that they will complete their action. It would not be surprising
 3 if they did this time, because there are other things which are
 4 on their minds during the course of the summer and early fall
 5 which will probably encourage them to complete their activities.

6 Is there any question about this? I know it is a
 7 quick runthrough but most of you are fairly familiar with it.

8 DR. ROTH: I would like to ask some specific questions
 9 about the earmarked HMO funds. Is this the right time?

10 DR. MARGULIES: Good a time as any.

11 DR. ROTH: Well, as this council probably knows,
 12 most of you know, some of us have been disturbed about the
 13 fact that money appropriated for the RMP has been diverted from
 14 our program, from RMP, into the promoting of the Health
 15 Maintenance Organizations, the HMOs, for which there is
 16 no existing legislation.

17 There has been no HMO legislation passed and no
 18 money per se has been authorized for the development of HMOs.
 19 Now, if I am correct, during 1971, the initial grants for HMO,
 20 the money was, shall we say, pirated from the CHP funds, the
 21 314E funds in respect to 38 grants which were aggregate, about
 22 \$3.3 million, and there were 15 grants which were funded under
 23 the provisions of Section 1110 of the SRS activities; and then
 24 there were, in other words, 14 contracts, amounting to about
 25 2.2 million that came under Section 304 of the Public Health

HMO
 ASHNS
 HEAL

1 Service Act; but since that time, there have been additional
 2 grants up to a total of 110, for planning and development of
 3 HMOs, and it has been made abundantly clear that this is
 4 planning and development only, that there is a specific restric-
 5 tion against operation of any of these.

6 I think, thus far, I am on sound grounds of state-
 7 ment of fact, is this approximately correct?

8 Now, there have been a number of concerns around
 9 this town about the way this money was achieved in the House
 10 Appropriations Committee Hearings. Some sharp questions were
 11 asked of the Secretary, and others as to where in the world,
 12 they got the authorization for this money. I believe I am
 13 correct in saying that there is still a specific investigation
 14 going on in respect to \$900 thousand of the one million, ten,
 15 that was diverted from Section 110 -- 1110 of the SRS funds.

16 The question being raised as to whether this was --
 17 I do not know whether the right word in this context is
 18 "illegally," but diverted in a fashion that should not have been
 19 permitted. Now, we get, in our distributional material this time,
 20 some very interesting opinions from Assistant General Counsel
 21 for Public Health. Now, one with relation to the area, health
 22 Education Centers, which makes it relatively clear that in the
 23 absence of specific legislation, there is very, very little
 24 RMP money that could possible be devoted to the support of the
 25 AHEC.

ter-6

1 That is not important except to view in a comparative
2 fashion with regard to what has happened with the use of our
3 RMP money for the support of HMO grants. I would like to quote
4 to you -- I think you all have this in your black book before
5 you -- I do not know -- it is under the Tab HMO, Grant Proce-
6 dures, and it is the item there, if you will -- it is Office
7 of General Counsel, under the date of May 3rd.

8 If you look down to the middle paragraph, "This
9 office has previously advised in the context of proposals for
10 HMO Planning and Development, that this is the important thing
11 to the extent that proposed HMO activities fall within the
12 purposes of Section 910(c), funds would be available"; and
13 below this, below the blank line, Section 910(c) is quoted as
14 saying, "The Secretary is authorized to support research,
15 studies, investigations, training, and demonstrations designed
16 to maximize the utilization of manpower in the delivery of
17 health services.

End #2

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mil-1

1 I don't know how many of these HMO grants you have
2 looked at closely and seen what they were requested for and
3 how they were being used, but my question is are any of them
4 by any stretch of the imagination being used for any of these
5 purposes in 19(c)? My opinion, maturely achieved, is no,
6 they are not. HMOs, we are told by the Administration, already
7 exist, to the extent that they service some 7.5 million
8 people of these United States. There are 30 organizations
9 that they call HMOs. Of these 30, I believe none were
10 subsidized in their organization by federal funds. They
11 operate without federal funds; there is no reserve.

12 "Studies" is a very vague word. I don't know.
13 This would be the weak point in my position, I suppose.
14 Any time you are doing planning, I suppose you are involving
15 some kind of study, but I think in the context of maximizing
16 the utilization of manpower, which is what all these studies
17 and reserves are supposed to be doing, that HMO planning is
18 far from the mark.

19 Such evidence as exists in respect to HMOs is that
20 manpower productivity is a little lower in this kind of
21 organization in terms of patient hours per physicians or number
22 of patients per week or per month, and so on. Obviously, the
23 planning is not being done in this area. The planning is being
24 done in the financing, the setting up of capitation mechanisms
25 and it is my position that this has robbed us of a number of

mil-2

1 millions of dollars and we on this council sit here session
2 after session approving grant applications, only to learn later
3 on that they have been approved, but unfunded because we
4 haven't got enough money to fund them.

5 Now, dammit, ⁹¹⁰19(c) -- Title ^{Sec 910}9, Section 19 money
6 can be some of the most valuable money in RMP, because you
7 aren't restricted to a region. We could be doing more with
8 ⁹¹⁰money in the emergency medical service field, just to pick
9 one place, than we could do with our specific grant money.

10 I would like to raise the question, and I think
11 there are several ways to do it, but I think the easy way,
12 hopefully, is in an unemotional, out on the board administra-
13 tive fashion, to find out if it is not possible to stop this
14 raiding of our treasury.

15 You have talked about 16.5 millions coming in with
16 an HMO earmark on it, and we might salvage seven of it. I
17 might be disposed to see what we could do to have 16.5 million
18 of it. I assume it would be impossible to get back any of the
19 millions that have already been diverted. I have no particular
20 appetite for a useless procedure for starting a congressional
21 investigation or getting some senators and congressmen raising
22 the devil with the Office of the Comptroller, but can't we do
23 something about it in our own group? That is my question.

24 DR. MARGULIES: Let me make a partial response to
25 you, Russ, and Gordon MakLeod is here and can certainly add to

ROTH

MARGULIES

mil-3

1 it. I don't do it on the basis of administrative decisions
2 and the fact that the funds would not really be available
3 to us if we didn't use them for this purpose. Let's set that
4 aside for the moment and raise the question of the appropriate-
5 ness of ^{cyo(c)} 19(c) for the health maintenance organization activity.
6 It really is a matter of judgment about what an HMO (notice)
7 can be.

8 From our point of view, we have felt comfortable
9 with the use of the funds for this purpose because the HMO
10 can offer to us the only system that is useful for some of the
11 things which we need to do and learn to do, which is a close
12 enough universe between the provider at one end and the
13 subscriber at the other end, so that you have an understanding
14 of what you want to achieve and a system in which you can do
15 it.

16 One of our great problems in achieving some of the
17 progress in RMP is we deal with a system which is not bound
18 together in such a way that you can say that these are the
19 providers and they act in such and such a way, and these are
20 the users of those services, et cetera.

21 I believe, and many of us on the staff do, that if
22 the HMO can be put together so that you have an understanding
23 about a contract for services to be performed, it will
24 provide the kind of laboratory for improved uses of health
25 manpower for improved monitoring of the quality of medical

mil-4 1 care, for a better understanding of what we mean by health
2 maintenance and an opportunity to test these ideas when the
3 opportunity is not nearly as well-defined or as controllable
4 as it is in the HMO. I think I would have to agree with you
5 that the beginnings of the HMO primarily have to do with the
6 development of a reimbursement system, with actuarial data and
7 with putting together the system itself. But thereafter, once
8 it has occurred, we, for example, in looking at the ways in
9 which we want to achieve a better provider management of
10 the quality being delivered, have found the HMO gives us
11 opportunities for better learning and for better application,
12 which the rest of the system does not, because it is too widely
13 scattered.

14 But perhaps Gordon, you would like to -- do you want
15 to come up here and comment on this?

16 This is Gordon MakLeod, whom I introduced a few
17 minutes ago.

18 DR. MAK LEOD: When I walked in the room, I asked
19 if Dr. Wilson was here, no; Mr. Riso here, no. I asked should
20 I be here, and he said sure. What I thought I would do now
21 is respond to some of the queries, but try to address the
22 issue at the level where I think I sit as the program director
23 and that this has in fact had high administration. There has
24 been departmental administration and concern for the different
25 system. They have looked at three important aspects and one,

mil-5

1 of course -- the first and perhaps the foremost one is manpower
2 and cost and quality. I am not sure how the balancing
3 works, but the three certainly do interrelate very closely
4 and in order to address these three problems as they have
5 been spelled out for the -- all of you innumerable times,
6 the HMO strategy was devised -- the HMO strategy really was
7 built upon the development of the last 20 or 30 or 40 years,
8 as Dr. Roth has said in terms of prepaid practice group and
9 in the last 15 or 20 the medical care foundation movement has
10 moved into this area.

11 This kind of activity has had authorities passed
12 by Congress to do certain things with respect to the health
13 care delivery system in the country. I have heard the
14 secretary explain before these congressional committees that
15 Dr. Roth has referred to that there is existing authorities
16 for the activities that we are involved with, perhaps as a
17 defense on his part, perhaps as an awareness in addition to
18 the opinion from legal counsel which is in your booklets,
19 there is another one which isn't published here, which we can
20 get where there is an approval from the Office of General
21 Counsel for the utilization of RMP money if the activity
22 is maintained to the planning and developmental phases.

23 It is with these guidelines that we have proceeded
24 over the past several months in addressing the planning and
25 developmental grant activity and also in the areas of contract

mil-6

1 activity for supporting HMO activity at this early planning
2 phases.

3 I think the -- from a substantive point of view, I
4 would be happy to respond to questions you might wish to raise
5 at the programmatic level. I do think it is perhaps more
6 appropriate to address some of the decisions with respect
7 to the issues Dr. Roth has raised at the higher administrative
8 levels and I might say one other thing just as I conclude
9 these very impromptu remarks, and that is that one of the
10 issues that has been discussed over and over again in a program
11 getting started such as HMOs is using existing authorities
12 in order to bring to the attention of the Congress the
13 experimental activity that we have been involved in and the
14 results of that experimental activity, so that Congress, in
15 fact, can react, "How do you do this? What sort of funds do
16 you use to get this kind of activity underway? And what has
17 happened in the past?" And this may also have happened for
18 RMP actually, is to have used funds from programs which are
19 interested in the same objectives to a certain extent, in
20 order to get them underway at a preliminary phase and at the
21 same time be going through the congressional process in order
22 to get the support for these activities.

DR. DE BAKEY

23 DR. DE BAKEY: May I ask a question in this regard?

24 Aside from the judgments that have been made concerning the
25 legality of the diversion of funds for these various purposes,

mil-7

1 may I ask to what extent is the role of the council in the
 2 funding that is approved by Congress for the regional medical
 3 programs -- to what extent is the council involved in its
 4 advisory role and -- as to the dispensation of these funds?

5 I realize there is a legal basis for the advisory
 6 role, but I am particularly concerned about what responsibility
 7 the council has? In other words, these funds have been
 8 diverted, to my knowledge -- I don't recall the council
 9 approving the use of funds for the specific purposes.

10 DR. MARGULIES: Dr. DeBakey has asked about the
 11 authority that the council has in determining utilization
 12 of funds. In actuality, the grant -- the use of grant funds
 13 from RMP sources for HMOs has not as yet occurred and there will
 14 be on the agenda for this afternoon, a consideration of that
 15 kind of use of grant funds. There can be no use of grant funds
 16 for any purpose in RMP without prior approval by the National
 17 Advisory Council.

18 The council has two roles, which I think you know
 19 more clearly than I do: One of them is to approve the
 20 award of grant funds for any activity ^{910/c1} ~~etc~~, or anywhere else
 21 in the program. It also has the responsibility for advising
 22 on policy and, of course, in that case we have, with no
 23 exception I can recall, accepted the advice of the council and
 24 followed it.

25 That, however, is obviously not binding on the

mil-8

MARGULIES

DE BAKEY

1 secretary because it is advisory. He can always set it aside.
 2 The other part of the machinery, however, which is
 3 a little less obvious, is the decision which the Administration,
 4 any administration, may take, saying we would like these
 5 funds used for this purpose. Now, that cannot be done.
 6 Supposing that an administrative decision should come along
 7 saying we should put X amount of money into an activity we have
 8 not heard of. What would usually happen is that the funds
 9 would be available for that purpose only, with an agreement
 10 between the Executive Branch, HEW, and the OMB. If the council
 11 chose to support that activity, the funds would be used for that
 12 purpose. If it chose not to, then the funds in all likelihood
 13 would not be released for RMP at all. So that that administra-
 14 tive decision cannot give warranty that the funds will be used.
 15 It can give warranty that they will be used if they are going
 16 to be used only for that purpose.

17 DR. DE BAKEY: The reason I asked this question, not
 18 because I didn't know the answer, but rather to bring to the
 19 -- for discussion, a matter that I think is extremely important
 20 in the role of every individual who is a member of the council
 21 and that is the responsibility involved here in relation to
 22 the program, programming. That, I think, is the most important
 23 responsibility of the council.

24 In an appropriation of funds released by Congress,
 the council -- one of the council's primary roles is to determine

mil-9

1 priority of the funding. This is done in determining the
2 awarding of grants, but it is also done in terms of awarding
3 certain funds for specific areas, specific programs.

4 Now if you introduce into the order of priority
5 for the use of these funds, a matter such as HMOs consideration,
6 then it seems to me that the council must determine whether
7 within the limitations of the funds available, this particular
8 program has the proper authority to refund them. This is
9 why I really raise the question because I think it is quite
10 important for the council to make decisions and indeed it is
11 the responsibility of the council to make its decisions.
12 This is its advisory role.

13 That is why I consider this a rather important
14 decision and not one that the Administration determines without
15 having the advice of council, because it does involve a
16 utilization of funds appropriated by Congress for a specific
17 purpose, regional medical programs activities. The diversion
18 of those funds for another purpose may or may not be legal.
19 This is not really an important question because really it is
20 a matter of judgment in interpreting whether or not it falls
21 into that program. My interpretation may be different from
22 yours.

23 But it is the responsibility of the council not
24 in that sense to make judgments, but rather to make its
25 determination within the priorities of its decision-making

DE BAKY

mil-10

process, whether or not this really falls within a high enough
priority within the limitation of funds to even be funded.

Therefore, it belongs within the consideration of
the council.

End 3

DE BAHEY

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1 DR. MARGULIES: I certainly subscribe to that
2 view. I would like to pose the administration's problems,
3 and I don't mean this administration's, any administration's
4 problems, however, in a consideration of what the council does.

5 One of the inherent strictures in effective policy
6 deliberations and one which we have all objected to accepting
7 when it applies to us is the separate status of interrelated
8 programs.

9 We recognize, for example, the relations between
10 HMO, National Center for Health Services, ^{RHD}~~RND~~, Migrant
11 Programs, and so on, and it's in the nature of the political
12 process and one that must be preserved that many of these
13 activities have a constituency of their own, have a method
14 of gaining support, and are as a consequence very sharply
15 focused on a final purpose which is to achieve what the
16 people who backed it wanted to achieve.

17 Now the problem of an administrator, whether
18 it is a secretary or the administrator of Health Services
19 and Mental Health Administration, or anyone else, is to
20 take that variety of activities, and many of them over-
21 lapping so you can sometimes identify anywhere from five
22 to 45 authorities which apply to an activity, look at the
23 funds available, the resources available, and try to
24 integrate in that process what is on hand to develop a
25 program which is coherent and which serves a total purpose.

ar2

1 In order to do that, the issue is not RMP
2 policy alone, but also RMP plus all of the other policies
3 which are interdependent.

4 Now setting aside whatever one may think about
5 HMO as a new policy, if I remember the early days of
6 RMP, one of the severe problems under which it operated
7 was the availability of authority, the availability of
8 funds, and the point of zero.

9 As a consequence, it took a long period of time
10 to go from ground zero to something better. In that way
11 the council felt uncomfortable, but felt they had to get
12 the show moving and use funds.

13 In attempting to build another activity which
14 becomes an administrative priority like HMO, that kind of
15 slow start and fumbling around can be diverted only if you
16 get something moving.

17 I know this is a dilemma for administration,
18 and it is troublesome for other people, but if one can
19 assume -- and I think it is a reasonable assumption that
20 HMO legislation will be passed -- it is a lot better to be
21 prepared for it by having already developed some understand-
22 ing, developed the people available, have things in motion
23 so that the results achieved will be ahead by two years
24 or more where they otherwise would have been.

That obviously comes into conflict with isolated

1 policy decisions and I think at least that's part of what
 2 we are discussing today.

ROTH

3 DR. ROTH: Harold, may I also say that I
 4 suspect most members of the council must recognize that in
 5 this we have gotten ourselves unhappily precipitated into
 6 the middle of an almost partisan political issue that has
 7 nothing to do with science or our fundamental job in sitting
 8 as an advisory council.

9 The HMO thing came in as a slowing began. It
 10 was espoused by administration, with a big A, and all sorts
 11 of interesting things began to happen as soon as this
 12 caught on, and the initials began to be popular. Both sides
 13 of the aisle have now taken proprietary interest in these
 14 initials and nobody really knows what an HMO is going to be
 15 until we get some definitive legislation.

16 We have three pieces of legislation in the current
 17 Congress, and lord knows whether anything will happen to
 18 any of them because of the diversities of sponsorship.
 19 Probably, my guess is, that nothing is going to happen in
 20 the 92nd, and you are going to get new bills in the 93rd
 21 Congress, and you may still have more new bills changing the
 22 definitions of HMO.

23 At the present moment, we have the Staggers bill,
 24 the Roy Bill, and the new Kennedy bill. They are quite
 25 dissimilar in their characters. There is a move to really

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1 liberalize the HMO concept to the point where it will
2 embrace virtually all the foundation.

3 Under some concepts of HMO, there are six founda-
4 tions that are already being funded to move in the HMO
5 direction. Our funds are being used to promote something
6 that has not been legislatively defined and I think this is
7 a far cry from my concept of why we sit around here and why
8 we stay home reviewing grant applications to try to work out
9 ways in which the medical profession can extend the
10 benefits of what we already know how to do for people who
11 need it. We are not interested. We are not funded, and
12 the original Congressional intent, I think Dr. DeBaakey
13 would agree, and nobody ought to know it better than he, was
14 not to be a research and development thing. It was to use
15 the knowledge and disseminate the knowledge that we already
16 have in this country and in this world.

17 It was not set up to be a poverty program, and
18 the moment we become one small drop in that poverty bucket
19 as a program or debt -- I think this council has a very
20 real role in this thing, and although we may be overruled
21 by what is done with the money through manipulations from
22 above, I think it would be appropriate for the council to
23 say strongly and clearly that we think this is an inappropriate
24 diversion of funds, and if this isn't where they wanted the
25 funds to go, they shouldn't have put them in RMP. They

ROTH

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~~19-C~~
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1 should have put them some place -- because what our
2 is being equated with now, it is being alleged that
3 has the same purposes as 314-E, for example, and CHB.

4 We have been spending years trying to point out
5 there isn't an identity of interest or conflict, that we
6 aren't on a collision course. We are supposed to be doing
7 different things.

8 I think we have just been caught up in a political
9 issue which is rather distasteful to one who is trying in a
10 nonpartisan way to do the best we can, to use the monies
11 for the purposes that we are all enthusiastic about.

HM

12 DR. MARGULIES: I think that there is some
13 embarrassment even now in the administration over the need
14 to use funds from other resources for HMOs. It is no secret
15 that the administration had every reason to believe that HMO
16 legislation would have been passed months and months ago
17 so that this would not have occurred.

18 What has culminated is an arrangement in which
19 there has been initiated enough -- pardon me -- enough HMO
20 activity to make it possible to look at what it is and to
21 keep it on a tentative basis until there is further defini-
22 tion. And whether the early offset of activities was --
23 what the council might have agreed with or not, there is an
24 investment in effort which we at the present time find
25 useful which would be set back, which would indeed be lost

ar6

1 if these funds were not for that purpose.

2 ~~_____~~
The Secretary accepted the idea in his testimony
3 that RMP funds should not in the future be used for this
4 purpose, and indicated to the appropriations committees
5 that this is the one and only time it would have been done.
~~_____~~

6 In fact, it isn't really in the ~~budgetary thinking,~~
7 Rus, a use of RMP funds, and this may sound a little like
8 sophistry, but it really went like this: Funds for RMP were
9 frozen in fiscal '71. There was a need for funds in fiscal
10 '72 for HMO. There was an agreement to release those funds
11 that were frozen out of RMP for that purpose. They would be
12 used for that purpose, but not for another one.

13 It was expected that the whole 16.2 million
14 would be available for HMO, and that was the case. However,
15 with the slowdown of activities which followed the slow-
16 down of legislative performance, not all of those funds
17 were to be used. So whether it is counted as a blessing
18 or not, it means we will get \$7 million for RMP activities
19 for this fiscal year, which would otherwise not have been
20 available to us.

21 I know that's not responsive to your question, but
22 what the administration tries to do, again, is find the
23 resources available to do something, to put itself in a
24 better operating position than it otherwise would have been.

25 I, for one, would be very regretful if we

ar7

1 completely handcuffed the administration, which does from
2 time to time have to move into different positions to
3 move things in a new expression.

4 The expression "tin-cupping" has been around
5 the federal government for a very long period of time, and
6 if you don't provide the opportunity to pick a little from
7 here and there to get something done that needs to be done,
8 it restricts the mobility.

9 If we confined every program to a rigid definition
10 of its purposes, we would have even more fragmentation than
11 we now have.

12 You, on the other hand, feel this is overdoing
13 it for a given purpose, and I recognize that difference.

14 DR. ROTH: I am glad you labeled it sophistry.

15 (Laughter.)

16 DR. MARGULIES: I said it may be.

17 DR. ROTH: Of course, all you have to do is go
18 one more step. This council and RMP are presumably going
19 to have nothing more to do with HMOs after this one fiscal,
20 this one year.

21 If you needed any other testimony to the fact it
22 isn't RMP business, I guess this would be a good piece of
23 testimony.

24 DR. DE BAKEY: The point that's important here
25 is that the funds used for any purpose that are in a sense

ROTH
DE BAKEY

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1 assigned by Congress to RMP is the business of this council.
2 That's the point I am making. I don't think that it's
3 proper, whether or not the organ which is used or acceptable,
4 is proper to use these funds without having consulting
5 council. I am not arguing with whether or not it should be
6 done this way. My argument is concerned with the role of
7 responsibility of the council. That's the only point I am
8 making.

9 DR. MARGULIES: They have not been used.

10 DR. DE BAKEY: It may well be that the council
11 would agree to do this. My point is that the council should
12 be consulted.

13 DR. MARGULIES: They will be. That is a -- on
14 the agenda. There have been no grant funds used. However,
15 you realize that these funds can be converted into contracts
16 in which case the council would not be involved.

17 DR. ROTH: May I ask another question?

18 Out of the 110 extant grants for HMO funding,
19 how many came out of this branch of HEW?

20 DR. MARGULIES: No RMP funds have gone into that.

21 DR. ROTH: No RMP funds? How about contract
22 grants?

23 DR. MARGULIES: No. Nothing in contracts either.
24 The exception to that -- that's correct, isn't it, Gordon?

25 DR. MAK LEOD: Yes. I think perhaps the closest

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1 thing to RMP involvement in HMO is myself, who was a
2 member of the consultant staff of RMP before I became a
3 member of HMO.

4 DR. MARGULIES: You shouldn't have said that.

5 (Laughter.)

6 DR. MAK LEOD: Our activity to date has been
7 funded within HSMHA through 314 money and outside of HSMHA
8 from the SRS authority, which you alluded to.

9 DR. MARGULIES: The exception to this, Russ,
10 would be any intra-RMP activity in support of HMOs that
11 you know about.

12 DR. ROTH: I know. This has been cropping up in
13 grant applications. That doesn't worry me at all. Maybe
14 this is better preventive medicine than I thought if
15 nothing has been done. Maybe we can prevent something.

16 DR. MILLIKAN: I was going to add that I don't
17 think there is any issue about us handcuffing the administra-
18 tion. This was a phrase that cropped up a few moments ago.
19 I share the feeling that it is the responsibility of the
20 council to make its feelings known about the fashion of
21 the policy level at which the objectives of RMP are molded,
22 and that we sooner or later should be called for a kind
23 of opinion review of a situation like this, albeit contract
24 or grant or whatever.

25 It seems to me if we are going to work as a

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1 community of folk in trying to put together over a
2 continuum, the real issues of RMP, we ought to do it in a
3 combined fashion.

4 I think at a given time there may be differences
5 of opinion among us, but that the administration may hand-
6 cuff us. We aren't going to handcuff them. We are only
7 advisory and we recognize that.

8 DR. MARGULIES: Except you control the funds.

9 DR. DE BAKEY: Could we go off the record for a
10 few moments.

11 (Discussion off the record.)

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DD #5
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1 DR. DE BAKEY: We can go back on the record, if
2 you want.

3 DR. MARGULIES: Tony?

4 DR. KOMAROFF: Last February when our sudden riches
5 were described to us but all of the earmarking was described, we
6 all, I think, felt richer and somehow more supine and I know
7 that the Review Committee has felt the same sense of frustra-
8 tion that we are hearing around the table.

9 Is there any way the specific issue of the HMO
10 funds aside of conveying this kind of sentiment to the
11 Administration because a devitalized advisory group is a
12 significant below to the viability of the organization?
13 Has that sentiment been conveyed? We all expressed it, I
14 think, in February.

15 DR. MARGULIES: Yes. And of course Dr. Wilson will
16 be here tomorrow morning and I think it is perfectly reasonable
17 for these issues to be raised. The point which Dr. DeBakey
18 just made is certainly a critical one in the RMP. It has been
19 my feeling that in the development of some strong regions and
20 most of them have become much stronger, that we are in a
21 position to do some things with the categorical diseases,
22 sensibly, better position now than we ever have been, that we
23 can carry out categorical control activities which will
24 really affect the whole delivery system rather than serve the
25 special interests of a handful of people as many of the early

ty 2

1 activities did.

2 However, the fact that I think so or the staff
3 thinks so doesn't satisfy the questions which Dr. DdBakey
4 raised at all. His points are very well taken. There is
5 also the very interesting question of how comfortable we are,
6 the Council, the Administration, and others with the process of
7 decentralization. This regularly comes up. There is no point
8 in trying to escape it. If you in fact do allow the program to
9 proceed in the direction of local judgments, local talent,
10 local efforts being applied to local problems and get stronger
11 and stronger peripheral programs, parallelling the movement
12 towards stronger state government activities and so on,
13 do you imperil the achievement of national goals? Are the
14 two necessarily inconsisent and that is something that this
15 Council needs to consider very carefully. It is a subject
16 for real deliberation.

17 I am surprised when we are told that the problem
18 with the individual RMPs is that they are not responsive enough
19 to national policy when our primary problem is to keep them
20 from all jumping in the same direction the minute that they hear
21 that is the way we are going to go. Within a few minutes the
22 telephone is ringing saying when do we get our application
23 grants in. That has never been an issue but that is not
24 generally appreciated.

ty 3

1 award that in a period of a matter of a few weeks the idea of
 2 emergency medical services and expanded education activities
 3 was advanced from an early inquiry to the full development
 4 of applications and a number of excellent ones. This took
 5 very little time. It wasn't a question of the local determina-
 6 tion process being indifferent to national policy but more a
 7 matter of whether they could be responsible to national policy
 8 and have it been meaningful locally. This is part and parcel
 9 to the whole question.

10 The issues you have raised today are the issues
 11 which the coordinators are raising, particularly the one of
 12 selecting priorities for funding and so on. I think there is
 13 nothing more legitimate than your very careful review of it
 14 and transmittal of your concern. This becomes particularly
 15 important -- let me just take advantage of the opportunity to
 16 bring up the other two issues which take relatively little time.

17 In considering new legislation, because there will
 18 be new legislation for the regional medical programs this
 19 year, our legislation has to be extended by July 1 of 1973.
 20 So also does the legislation of the other programs, which you
 21 have been discussing today and a number of others. It would
 22 be rather natural for those who review it in Congress and in
 23 the Administration to try to look at these legislative
 24 proposals together and get something more comprehensive than
 25 has been available in the past.

END HMO DISCUSSION

ty 4

1 The comment you have been making today, whether
2 positive or negative are pertinent to the development of
3 legislation which produces whatever specificity or whatever
4 flexibility you think should be in our legislation and those
5 that are apposite to it.

6 On the other hand, there are specific requirements
7 which are imposed by Congress which are of an entirely
8 different kind. One example of that wasthe expression by
9 Congress of their insistence that pulmonary pediatric centers
10 be funded at the level of the preceding fiscal year. We are
11 making every effort to make sure that occurs. This was part
12 of the appropriation language and is a specific act by Congress
13 which expresses the will of the people. There is no reason to
14 question it.

15 We will, as a consequence, be looking at some pul-
16 monary pediatric activities, either new or extensions, which
17 will allow us to maintain that level of \$1.7 million in total
18 for the pulmonary pediatric centers. But this again is a
19 different kind of an issue when it is a Congressional question.
20 What you are really looking for I think is a better way of
21 dealing with the Administration on policy issues and I am
22 obviously not an adequate representative of those policy
23 considerations because I represent RMP policy considerations
24 andam responsive to those decisions which are made elsewhere.

I think it is quite right that these questions be

1 raised and that you get the kinds of answers which you are
2 pursuing. This also has something to do with the description
3 of the role of the Council in new legislation.

4 The categorical issue, you are absolutely right,
5 Mike, the -- there are a number of reasons why people have
6 felt that RMP is not appropriate for some of the large
7 increases in funds for categorical activities and probably the
8 most significant of them is the brief final life history of
9 the chronic disease control programs which is the point at
10 which I entered regional medical programs at the first place
11 and was under hot debate at that time. This has made a lot of
12 people feel this is not an appropriate place for those
13 activities to be carried out.

14 I did meet with the President's Advisory Council
15 for Cardiovascular Disease and expressed to them our willingness
16 and eagerness to engage in effective categorical disease acti-
17 vities.

18 The one thesis that I presented, which I feel
19 strongly about, which the Council may wish to consider, is
20 that an excellent categorical disease program inserted into a
21 bad delivery system will end up with bad cardiovascular
22 disease delivery and that you cannot carry out a control program
23 by setting up a few major demonstration centers and depend
24 upon something called education which is really exhortation to
25 get the providers and the consumers to do what they ought to

ty 6

1 do.

2 At this point if RMPs and certainly where they are
3 at their best it is true -- if RMPs play a role they can play
4 a control role which will carry it from knowledge into the
5 delivery system better than they could have in the past. When
6 I first entered this program, it was the scattering of activities
7 with a coronary unit here or there or a training program
8 for emergency medical services with no emergency system or
9 registry of some kind which wasn't tied into anything at
10 either end which tended to characterize too much in the program.

11 But if you are going to have a well knit structure
12 out there, and policy here, and you are going to decentralize
13 to the best that local judgment can be utilized, it is going
14 to require a high degree of observation and negotiation at the
15 Council level to make sure that the central purposes are
16 carried out effectively in the periphery.

17 I doubt that we have debated that as well as we should
18 have up to the present time.

19 DR. MAK LEOD: May I add something on that? I
20 would like to just add that the -- where the process is today
21 is clearly part of the Administration's approach to handling
22 this particular issue and the Administration has proposed to
23 have Council act en bloc following the recommendation of the
24 National Advisory Council some months ago.

1 what the process has been to date.

2 The one other point that I think is not directly
3 germane to that particular action but it is the development
4 group of which the RMP, National Services Research and Develop-
5 ment, Comprehensive Health Planning, Hill-Burton and the
6 HMO make up the group is -- was included -- included HMO's
7 at the outset and I was part of the dialogue that went into
8 that. It was considered to be a developmental activity.
9 There was some considerable debate as to whether it should go
10 into the service group, because of the service orientation.
11 But the decision was made to include that as part of the
12 developmental activities and perhaps at some later date on
13 passage of legislation to have its -- convert from this
14 particular level of activity.

15 I would just want to be very responsive to what Dr.
16 DeBakey has said and say that we have as part of this
17 reasoning process, and you will hear the recommendation of the
18 ad hoc group later on, looked at the -- what we consider to be
19 important RMP considerations and they included the coordination
20 of the sources and services and the improved manpower
21 utilization and productivity, effective medical records,
22 information systems, approaches to the increased accessibility
23 of medical care. We did it to the extent that we had
24 anticipated and had actually received something on the order of
25 \$8 million in grant requests and we have tailored that down,

1 prior to the presentation before the ad hoc group, to just a
2 little bit over 4 million trying to bring it into line with the
3 objectives of the regional medical program service as we
4 have seen it, recognizing that they aren't specific to the
5 heart, stroke, and cancer but perhaps in a broader area
6 related to the general disease.

7 We wanted to look at the total approach at this point
8 in time.

9 DR. MARGULIES: I would like to -- we can come back
10 to the discussion and we certainly will when we go to the
11 bloc review activities. I would like to follow up. As a
12 symptom of the relationships between this Council and the
13 decentralized RMPs, by pointing out to you that you have right
14 from the time over two years ago to the present had a series of
15 regional medical programs in which the coordinator was
16 particularly singled out for his level of ineffectiveness,
17 where over a period of time there were frequently recommendations
18 that he be given somebody to help him out in an administrative
19 deputy role.

20 We have at the present time a replacement of something
21 between 75 and 80 percent of those who I was hearing all about
22 at the time that I entered. It can be done, you can have a
23 separation of central direction and local function and still
24 carry out some major alterations. I think you will also, as
25 you look, and you have been, that the regional advisory group

1 will see some striking changes going on. There will be more
2 of them. So the degree of management is significantly greater
3 than sometimes people think that it may be. I think if you
4 go over in your own minds the list of changes or taking a
5 look at Rochester, North Dakota, Oklahoma, Colorado,
6 Wyoming, Syracuse, and on down the list, with the exception of
7 two or three, those that have been a source of real distress
8 have been relieved significantly and were some very good
9 replacements so that it can happen.

10 Let's move on in the agenda, on the assumption we
11 can get back to this if you like.

12 I would like to call your attention there is a
13 result of the multiphasic health conference with the report
14 in the agenda books. I don't know how much opportunity you
15 have had to look at it but it is there primarily for explanation.
16 If there is any further action you want to take on it, it is
17 subject to your review.

18 The conclusions in it are an affirmation of earlier
19 action taken by this Council. You will recall in general we
20 felt there had to be a much better evaluation of what is going
21 on in these activities than there have been. I asked in
22 turn that this be considered as a HSMHA kind of a responsi-
23 bility because there are similar activities in a number of
24 other programs. The conference supported that view and if you
25 would like, you can take action, if you have had an opportunity

1 to look at it, to accept this report as consistent with the
2 existing views of the Council or put it off until you have a
3 chance to look at it.

4 DR. KOMAROFF: John, those recommendations, that
5 certain of the projects will be changed so that a joint
6 perspective study will be done? Okay.

7 DR. MARGULIES: Russ?

8 DR. ROTH: Harold, this maybe sort of superfluous
9 but this has been such a fascinating thing to me to see
10 some of the readouts and I am just singling out one, the
11 Illinois project, multiphasic screening to detect coronary
12 in persons and individuals with subclinical heart disease.
13 I think RMP in this project has shown an extraordinarily
14 important thing and that is that it tells us here that 22,929
15 of these examples have been evaluated and they have notified
16 the people who showed evidence in the opinion of the
17 examiners that they were to be regarded as precoronary or
18 coronary prone or that they actually had subclinical heart
19 disease and the statement comes along that 50 percent of those
20 people went to physicians.

21 This is very different from saying you ought to
22 have an annual physical examination. Here these people,
23 presumably intelligent enough to hold jobs in industry, and
24 with insurance protection, you can bet on that, practically
25 100 percent, are told you have something wrong, you have

1 heart disease, or you are set up for a coronary, and still 50
2 percent of them don't do anything about it.

3 Gee, if this isn't something we ought to make
4 something of and try to find out the answers on how you get
5 these people to do something about these findings, I am sadly
6 mistaken. This is one of the more exciting things and at the
7 same time depressing to come out of our studies. I just couldn't
8 let it pass without pointing it out.

End #5

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1 DR. MARGULIES: The professional and technical devel-
2 opment staff has felt very strongly about that sort of thing.
3 So far as I am concerned it also underscores the difficulty of
4 carrying out a meaningful control program unless you deal with
5 that particular fact.

6 You can demonstrate as long as you want, but if there
7 is no one out there to respond, it isn't going to matter.

8 DR. ROTH: I don't want to use this for a soap box,
9 but I have long been using the illustration of a hospital admin-
10 istrator whom I knew well for 50 years who sits in her office
11 and allows a carcinoma breast to get flungating and metastasized
12 surrounded by the talent to do something about this early.

13 It wasn't lack of money, lack of education. It was
14 fear, basically fear or mistrust on her case of the people she
15 worked with every day.

16 In the case of the 50 percent of the Illinois union
17 members, you have to do more studies to find out exactly what
18 these bare years are.

19 DR. DE BAKEY: Yes, but I think, Russ, I think one
20 of the important things though is to look at the positive side
21 of this.

22 Over 50 percent of them did respond and they picked
23 up this group.

24 Now, I think this is important -- an important
25 objective of the program. To be sure, there are 50 percent of

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1 them that didn't respond, but the fact remains we picked up some
2 people in terms of the control program that needed attention
3 which would not have been picked up without this.

4 DR. ROTH: I am happy to be happy about the 50 percent.

5 DR. DE BAKEY: I agree with what you are trying to
6 say, but what I am trying to bring out is here is an example of
7 one of the real objectives of the program.

8 You know, this is the kind of achievement that I
9 think needs to be emphasized. There are many others. I don't
10 want to get started on it because I would take up too much time
11 with the council.

12 I have given my speeches before in this area,
13 because of the lack of achieving control.

14 DR. SCHREINER: I think the point Russ is making
15 about studying the bare years, go beyond that. I wouldn't
16 accept the fact that 50 percent of the people are going to doc-
17 tors is doing anything about it.

18 We ran into this basis. You can report back and get
19 the man to go to his doctor, but the doctor doesn't know what to
20 do about it or there is no concerted program to take it from
21 point C to point B.

22 DR. ROTH: What did the 50 percent that went to their
23 doctors do?

24 DR. SCHREINER: They may have ended up producing more
25 cardiac neuroses. We don't know what happens after they are

sw3 1 picked up.

2 DR. MARGULIES: It is precisely that failure
3 with these activities to pursue to see what happened with both
4 50 percents that has made us feel we have to evaluate this
5 thing much more before we set up any more. We don't know what
6 that means.

7 All we are saying in this report to you is that we
8 still feel that that kind of a study needs to be carried out
9 before we put more RMP money into it.

10 If there is no objection to this report, we will
11 ~~consider it acceptable to the council at the present time.~~

12 Let me then remind you on the three cycle review
13 process that we are well established into it, that the regions
14 which had to change their anniversary dates have all gotten new
15 anniversary dates.

16 This has given us a certain amount of finding flexi-
17 bility in this interesting budgetary year and at the same time
18 has gotten people on to a three cycle arrangement quite comfor-
19 tably with actually relatively little objection to it.

20 A few minor bookkeeping skirmishes and that is about
21 all.

22 What we are doing with the regions is negotiating
23 new levels based upon an extended fiscal year so that a region
24 which was moved, we will say, from July 1 begin date to four
25 months later, has been given funds to carry it through 16 months,

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1 but these have been limited so they can renegotiate new levels.

2 In the process of renegotiating the new level, it
3 gives us the ability of supplying the funds either in this fis-
4 cal year or next fiscal year which allows us then to consume
5 a very wide range of potentialities in the money we have
6 between now and June 30.

7 We were not surprised that we would be -- as we were
8 on June 1 uncertain of our total funds available to a total
9 of about \$1.5 million with 30 days to decide.

10 In fact, we rather suspect that would be the case
11 and we are well prepared for it. Part of it has been to put the
12 regions on a new kind of a cycle.

13 We have, in the process of doing that, been able to
14 achieve two other things. One of them is to schedule staff
15 visits to the regions three to four times per year on a regular
16 basis so there is no uncertainty about it in the minds of the
17 regions or the staff with a higher level of priority to the
18 regions which have in the review process shown up rather poorly
19 so we can use our skills where they are most needed.

20 This is going to be on a scheduled basis as the needs
21 are dictated by the status of the program as determined by the
22 review process.

23 We have also been able to cut down the staff paper
24 work.

25 In fact, we had to do it and it looked like a certain

sw5

1 accommodation to the exigencies of life and it was.

2 On the other hand, I think it has improved the paper
3 work by making it simpler. However, if you find that the
4 simplified versions available to you are not quite as adequate
5 as they have been in the past, they don't give you as much
6 information as you would like, we can respond in a limited way
7 to changes which are requested, but if we are going to have a
8 smaller size staff as we have, a larger budget, the possibility
9 of increased demands of the kind Dr. DeBakey is describing, more
10 staff visits, we can't do the same kind of paper work and we
11 are going to be doing some adjusting between various levels of
12 good so we may have a little more of one good and a little
13 less of the others.

14 I hope you will be tolerant. That is a rather
15 familiar administrative exercise.

16 I would also like to bring to your attention -- and
17 this may become extremely important in the light of the
18 discussion we just had during the first part of this morning --
19 that there are draft guidelines and regulations which have been
20 prepared by the staff. They are in the agenda book under the
21 title "proposed regulations."

22 What will be done with those regulations if they are
23 left unaltered is they will be put in the Federal Register.
24 You would be well off to review those carefully, because once
25 in the Federal Register, and once accepted in general, they do

sw6

1 become the regulations under which we operate and the deal with
2 the very tough question of the relationships between the
3 grantee, regional advisor group, and the coordinator and his
4 program staff.

5 That in turn has very heavy implications for what
6 this National Advisory Council does, because it has been a
7 strong feeling as an expression of the legislation, not a clear
8 definition of the legislation, an expression, that we entertain
9 grants which come to the regional advisory group which in turn
10 have been subject to their scrutiny and which represent their
11 policy of determinations.

12 At the same time, a number of the regional medical
13 programs have gone thorough varying degrees of conflict of
14 regional advisor group and grantee.

15 We still have some instances in which the grantee is
16 convinced that the final decision belongs with it and that if
17 the regional advisor group says we should do B and they don't
18 like it, they can cancel out that request.

19 If that is to be altered, and we are trying to
20 express what appears to be the Council view, it will have to be
21 altered in the very near future.

22 Those regulations are not going to be circulated to
23 the regional medical programs now because they are not official
24 and if they get altered we will simply have more confusion.

25 In the meantime, they represent a basic effort which

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1 has been an extremely hard labor on the part of the staff here.

2 DR. PAHL: I would just like to interrupt for a
3 minute and say in my presentation, when you finish our other
4 point on agenda, I would like to bring the Council back to this
5 section of your black loose-leaf binder as well as an item which
6 Dr. Margulies has been referring to which is actually in your
7 folder.

8 If you want to proceed with that general introduction
9 we will have a few more specifics later.

10 DR. MARGULIES: At the risk of no later taking
11 advantage, but perhaps Bob, you have gotten some sense of the
12 Council in the period of time that you have been here, we are
13 very pleased with the fact Bob Van Hoek has taken over as
14 director. All of us have felt that there is much more that we
15 can do together than we have in the past because he is there
16 and although he has only been director for a brief period of
17 time, I am sure you know that Bob Van Hoek has been a very
18 active part of HSMHA since it was organized or right from the
19 very beginning, has occupied key roles as deputy administer and
20 deputy director in a variety of circumstances; and I have asked
21 him to come here.

22 If you will Bob, come up and acquaint us with what
23 you are doing and encourage the Council to be argumentative.

24 *DR.* MR. VAN HOEK: Thank you Harold.

25 I appreciate the opportunity to visit with the

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1 council.

2 I have only been in the present position two months
3 and I am getting acquainted with many of the details of the
4 center and its programs.

5 Much about what I am going to say in the next few
6 minutes in opening really comes from the perspective of my
7 three years experience in the office of the administrator in
8 which I was involved in evaluation, planning, budget, operation
9 of virtually every program in HSMHA.

10 And during that time one of the things that
11 concerned Dr. Wilson and the staff of the agency was the diffi-
12 culty of getting plans and programs developed in a cooperative
13 fashion among the various programs.

14 It appeared to us that in general the programs
15 and some of it, of course, based on the history of the
16 programs themselves and the agencies' formation functioned
17 quite independently and developed their programs with certain
18 priorities and objectives in mind which were related to the
19 objectives and programs of other activities in the agency.

20 So there would be times when looking at a particular
21 area of activity, it appeared at least that many of the programs
22 were doing the same kind of things, supporting the same kinds
23 of activities, with very little interrelationship.

24 It was interesting to sit here this morning and
25 hear some of the discussion about multiphasic screening and

1 other activities and this can be -- we can take similar
2 areas of development in the area of manpower development
3 and the utilization of manpower and the development of
4 ambulatory care clinics, or developments for the poor, some
5 of which have been jointly planned and some of which have not.

6 From the standpoint of the center, I see the
7 center's role one of participating in as well as carrying
8 out through its programs studies on how health services are
9 delivered, the components of the related services activities,
10 and the effectiveness of those activities and also to
11 identify problems and to develop answers to those problems.

12 Let me take off, since the multiphasic activity
13 was discussed, let me take off there as an example.

14 For instance, one of the basic questions I am contin-
15 ually asked wherever we deal with preventive care, disease
16 control programs, multiphasic screening programs, and so
17 forth, is what is the level of patient acceptance, patient
18 followup, and response to whatever professional guidance may
19 be given.

20 It is amazing at least from the standpoint of
21 the national center how few studies are actually being
22 conducted in that area, probably one of the most important
23 areas in the health field, simply, once the individual or
24 patient or consumer is in the system, and there is followup and
25 the patient has direct contact with the health services

dw 3

1 system, what is the professional response to that -- the
2 identification of that problem.

3 In other words, what is the quality of care and the
4 quality of services rendered and in what manner is it
5 presented?

6 Is the fact that the patient's acceptance or
7 consumer's acceptance is low, is that partially due to the
8 lack of education from the standpoint of the professional to
9 the consumer or the types of knowledge that are available to
10 the professional in providing that service.

11 That, again, is an area in which there are a
12 number of projects in which the Center has done relatively
13 little.

14 As far as I can tell, from my own experience,
15 very little in the agency as a whole has been done.

16 I would say at the moment from the standpoint of
17 the Center, I see those as two of the highest priority
18 areas.

19 This is not to say that these are programs which
20 will be done independently with the Center, but in conjunction
21 with the 314(a) programs in both designing the studies as
22 well as carrying them out.

23 I might point out that the budget of the Center is
24 on the order of some 64 to 65 million dollars which represents
25 only three percent of the HSMHA budget and one tenth of one

1 percent of the total dollars in health care expended in this
2 country.

3 Therefore, it is important for us to use that fund,
4 invest that money in conjunction with other developments in
5 the -- trying to improve health services.

6 Another area that I feel the Center should
7 place great emphasis on and which will require the participa-
8 tion of any HSMHA programs as well as non-Federal programs, is
9 in the area of resource utilization and productivity.

10 By this I mean a combination of studies on man-
11 power, studies on technology -- the application of technology
12 to health delivery and the utilization of facilities with the
13 major emphasis on ambulatory care.

14 And rather than the Center supporting the train-
15 ing of new kinds of manpower or the construction of experi-
16 mental facilities and so forth, the major emphasis will be
17 placed on actual studies of productivity, using industrial
18 engineering and systems engineering approaches, economics
19 studies, and studies on proficiency of health manpower and
20 development of testing and education -- testing techniques
21 which can measure proficiency productivity which can then be
22 used as a feedback into the educational or training processes
23 and also working with professional organizations to feed back
24 into recertification and relicensing as that develops through
25 the various specialty boards and licensing bodies.

dw 5

1 I think that in in general, those are some of the
2 thoughts that I have and I would be interested in your reaction
3 to that.

4 I hope that in the future we will be -- we will
5 continue to have joint discussions on our program activities.

6 Harold is going to be participating with me in
7 a meeting of our advisory council later this month in the
8 same way.

9 Thank you, Harold.

10 DR. MARGULIES: Thank you.

11 Are there some --

12 MRS. WYCKOFF: How do you relate to the community
13 base manpower programs that we are working on now? Does your
14 agency relate to those?

15 ~~DR. SCHREINER:~~ ^{VAN HOEK} At the moment, and I am speaking
16 from a little information, I don't believe we have had any
17 direct involvement in those community based programs. This
18 is an area where I think it is extremely important that we
19 develop a mechanism for joint planning and joint program
20 development and implementation.

21 One of the areas I found a major problem in, again
22 from my experience of several years in the agency, is that we
23 have a tendency to start programs with certain assumptions or
24 initiate new programs with certain objectives which could
25 be stated in quantitative terms or output terms, and then we

1 could measure what we have achieved at some point subsequently.

2 The tendency to take many of the things as an
3 acknowledged fact or impression, a fact unsubstantiated by
4 some very limited information or studies seems to me that what
5 we need to do in health services, research and health services
6 delivery, is model some of our programs on the clinical
7 research collaborative models that have been carried out and
8 that is to develop some uniform protocols for large scale
9 programs, either for demonstration or developmental activity
10 which then a number of groups in the country can participate
11 in with you with very well defined objectives, well defined
12 procedures and stages for evaluation so that at some point,
13 three years or five years from then, we can determine what we
14 felt was a way to go, in fact, proved to be the case.

15 There are many examples of this that I could
16 cite in programs, concepts such as Outreach in ambulatory
17 care programs.

18 If you look at what we support in Outreach
19 activities, they range all the way across the board in the
20 characteristics of the Outreach, what kind of services it
21 provided, and there is no way of comparing the different
22 programs other than by very intuitive subjective judgment.

23 DR. MARGULIES: We have felt when Bob and I have
24 talked that there is a continuum between RMP and RMD which
25 has not been adequately developed.

1 This is emphasized by the kinds of discussions we
2 have had today but also by the fact that we do not regard
3 RMP as a source of innovative new reserach into delivery
4 systems but rather as a mechanism for making sure what is
5 worthwhile becomes a part of the system.

6 Too frequently the problem of the transfer of new
7 understanding is not addressed and it really doesn't matter
8 whether you are talking about new scientific knowledge,
9 which was the original focal point for RMP or the transfer
10 of new delivery knowledge.

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1 We have all heard the coordinator complain something
2 was happening in his backyard he didn't even know it was there.

3 I doubt -- if there aren't more questions, the room
4 is getting very hot and it is time for coffee.

5 Fifteen minutes, please.

6 (Recess.)

7 DR. MARGULIES: Could we reassemble, please?

8 I think if we get started again on the council
9 agenda we can move along. There are several people who have
10 to leave early and we want to get as much business out of the
11 way as possible before we go. I am going to shorten some of
12 the things which I had planned to tell you because they are going
13 to come up again in relationship with the review processes and so
14 we will skip over them. We will be talking about the
15 emergency medical system applications and the distinction between
16 what we are reviewing and the contract activities. We can do
17 that when we get to those reviews so you are clear about it.
18 I can at that time also let you know who the subcommittee
19 members were for the various special supplementary grant review
20 processes which were carried out.

21 I would only like to make one special point about
22 the educational activities which are going to be under review
23 for supplementary award. We are not empowered to support some-
24 thing called an area health education center but that is around
25 a very clear cut definition of what the area health center is

1 and that definition is tied closely to the original Carnegie
2 Commission record which describes the AHEC as the **satellite**
3 of the university health science center with the understanding
4 that the recipient is the health science center which develops
5 a collateral activity in a community and has the general
6 managership of it on the training of undergraduate medical
7 students, residents, and other graduate physicians in primary
8 medical care.

9 We have invited as a consequence, applications
10 which are really carried under no particular title and believe
11 me we are better off without a title for a number of reasons
12 but which are community based, which are an extension of RMP
13 activities of the past several years and which deal with
14 certain educational goals that are appropriate to RMP.

15 We will get to them in the very near future. These
16 primarily came out of the St. Louis conference and -- with
17 the coordinators and the number of discussions we have had.

18 There is, however, one action which the council
19 is being asked to take. The last time which the council met it
20 agreed to -- I would like to have you look at tab No. 8 on this
21 one. Congress agreed to delegate to the director of RMPS the
22 authority to provide funds for the planning of area health
23 education centers with certain limitations, \$50,000 for each
24 one, a maximum of five such activities in any one regional
25 medical program.

1 MR. BAUM: It is community based education criteria.

2 DR. MARGULIES: Sorry. I was thrown a curve.

3 Community based education activities which is not their title.

4 That is just a way of locating them.

5 DR. PAHL: The document being referred to is behind
6 the tab delegation of authority which is about half way through
7 the black binder.

8 DR. MARGULIES: At the time you met, you did
9 delegate the authority to provide for some planning activities
10 for what were called area health education centers and since
11 we are not doing them, we are asking you to change that
12 delegation to one which refers to community based education
13 activities for the same purpose. It is really a matter of
14 new language and conforming to our new position.

15 MRS. WYCKOFF: I move we change the language and --
16 area health education centers to community based indication
17 programs.

18 DR. MARGULIES: Mrs. Wyckoff has moved that this
19 delegation be altered as indicated in the tab in your book.

20 DR. OCHSNER: Second the motion.

21 DR. MARGULIES: It has been seconded. Any further
22 discussion?

23 MRS. MARS: I don't quite understand the reason for
24 this.

25 DR. MARGULIES: The reason is to allow us to respond

1 to early planning activities, Mrs. Mars, during the cycle when
2 the program might be ready to plan something, nine or ten
3 months ahead of the time when it would be coming in for its
4 regular review processes and since it is a relatively new
5 activity in some regions, it would be delayed up to a year in
6 what is an early planning or feasibility activity unless
7 we can provide them with the funds to do that earlier. Some-
8 times it would also run into conflict with the -- when their
9 award level is at the level of the council approval and they
10 say you have to wait until it is time for their review to
11 come in which would slow them up too much.

12 MRS. MARS: Thank you.

13 DR. MARGULIES: Any further discussion? All in
14 favor say "aye."

15 (Chorus of ayes.)

16 DR. MARGULIES: Opposed?

17 (No answer.)

18 DR. MARGULIES: I would like to recognize the fact
19 Dr. Scherlis has come in. He is on the review committee and
20 will be here for the discussion of the applications for
21 supplementary awards for emergency medical care.

22 I wonder if this would not be a good time to ask
23 Mr. Champliss to bring you up to date.

24 DR. CHAMPLISS: As a matter of special interest,
25 the council staff felt that the council would like to be

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1 apprised of the new review committee memberships. As of June 30th,
2 there will be four members of the committee retiring, Dr.
3 Michael Spellman, Dr. Gerald Besson, Dr. Philip White and the
4 past chairman of the committee, Dr. William Mayer.
5 All will be leaving the service of the review committee. That
6 will leave four vacancies on the committee and the need for the
7 appointment of a new chairman. That new chairman will be Dr.
8 Max Schmidt who has served with a great amount of distinction
9 already on the review committee. Dr. Max Schmidt.

10 Also there has been one appointment to the committee
11 that has been formally accepted. That person is Mrs. Maria
12 Flood from El Paso, Texas. There are two other names that have
13 already been approved but it would be injudicious at the moment
14 to give them until that process has been fully completed.
15 Those two appointment will be made, hopefully, soon.

16 Another matter that it was felt the council would
17 be especially interested in has to do with a question that
18 arose from the Washington-Alaska regional medical program having
19 to do with the use of the proceeds of a grant activity covered
20 by or supported by regional medical programs. They raised
21 a question as to whether that could be granted to them for the
22 benefit of a private company, the Video Record Corporation,
23 which we understand is a subsidiary of RCA. They asked a ques-
24 tion as to whether that corporation could be given a non-exclu-
25 sive right to duplicate and then sell the proceeds of some films

eak 6

1 that were made under a RMPS grant. We felt this was a policy
2 issue and it was submitted to the office of the general council
3 for determination.

4 We took the position in RMPS that whatever was
5 most favorable to the regional medical program, we would support
6 that position and in our inquiry made to the general council,
7 a decision has come forth which is, in fact, favorable to the
8 RMP. They asked the -- the question was raised and they answered
9 it with three answers.

10 First, they said that the grantees of RMPS funds may
11 produce and distribute video tapes or the proceeds of those
12 tapes which were -- which were the -- which were funded through
13 RMPS without prior review by RMPS. In other words, they can
14 make a distribution of the proceeds of grants, tapes, films,
15 and so on without our approval.

16 However, they did say that these items were items
17 of property and that the distribution -- the use of property
18 was a matter for the grantee institution to decide and not for
19 RMPS to decide.

20 The second question they raised -- they dealt
21 with, that since the proceeds of video tapes are copyrightable
22 materials, that this -- these copyrights to be subject to the
23 right of RMPS to a royalty-free non-exclusive irrevocable
24 license for the use of the video tapes. This means that RMPS
25 would have a property interest in the tapes and that this

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1 property interest would come to RMPS royalty-free and at no
2 cost.

3 The third point that they dealt with had to do with
4 royalties or the proceeds, the monies coming from the use of
5 these tapes. The general council office finally said that all
6 royalties or other fees received by the grantees from the use
7 or distribution of video tapes produced with grant funds up to
8 the amount they charged to the grant for the production of
9 video tape, that is to say there would have to be a recoupment
10 by the RMP of the exact amount of money that was put in it
11 supported by a grant and after that amount was recouped, then
12 that amount would have to be refunded to RMPS but it went
13 on to say that RMP should look favorably upon the use of those
14 funds that were recouped for the continuation of other grant
15 activities.

16 So, here we have a policy determination by the
17 general council office on the use of the proceeds of grant funds
18 in the area of video tapes and films.

19 We think that this is something of an advancement
20 of the RMPS mission because now after the recoupment, the
21 proceeds of activities supported by grants can be used further
22 for the supporting of other grant activities, assuming, of
23 course, this has been cleared by RMPS.

24 Thank you.

25 DR. DE BAKEY: You say that the money can be used,

eak 8

1 the proceeds could be used for the advancement of the RMP pro-
2 gram. Do you mean that once the amount of money that the RMP
3 puts into the program has been returned, that total amount,
4 then what happens beyond that point?

5 DR. CHAMPLISS: It means that the grantee can use
6 that amount, can use the further proceeds to further its
7 activities.

8 DR. DE BAKEY: Can or will?

9 DR. CHAMPLISS: Can or should.

10 (Laughter.)

11 MRS. MARS: For the same purpose, in other words,
12 to make further films?

13 DR. CHAMPLISS: Or for whatever purpose --

14 MRS. MARS: Any purpose? It doesn't necessarily
15 have to go back and make further films?

16 DR. CHAMPLISS: That is right.

17 DR. SCHREINER: What happens to the recouped money?

18 DR. MARGULIES: That becomes RMPS money which you
19 can leave there or bring back in.

20 MRS. MARS: Doesn't have to be used apparently
21 to make further films, for any program activity.

22 DR. MARGULIES: At this point, the amount involved
23 is not going to represent a windfall but the issue is of broader
24 importance when you think of the potentialities in various
25 programs for bringing funds in, particularly, demonstration

eak 9

1 activities involved in patient care, for example.

2 DR. DE BAKEY: It seems to me that this sort of
3 is not really a very clear policy.

4 DR. CHAMPLISS: I would agree there. We understand
5 that further clarification of this policy is already in the
6 making.

7 DR. MARGULIES: Mike, it is a legal opinion.

8 DR. DE BAKEY: That is why it is not clear.

9 (Laughter.)

10 MRS. WYCKOFF: Sounds like we are going into the
11 grocery business.

12 DR. MARGULIES: If there are no further questions
13 on this, I do want to return to that important document and
14 regulations which I think is of very high interest to the
15 council.

16 DR. PAHL: In recognizing that a number of people
17 will not be here tomorrow, I feel it important to take up
18 a number of documents that we have either sent to you or have
19 in your folders and I will try to highlight the aspects for you
20 which I believe we want to call to your attention and leave the
21 rest of it for your more leisurely perusal later on.

22 DR. DE BAKEY: Could we get some clarification
23 before we start on where these proposals stand? None of them
24 have been published?

25 DR. PAHL: No. Let me say for the benefit of you and

1 particularly the new members of the council, we have a tab in
2 the middle of the black binder called proposed regulations
3 and it is titled first draft regulations and it means just
4 that. These have not been issued. They are in draft form and
5 the thing which I was going to end up on, I will say now we
6 earnestly request that you look at these today, tomorrow, and
7 take this section back with you if you will, look them over,
8 and sometime within the next two to three ^{weeks} ~~years~~, we would
9 appreciate any constructive comments, additions, deletions,
10 and so forth in writing from you and the letter can be
11 addressed to Dr. Margulies or to me.

12 We will then take whatever comments you have and
13 begin work with the general council office in developing the
14 final regulations which will then have to be published in the
15 Federal Register subject to, again, a time period for comment
16 to come in from anyone in the country.

17 Again, any modifications made on that basis have
18 to be published. So we are at the stage where these are truly
19 draft and nothing will be done, I would say, until the latter
20 part of June in working again with the general council office.
21 We would like to have your comments.

22 DR. DE BAKEY: One question, that is how do these
23 differ from what has been published so far in the Federal
24 Register?

25 DR. PAHL: This is really an updating of the

1 earlier regulations, taking into account our mission statement
2 which was endorsed by the administrator and his council a year
3 ago and also putting into effect --

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1 DR. DE BAKEY: The reason I want to know is I think
2 in evaluating these regulations, we would like to know, you
3 know, what has been published in the Federal Register, or at
4 least, be able to bring it up to date. What are the changes?

5 MRS. MARS: Yes. What are the changes?

6 DR. PAHL: Let us ask Ken.

7 DR. MARGULIES: One point that should be made, how-
8 ever, is that back of this lies the decision to move away from
9 the excessive use of what are called guidelines, to the use of
10 regulations which are published and which allow public access
11 and comment, so much of what we are entertaining here has been
12 carried under guidelines which are not really regulations.

13 DR. DE BAKEY: We went through a lot -- in the
14 early days, went into the Federal Register, and I just wanted
15 to be sure we are brought up to date on the relationship of
16 these to what exists now in the Federal Register.

17 MR. BAUM: Let me explain what has been done.

18 The regulations that we have now are the regulations
19 that were originally promulgated from the program and have not
20 been changed since 1965, or whenever they were pushed through.
21 There was a need to do really two things with these regulations.

22 One was to bring them up to date so that the regu-
23 lations are consonant with the new law that we are currently
24 operating under. That made a number of changes, broadened some
25 of the statements of purposes, widened the representation

1 required on regional advisory groups, completely changed
2 Section ~~47~~⁹¹⁰, added construction, and those are not reflected in
3 the currently applicable regulations that were passed back in
4 1965. So, these regulations are designed to close some of those
5 gaps.

6 The second thing is that within the last year, the
7 Secretary has issued a directive that instead of promulgating
8 policy, you make the rules for your program in a formal and
9 official manner, by putting things into regulations as opposed
10 to having policy statements, which can be changed by staff,
11 day-after-day.

12 And, in order to go through the rule-making proce-
13 dures we have required first of all, by law, to consult with the
14 Counsel. Secondly, the departments' rule-making procedures
15 require that anything you are going to make a regulation be
16 published in the Federal Register and there be an opportunity
17 for people to comment on those for 30 days.

18 That they then be finalized and possibly changed
19 substantially, republished for comment for another 30 days.
20 But they are finalized 30 days afterwards. Now, these regula-
21 tions take into account the changes that were made in the law
22 and in addition to that, they try to incorporate some of the
23 materials that reflect the way the program is currently being
24 operated.

25 For example, the mission statement that was developed,

1 what was it, Herb, about a year ago; the review process require-
2 ments and standards which we have put out saying what the local
3 regional medical program must do in order to meet the standards
4 for reviewing their own projects, and things like this have
5 been built in.

6 The document you have in front of you was drafted
7 up in the presumably proper legal language, by the General
8 Counsel Office, after they have taken a look at these program
9 documents and then built them into this.

10 Since they gave us their first draft, we have
11 developed some additional papers and some additional things
12 and they are kind of reflected on some language on the back
13 page of the draft, which we wrote up and they have to be put
14 into appropriate legal language.

15 That, essentially, is what we have been doing with
16 these.

17 DR. MARGULIES: I think it is also fair to say, that
18 at least some of the detailed relationships were never spelled
19 out in prior guidelines with the specificity that is in here.
20 They have been left to sort of definition, as we went along.
21 We have had a variety of understandings. The effort here is
22 to put them in very specific language with the understanding
23 they may, or may not be acceptable.

24 MRS. MARS: Excuse me. This will provide, then,
25 all the mission's statements, the guidelines? These will be

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1 torn up as bits of paper and it will all be in here?

2 DR. PAHL: No. No. These represent the published
3 regulations and the more detailed statements such as the mission --
4 the mission statement per se is not incorporated in here.

5 The concepts of the mission statement are. The mission
6 statement itself, will still be utilized as a program document
7 but it would not have the force of a regulation.

8 Now, in returning --

9 MRS. MARS: What about the guidelines?

10 DR. PAHL: Our guidelines will return to being
11 guidelines and those things which are requirements will be put
12 in the form of regulations. So, anything which ends up as
13 a regulation will be a requirement placed upon a regional
14 medical program, and an additional implication and understand-
15 ing, policy matters, will come out as guidelines if there is
16 some degree of interpretation and flexibility possible.

17 These will be firm program requirements.

18 MRS. MARS: This is really a finalized situation,
19 so to speak?

20 DR. PAHL: And they represent the firm program
21 requirements, organizational structure, priorities, things of
22 that nature. We will still be issuing guidelines, and policy
23 statements, but they would not have the force of a regulation
24 in terms of placing a strict requirement on a RMP. You need

25 You need both.

1 DR. MARGULIES: There are two practical advantages
2 to this, aside from the content.

3 One of them is that it now allows the guidelines to
4 be guidelines instead of being both guidelines and regulations
5 which has confused regional medical programs regularly.

6 Secondly, it will allow us to have the force of
7 real validity when we deal with aberrations in the internal
8 management of a regional medical program, such as a Grantee
9 Regional Advisory Group relationship which does not fit our
10 understanding.

11 At the present time, all we can refer to is the
12 broad language of the legislation, which is too nonspecific,
13 or guidelines when there is authority. When there is violation,
14 the regulations will give us a firmer basis for carrying out the
15 will of the council as expressed through those regulations.

16 MRS. WYCKOFF: On the other hand, these are frozen?

17 DR. PAHL: They will be frozen.

18 DR. MARGULIES: They are not readily changed.

19 DR. PAHL: This is why they are written by the
20 General Counsel Office, in appropriate legal language, as well
21 as the fact that they are broadly written, so they would not
22 have to be changed from day-to-day. they are not frozen in
23 the sense they cannot be changed.

24 It is just that one has to go through the Federal
25 Register procedure for any modification, and this is some months

1 of work and so it would not be advisable to include in this
2 language of such a specificity that it would be out of date
3 three weeks from now.

4 MR. MILLIKEN: Are these more appropriate than a
5 sight-visit?

6 DR. PAHL: If questions come up, these represent
7 program requirements and so serve as a reference point for the
8 program. They are the force of law. An RMP must. But there
9 will be additional guidelines and so forth for sight visits,
10 etc.

11 DR. MARGULIES: It is -- as a way of illustration,
12 some amplification, all that the law says is that the Council
13 will consider an application which has been submitted by regional
14 advisory group. It does not say, in our legislation, what the
15 role of the grantee is in determining the responsibility of
16 that regional advisory group, what the extent of its responsibility
17 is, or what the limitations are.

18 That is why you have regulations to identify the
19 intent of broadly-stated legislation. Then, the way in which
20 you make that -- make sure that functions is the way.

21 You have three levels. Basic legislation and regu-
22 lations, and guidelines, which are much more a matter of the
23 management.

24 DR. PAHL: I can illustrate that. I had not planned
25 to do it in this order, but if you look at the last page of

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1 these suggested regulations, it is not numbered, it is after
2 page ten in the document, Section A is titled "Grantee Coordi-
3 nator Relationships." Please do not read it at the moment.

4 What I want to do is point out it is a brief para-
5 graph in rather broad language. I will call to your attention
6 in a moment, that in your folder there is a four-page document
7 which spells out in much greater detail than we would want in
8 regulations, the actual roles and responsibilities of the RAG.

9 The coordinator and the grantee. This would be a
10 good example of how the regulations give a firm requirement
11 of a conceptual nature, and the subsequent guidelines interpret
12 and give much more specificity and give a basis for actual
13 program operation.

14 Now, I would like to call to your attention, for
15 consideration now or at your pleasure, at this meeting and cer-
16 tainly subsequently to this meeting, in terms of writing us
17 comments; Section 51(b) on the bottom of page three and most
18 of page four.

19 This is the section entitled, "Priority of Regional
20 Medical Programs," and consists of a listing of items which you
21 may wish to consider. Again before you read this, I would like
22 to go through the whole little presentation. Then we can come
23 back; otherwise you would not get the whole perspective.

24 This section is of specific interest to the Council

1 evidenced by this morning's discussion. It has to do with prior-
2 ities, which would be published and of some force of require-
3 ment on regional medical programs. That section is particularly
4 important.

5 Most of the sections have to do with the mechanics
6 of the program, and I do not think we will do violence to any-
7 thing that we are accustomed to. And the last page, the
8 suggested additions to the proposed regulations, has a section
9 on the Grantee--RAG coordinator relationship.

10 It has a -- this is the last page of the document,
11 page eleven. It has a section on ⁹¹⁰19, and a section on con-
12 struction. These would be new parts of the regulations which
13 have been added as a result of the authority under our present
14 law, and program decisions made subsequent to the enactment of
15 the legislation.

16 I would like to indicate the following: It is diffi-
17 cult to know how these relate to what has already been published
18 and, Ken, we can get copies of what are now the present regu-
19 lations, and give them to you at this meeting, or get them to
20 you immediately in the mail; so that you will see what are
21 our present regulations, published regulations, and then send
22 you also, a copy of this so you will be able to compare.

23 This is what the General Counsel Office did. They
24 took our present regulations, our present legislation, and the
25 important policy documents that have been developed by us, and

1 developed this revised set of regulations, proposed regulations,
2 from a consideration of all of those. We would be most happy
3 to have you review, whether you think the present regulations and
4 what you know to be the direction of the program and the documents,
5 whether these are accurately reflected.

6 We do earnestly solicit your comments here or
7 written comments upon your return.

8 Now, having said that, I would like to ask whether it
9 would be your pleasure to go over that section on page three,
10 and foru, now or whether perhaps, you would like to have an
11 opportunity to review this over lunch hour, or something and
12 take some time this afternoon, after you have given it some
13 thought?

14 Clark, you raised the issue with me?

15 DR. SCHREINER: Bear in on it.

16 DR. PAHL: Okay.

17 Open for discussion.

18 DR. DE BAKEY: The first question I want to ask, is
19 in relation to the priority. Are these listed in any order?
20 Because that is not clear the way it is stated here. In other
21 words, you have given some indication of what constitute priori-
22 ties, but what is not clear is whether these represent priorities
23 themselves. In other words, does, for example, under 51(b)106,
24 Paragraph A, and then Section One, does that have priority over
25 Two?

1 MR. BAUM: As I recall, and I do not have the docu-
2 ment in front of me, these priorities were taken out of the
3 mission statement of a year ago. I do not know if they used
4 exactly the language of the mission statement or rearranged it.

5 I would have to compare it. But essentially, what
6 we did was to furnish the General Counsel Office with some
7 documents like the applications statement, some others that I
8 mentioned, and they took those documents, extracted from them,
9 and put them into what they feel is the correct legal form, and
10 I think that is where you get this set of priorities.

11 I would have to look at the mission's statement. It
12 was done by the Legal Department, not by us.

13 DR. DE BAKEY: If I recall, the mission's statement
14 was just a listing with no intent to give priorities to the
15 mission.

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16 DR. MARGULIES: I do not think there is an intent.
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MR. BAUM: No.

DR. PAHL: There is not an intent but this is not clear.

DR. DE BAKEY: You are dealing here with priorities not with mission.

DR. PAHL: That is correct. It is not clear here and we would clarify it.

DR. MILLIKAN: Looking at A, there are eight items, and in five of the eight, the word "care" is a key word.

Could we have a definition of the word "care"?

Items 1, 3, 6 and 7, the word "care" appears.

I think that is important enough that it might even want to be included under 51-B-102.

DR. PAHL: Section on Definitions.

DR. MILLIKAN: I would like to hear some discussion on it.

DR. DE BAKEY: I think this is important because I don't think there was any -- that there was ever originally or in the new law that carried on the regional medical program, certainly, a concept of providing any care that would, say, be the type of medical care we usually speak of as reimbursed care.

So it becomes rather important, I think, to distinguish this type of care.

1 DR. MARGULIES: You need to describe -- I think
2 what it is and what it is not.

3 What it is not is payment for services and what
4 it is needs to be defined in some aspect of health services
5 delivery.

6 DR. ROTH: It also makes reference to primary
7 and secondary care and this has been subject to various
8 definitions, depending on what you are talking about.

9 I think primary and secondary care should be
10 defined.

11 DR. DE BAKEY: Now, in paragraph 4, that same
12 area, this is a question which I am asking because I think
13 it is important.

14 In the Mission statement, under Paragraph 4, where
15 it says "need to increase utilization," and then it says
16 especially.

17 Now, I think the reason I bring this up is because
18 that adds in a sense to the priority.

19 I want to know if that is in the original Mission.
20 If not, we have added something to it.

21 MR. PETERSON: I am pretty certain and I can get
22 some copies of the Mission statement.

23 DR. PAHL: We will get copies of the Mission
24 statement.

25 I don't know. Even if it is in the Mission statement,

dw 3

1 it doesn't have to be in the regulations, if it is council's
2 opinion or the opinion of the public at large that this should
3 not be in the regulations.

4 So we are not bound by that, whether it exists
5 or not.

6 DR. DE BAKEY: The only reason I am concerned
7 about it is because it, in a sense, provides a form of
8 priority.

9 DR. PAHL: Yes, it does.

10 DR. DE BAKEY: I am not at all sure that that ought
11 to go into regulations.

12 Priorities from the standpoint of the council's role
13 can vary from time to time. They can vary in terms of the
14 funds that are available, they can vary in terms of what is
15 timely and effective.

16 It may well, for example, prove that -- let's
17 say allied health personnel, certain types of allied health
18 personnel, does not increase the capability of achieving
19 the goals of the program.

20 I am just using that as an illustration.

21 Well, you would be tied down to your form of
22 priority in the regulations that would, in a sense, frustrate
23 council's priorities at that particular time.

24 So I think it is important to -- in terms of
priorities, because these become sort of rigid, once they

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1 are published in the Register -- to be very careful about the
2 wording of priorities.

3 You see, this comes -- this is really the whole
4 sort of heart and core of a council's role. This is --
5 you are almost saying, well, you know, you are almost -- you
6 almost don't need a council if you set up a set of priorities
7 that is so rigid that you can have a bookkeeper take care of
8 it for you.

9 I think -- I personally think it extremely important
10 to word this in such a way that there is great flexibility
11 provided the council in exercising judgment for priorities.

12 DR. PAHL: Yes.

13 MR. HIROTO: Would it be necessary to list the
14 priorities at all? Couldn't it just be listed as
15 areas of concern?

16 DR. MARGULIES: Actually, if you read it, they are
17 not priorities but they are the basis for determining
18 priorities.

19 I think the point that Mike has made on this one
20 is one that we would like an expression of council opinion
21 on.

22 You can leave it as it is, you can alter it, you
23 can delete it.

24 I think this is as good a time as any to consider
25 which way you would like to go because you are quite right.

1 It does single this out particularly with the word
2 "especially," which raises it to a higher level.

3 DR. DE BAKEY: Well, Harold, I wish you had had
4 more of an illustration. I am very much concerned about
5 establishing in regulations a set of priorities.

6 I think once you have these established in the
7 Register, they assume all the authority of law and you don't
8 really have any more capability of modifying that law which
9 you have now so long as you are exercising judgment within the
10 framework of the law, you see.

11 Now, you establish these which, as you say, are
12 Missions and bases for determining priority.

13 Well, if they are bases for determining priority,
14 then they constitute the Mission.

15 Therefore, it is up to the Council to make
16 decisions regarding the priority of achieving those missions
17 in terms of the applications that it has before it, in terms
18 of programmatic discussions, policy, and so on.

19 So I am really raising the important question here
20 as to whether or not it is desirable to put into regulations,
21 really, or into the Federal Register, which, as I say, has
22 all the authority of law, a set of priority values or
23 criteria that obviously can vary from time to time, but if
24 you write them down in the form of law, they no longer vary,
they no longer vary. This it seems to me ties the hands of

1 the Council and I am not really certain that it isn't a
2 violation, so to speak, of the responsibility assigned to the
3 Council.

4 That is the real point I am raising here.

5 DR. SCHREINER: What would you think of saying,
6 in determining priority of considerations, the Council shall
7 take into consideration and then have a paragraph rather than
8 a list of one, two, three, four, five, six, seven, eight,
9 nine, ten, so you don't get this rank order, and include some
10 of these items that the Council will take into consideration.

11 In other words, instead of saying the secretary,
12 say the council. That puts it back where you want to put it.

13 MRS. MARS: You have to have some criteria,
14 whether you call it priorities.

15 DR. ROTH: I was just going to make a tongue-in-
16 cheek observation that the moment you put down specifically
17 these things as priority items, it seems to me that you
18 virtually cast in concrete the shape of every grant
19 application because every good grant man is going to go
20 down one, two, three, four, five, six, seven, eight, and
21 cover them in his application.

22 This is what has been happening to us in the past.

23 DR. PAHL: We are somewhat caught because what the
24 secretary has said some moments ago is that we can't continue
25 to issue "guidelines" and operate on those guidelines as if

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1 they had the force of law without actually giving the public
2 at large an opportunity to see that they are being applied as
3 univorm requirements across the RMPs, so we would be back
4 in the same position where our regulations didn't really
5 reflect what our true program requirements are.

6 Now, I think there is a very good point here
7 that we don't necessarily have to have lists and one, two,
8 three, four, but if we are going to use these as the
9 basic requirements for considering grant applications,
10 then in honoring the spirit of the secretary's mandate, we
11 should have something in our regulations pointing out to
12 applicants what we really are looking at in terms of their
13 programs which, of course, will be reflected in funding
14 decisions.

15 MRS. WYCKOFF: I would like to see a definition of
16 "allied health."

17 DR. MARGULIES: Come on, now.

18 (Laughter.)

19 DR. KOMAROFF: What about, as George suggested,
20 that paragraph saying very broadly that RMPs are designed
21 to link facilities and to disseminate information from a
22 central source in both the category 5 diseases and in various
23 improvements in the health care delivery system and let it go
24 just that vaguely.

1 sexy to us today and you fulfill kind of cheaply the
2 mandate of the secretary.

3 DR. MARGULIES: We have no objections to that, but
4 we also continue to receive considerable criticism which has
5 been extended this morning on the failure of the RMPs to more
6 carefully define what it is they are setting out to do so that
7 whether we do it in regulations or somewhere else, I think
8 we have to make sure that it is understandable and probably
9 the part that needs to be underscored and Herb has already
10 said it, but it needs to be said again, is that this does
11 provide for public review.

12 That doesn't necessarily mean grantees, but any
13 part of the public that wants to know what it is the RMP
14 proposes to do and want a comment on whether they think they
15 ought to do it.

16 It will probably be followed at sometime in the
17 future with greater disclosure of this kind of meeting.

18 It will be very difficult for someone to look
19 at the minutes of this meeting and judge whether some
20 action has been taken without some understanding on the basis
21 of regulations of what it should be.

22 It is somewhere between those kinds of demands that
23 I think we have to find our course.

24 DR. DE BAKEY: But Harold, it is one thing to
25 set up a definition of Mission in the program and it is still

1 another thing to set up in terms of priorities of how you
2 achieve that Mission, regulations, really, that are factors
3 in making the assessment of judgment.

4 DR. MARGULIES: I am not disagreeing with you.

5 DR. DE BAKEY: That is the distinction I am
6 trying to make.

7 I have no objection, of course, to amplifying in
8 some form the Mission in the form of regulations. I think
9 that is quite desirable, but I am raising a very serious
10 question as to whether you allow those then to become the
11 rigid criteria of judgment.

12 DR. MARGULIES: I think we could function without
13 the priority statement. I am not deeply concerned about
14 that because that is a temporal kind of thing, a formative
15 one.

16 DR. PAHL: I think that is an excellent point
17 and if the Council wishes, because of the major impact that
18 that would have on this statement, rather than have you
19 respond to this statement more fully when you return, if you
20 would permit us to revise this section and resubmit it to you
21 ~~for your further comments and if a definition of "care" is~~
22 ~~required, under the revision, to have that included also,~~
23 we would then ask you to look at the revised statement at
24 your leisure at home and write us comments rather than trying
25 to pick each point.

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1 We would also go through the statement very
2 carefully in the sense of not alluding to priorities.

3 I do not mean to terminate discussion on any part
4 of the document. I thought perhaps I should say we should do
5 that.

6 MRS. WYCKOFF: If we were going to do the things
7 that are listed here, it would mean an appropriation of at
8 least a billion dollars.

9 DR. DE BAKEY: Perhaps we should.

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1 DR. MARGULIES: That would be one way of getting to
2 it.

3 DR. SCHREINER: This gives the procedures for
4 approving which are essentially what the secretary is doing.
5 The only value it seems to me in giving priorities is to get
6 the potential grantees who are reading this, have a feel for
7 what kinds of things are in mind of the council and I think --
8 that is why I think that the secretary is going to assign
9 priorities in 15-B-06 after first saying that he is going to
10 approve -- that these are the ways in which he approves the
11 action of the council and the next thing says the priorities
12 of the council. That negates the whole purpose of the council.
13 It seems to me, you should have a paragraph saying -- even as
14 a historical statement -- saying the council has given emphasis
15 to these kinds of things and then the kinds of things mentioned
16 without 1-A, 1-B, 1-C. It gets specific enough to give people
17 hints about what it is they should apply for but it doesn't
18 say that one is going to be ahead of two or four is going to
19 be ahead of eight. That is going to be something the council
20 determines. It is sort of a preamble.

21 I think it is fine to put down your philisophy even
22 if it is a historical statement.

23 DR. PAHL: We will do away with the priority sense
24 and recast this whole section in a different way.

25 DR. ROTH: I would just like to speak strongly to

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1 to this and emphasize one thing that those of us who have been
2 going through this presentation of grants have had drummed into
3 us but it hasn't been mentioned here today: A program which
4 would be totally inadequate and be worth nothing for funding
5 in sophisticated Boston area may be extremely important in--

DR. DE BAKEY: Houston.

(Laughter.)

7
8 DR. ROTH: We have been hung up on this business
9 of equating excellence and facilities and so on and so forth
10 to needs. I think we always have to remember what is going
11 to come up.

12 Many times in our emergency medical services we are
13 told if need is a qualification one program may rate a four or
14 a five plus whereas if resources and ability to effectuate a
15 program, they are down at the zero level. We don't want
16 to get hung up on these priorities.

17 DR. MARGULIES: I think as Herb indicated we can and
18 I think these points have been extremely helpful. There is
19 one aspect of the regulations that probably has a -- question-
20 ably has a higher priority in time than anyone else because
21 we have so many programs hanging fire waiting to know what
22 we are going to finally do and that has to do with the
23 coordinator RAG grantee relationships.

Maybe you want to comment on it?

24 DR. MILLIKAN: Are we leaving this?
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1 DR. MARGULIES: No. Not if you want to continue
2 with it.

3 DR. MILLIKAN: Even if you change it to goals
4 missions, et cetera, I think there needs to be a great deal
5 of attention paid to each of the items mentioned in the eight
6 under A. For instance, look at Item 1. This is a complete
7 change. I think you need to go over these things very
8 carefully. Item 3 mentions metaphores. For improved knowledge
9 and treatment. There is a real mix for you. On the one hand,
10 you have an educational function, on the other hand, you are
11 right out there treating patients for funding. That is a real
12 dandy.

13 DR. ROTH: Back up to 2, which says, prior early
14 increases in reliability or accessibility and moderation of
15 the costs. I am not sure but what an RMP function is not to
16 moderate the cost but to determine what the costs may be and
17 to find out what the problems in funding are.

18 To say that the RMP project has not to be directed
19 at moderating costs is a perversion of the kind of research
20 and development that RMP may be appropriately doing.

21 DR. MILLIKAN: In Item 5, this is where we came in
22 this morning. Take a look at Item 5.

23 Here is the authority in our regulations for HMO.

24 DR. MARGULIES: That would disappear in any case.

25 DR. SCHREINER: It is interesting that Title 9,

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1 Diseases are mentioned.

2 DR. PAHL: Without belaboring the point, I think
3 I am going to reiterate what Mr. Millikan has said and this is
4 not to throw off responsibility but has been drafted by
5 general counsel on the basis of their interpretation of what
6 our documents and existing regulations policy guidelines
7 criteria and so forth either say or imply.

8 To the extent that these words keep in either our
9 documents are not sufficiently clear or the interpretation
10 is too broad for our purposes but I do want to indicate again
11 whatever revised language we come up with must go through the
12 General Counsel's Office because it winds up to be a legal
13 document and these words mean more things to us also as staff
14 than -- we don't have to do everything because it is stated
15 in the regulations, but these are the interpretations which
16 General Counsel's Office has gotten out of our officially
17 publicized program documents.

18 To that extent we have to work back and forth and
19 eventually come to an agreement, but we take all of our
20 statements very seriously.

21 DR. DE BAKEY: Where it gets important is when you
22 get down to the money.

23 DR. PAHL: Of course.

24 DR. DE BAKEY: I hate to bring up this, but that is
25 how things get done. The regulations can affect both the

nb-5

1 expenditure of the money and how the money is to be used. That
2 is why this becomes completely important.

3 You see, if you go back to the Mission statement, you
4 see, that was a kind of a policy guideline and indicating some
5 changes. That doesn't have the kind of authority for spending
6 money that the regulations would have. That is why this becomes
7 so important and that is the point I was making about the
8 rigidity which regulations once they are published in the Fed-
9 eral Register become the rigid guide they become on how you
10 spend the money.

11 DR. PAHL: Well, I think speaking on behalf of the
12 staff and all those who participated in this, we not only
13 recognize but understand the statements, will recast this
14 and will be again very appreciative of additional comments
15 after we send you a revised version.

16 It is important and we are truly seeking council
17 participation before we get to this point. Of course, even
18 after council has approved and general counsel has approved
19 to whatever the final wording is and it gets published in the
20 Federal Register, there is still time for the public at
21 large and yourself to take exceptions to statements.

22 We will have time after publication for time to
23 review and come in.

24 DR. MARGULIES: Clark, you have more on that
25 section?

nb-6

1 DR. MILLIKAN: Not at the moment.

2 MR. MILLIKEN: I have a question on this priority
3 concept. The discussion here it seems to me we may be saying
4 two different things. Some of the council may be saying let's
5 wipe out the priority concept, you know, let's not go it.
6 I hear staff saying, perhaps, council along with everyone else
7 is stuck with a priority responsibility, but how this is worded
8 is the fine difference.

9 DR. MARGULIES: If I get the sense of the council,
10 what they are saying is that the establishment of priorities
11 is something which must be determined by the council with
12 recommendation to the secretary, obviously you cant leave him
13 out, he is the person who has the authority to spend the money
14 but this is something which we should feed in the language
15 which indicates it is the responsibility of council to address
16 priorities and to make those priorities well known to the
17 the public and regional medical programs in conformity with
18 the law.

19 That is a much more comfortable position to be in.
20 So you may find if you go back over this Mission statement,
21 I think you will find if you reread it that you would like
22 to amend it now. It is a year old and it is subject to
23 revision.

24 DR. PAHL: If we are finished with the discussion on
25 the regulations, I would like to turn your attention to two

nb-7

1 documents in the manila folders at your desk because this
2 should follow closely upon the present discussion. There
3 should be a manila folder at your desk.

4 A separate manila folder and behind the --

5 The first statement is beyond two maybes of how to
6 get to coffee and supper, is a statement called Governing
7 Principles and Requirements Discretionary RMP Funding dated
8 May 26. This is for information purposes for you and at this
9 point has not be distributed beyond some of our own staff and
10 to you. It is a statement which tries to set forth generally
11 applicable principles and gives those specific conditions
12 under which RMPs must obtain approval from headquarters staff
13 for certain specific kinds of rebudgeting in their programs.

14 This is not the development of new policy. It is
15 trying to put into written form the principles which we have
16 been following and I would call your attention primarily to
17 the fact that we have made a separation between those RMPs
18 which are within the three year triennial period and those which
19 have not yet been approved for a triennial period, but that
20 governing both of those kinds of RMPs are a set of four
21 general principles given at the top of the page.

22 What we propose to do is have you look this over
23 at your leisure and unless there are some severe changes
24 which should be made, we propose to send this out and have
25 this as an administrative policy. We would appreciate your

nb-8

1 comments now or in the next few days but it doesn't represent
2 anything which has not been our operating guideline, I believe.

3 Dr. Roth?

4 DR. ROTH: May I ask a question?

5 The requirements -- prior RMPS approval is required
6 in the following instances. Now, would you tell me what
7 prior RMPS approval, what is the methodology of accomplishing
8 this? What is that?

9 DR. PAHL: What really happens is that depending upon
10 the nature of the inquiry it would be the correctors approval
11 alone or would come to the council for example renovation in
12 excess of 25,000 or any new construction. We would tend to
13 use administrative judgment and if a request came in for
14 \$33,000 and was appropriated to what the council had intended
15 and had approved through its discussion of the application,
16 perhaps six months ago, then we might feel quite free to
17 grant that authority in that specific instance or even though
18 it were a small sum, if we had questions, then we would bring
19 it back to council for consideration if it were of a policy
20 nature.

21 We didn't know exactly how to spell out in detail
22 just what the dividing line would be because most of these
23 things you would not wish to have come to your attention.

24 In fact, they have not been large volumes of
25 requests.

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Take 11

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1 DR. ROTH: I just get hung up when I take my
2 first fast look at it and see you need prior RMPS approval
3 for anything involving, 1B, human subjects.

4 To me that is people.

5 MRS. WYCKOFF: Yes. What is "human subjects"?

6 DR. PAHL: This is an impossibly difficult area,
7 as you know.

8 There is a whole departmental operation and
9 regulation for those kinds of federally supported projects
10 which really involve human subjects for experimentation.

11 What we have basically done here is recognize
12 in print that there is a departmental policy and NIH, of
13 course, has the most elaborate review mechanism for this kind
14 of activity and we are merely putting in print for the first
15 time that there is this departmental regulation, and if the
16 request came in, which in the opinion of our staff
17 required departmental approval, then we would invoke the
18 necessary and established mechanisms for providing that
19 review, namely, through the NIH, and an official letter of
20 approval back.

21 If the nature of the activity being requested was
22 such that it did not have to invoke such an activity, we
23 would merely say over the phone, and send a confirming letter,
24 no approval is required, proceed.

25 This is really providing a guarantee to the applicant

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1 that he won't get in trouble later with a departmental
2 regulation.

3 As you know, it is very difficult in the area of
4 human experimentation to draw the line. It involves such
5 things as questionnaires and the social and behaviorial
6 sicences.

7 It is not just a medical experimentation.

8 DR. SCHREINER: The word "experimentation" is not
9 mentioned.

10 MRS. WYCKOFF: What is this immunization?

11 MRS. MARS: Why not spell it out more clearly?

12 DR. PAHL: That is the problem.

13 It is not that easy to spell it out clearly.

14 DR. MARGULIES: It may not be experimentation. It
15 may be an invasion of privacy.

16 DR. PAHL: Sending a questionnaire under certain
17 circumstances is an invasion of privacy.

18 To spell out "invasion of privacy" would require
19 a tome.

20 What we are doing is alerting. This is not a
21 regulation. It is an administrative guideline and we are
22 alerting applicants, if they are involving human subjects,
23 they have the responsibility to bring that to our attention
24 and we can decide whether it is within the scope of the
25 departmental requirements or not.

dw 3

1 DR. DE BAKEY: I think things like that are best
2 treated vaguely.

3 DR. PAHL: It is an extremely complex area.

4 DR. MARGULIES: If you were to set up two activities
5 and compare the results on health outcome over a period of
6 three years with one group getting what you think is good
7 treatment and the other group getting the control, you run
8 into some problems. You can't just pass that off.

9 Maybe it is an experiment, maybe you should say
10 leave that group the way it is, that is not an experiment.
11 This is the time we need to bring it back in for Federal review.

12 There have been rules written to cover that.

13 DR. PAHL: There is a body of regulations covering
14 that area.

15 We don't propose to duplicate it.

16 This is for your information only, but if there are
17 comments in the next few days, we would appreciate having them

18 Otherwise, we will have this as an issued
19 document.

20 The second document is one I do wish to call to
21 your attention very seriously.

22 It is the RMPS policy concerning grantee and
23 regional advisory group responsibilities and relationship,
24 also dated May 26.

25 There is a covering memorandum of May 26 on that

1 document.

2 Mr. Margulies referred to this earlier and the
3 reason we want to call to your attention this document is
4 that again this would not be a regulation, it would be an
5 elaboration of what that paragraph in the proposed regulations
6 intends to say and what it proposes to do is spell out for the
7 first time in the history of the program what headquarters
8 and council, because we seek your endorsement of this, what
9 headquarters and council feel to be the proper relationship
10 between the grantee and the regional advisory group.

11 As you know and as will become more clear in the
12 course of the meeting, this time there are serious problems
13 which arise because of lack of clear guidelines as to what
14 the roles and relationship of the grantee, the coordinator
15 and the regional advisory group are or are intended to be.

16 We have a number of problems now because of lack
17 of understanding or lack of agreement as to what those applied
18 understandings are.

19 This document makes it very clear that there are
20 two legislatively established units in a regional medical
21 program, namely, the regional medical group and the
22 grantee.

23 Tradition, custom, history and practicality have
24 established the coordinator or the director of the regional
25 medical program as the third important unit in this local

dw 5

1 organizational framework but he is not mentioned in the
2 legislation and in this document we have placed the responsi-
3 bilities and role of the director or the coordinator under
4 the title Chief Executive Officer and have that as a
5 major subsection of the grantee because the coordinator is
6 an employer of the grantee.

7 What this document therefore intends to do is to
8 try to set forth as clearly and unambiguously as possible,
9 and has gone through numerous drafts and has been approved
10 at this stage by the HSMHA branch management policy office,
11 so that unless otherwise changed, it has the approval of
12 HSMHA and would be a HSMHA policy as well as an RMPS policy.

13 I want to call to your attention three things
14 in this document.

15 The first is -- on the first page, under Section
16 B, Grantee, the key statement.

17 The grantee organization is charged with the
18 responsibility as follows:

19 The grantee organization shall manage the grant of
20 the regional medical program in a manner which will implement
21 the program established by the regional advisory group and
22 in accordance with Federal regulations and policies.

23 This statement, together with supporting
24 statements under the section titled "Regional Advisory Group"
25 later in the document clearly sets forth the regional

1 advisory group as having the responsibility for establishing
2 the program.

3 It is not the grantee, it is the regional advisory
4 group.

5 That is a very important point which, took some
6 degree of discussing as the document was being formulated and
7 redone.

8 The second -- well, let me follow that up by
9 saying on page three, under the regional advisory group, to
10 make sure there is no misunderstanding, the overall
11 responsibility of the regional advisory group is stated to
12 be "The regional advisory group or RAG has the responsibility
13 for setting the direction of the RMP and formulating program
14 policies, objectives, and priorities."

15 Now, the second point which I wish to direct your
16 attention to again is on page 1 under grantee and that is
17 Item 3, first of all.

18 That is Section B3. The grantee shall select the
19 chief executive officer, that is the coordinator, on
20 the basis of regional advisory group nomination.

21 So even though the chief executive officer, the
22 coordinator or director of the RMP, is the employee of the
23 grantee organization, he can only be selected, he or she
24 can only be selected by the grantee on the basis of
25 nomination by the regional advisory group.

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DR. OCHSNER: Is that the way it is now?

DR. MARGULIES: It is and it isn't.

DR. PAHL: Nothing is uniform across 56 regional medical programs.

Any statement we write here is going to have three unhappy medical programs.

It is impossible to develop understandings after a program has been in operation five years and not affect somebody adversely.

It doesn't matter what words are written, there can't be happiness throughout 56 or 57 RMPs.

MRS. WYCKOFF: It isn't retroactive, is it?

DR. PAHL: No. And there will be implementation in a logical and phased way.

But what it is saying is that this is what we perceive to be the proper role and relationship of the coordinator to the grantee.

DR. MARGULIES: I think in further response to your question, in practice, certainly in the last two years, the grantee has not selected a coordinator without fairly heavy involvement with the regional advisory group.

That part, I don't think, is going to cause any particular difficulty.

I think the last point will come to haunt this council. It should be made clear here.

1 In all honesty, I think we better face up to it
2 now.

3 I would like to call to your attention Section
4 B2.

5 This has to do with the election of the chairman
6 of the regional advisory group and if there is to be trouble
7 in any of the regional medical programs as a result of this
8 document, we believe it will be as a result of this particular
9 section.

10 What this says is that the grantee will confirm
11 -- and says subsequent selection of RAG chairman and the word
12 "subsequent" refers to the fact when an RMP is first being
13 established, then the applicant, who is usually the grantee,
14 has to select the usual chairman.

15 After the RAG bylaws are developed and approved
16 by RMPS, up until now it has been the practice, I believe,
17 of the majority of the regional medical programs to have the
18 selection made by the regional advisory group without any
19 need for confirmation by the grantee.

20 It is our position, the few of us who have been
21 instrumental in developing this statement, it is our position
22 that the appropriate relationship, not what exists, but the
23 appropriate relationship, and one which must exist for a
24 truly effective and viable RMP, is one in which the regional
25 advisory group chairman is confirmed by the grantee.

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1 We believe, as we conceptualize it, that in the
2 region there is a grantee organization, a coordinator, and a
3 regional advisory group.

4 Unless the relationships of all three are good work-
5 ing relationships, then, in fact, there is a serious problem
6 and over the last year and a quarter a number of these problems
7 have come to your attention and to Dr. Margulies' continuing
8 attention necessitating sometimes changes of grantee, but
9 more often than not, changes of coordinator or RAG chairman.

10 What this document proposes to do is say what should
11 be a functioning relationship in a triangular relation.

12 This means the coordinator is nominated by RAG
13 but selected by the grantee, since it is the grantee's
14 employee.

15 The RAG chairman is again selected by the
16 regional advisory group, but confirmed by -- confirmed by
17 the grantee organization, which means that at least there
18 is an acceptable individual in a position of importance on
19 the RAG, acceptable to the grantee.

20 We feel this is imporant and if this document, which
21 has not been submitted to the regional medical programs as
22 policy, if this does have your endorsement, there will be
23 a few regional medical programs that will find it very
24 uncomforatble.

25 We know that already.

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1 If we don't have this, the regional medical programs
2 will find it more satisfying and comfortable as a
3 document but it won't lead to an improvement in the relation-
4 ships which do exist.

5 We will continue to have, in our opinion, in my
6 opinion, the same kinds of problems which have been coming
7 to this council as a result of difficulties in this
8 triangular arrangement we have, which we call a regional
9 medical program.

10 With that, Dr. Cannon, if everyone is comfortable
11 with it, and we hope they would be, we can have this
12 endorsed.

13 We are trying to say to you there has been some
14 problem from some RMPs, particularly with regard to this
15 point.

16 DR. CANNON: I think there would be less problems
17 than we had in the past.

18 DR. MARGULIES: Having a set of rules is more
19 important than full pleasure in them.

20 I don't see any great problems in what we have
21 said.

22 DR. CANNON: I move that we accept this.

23 MR. MILLIKEN: Second.

24 DR. MARGULIES: We have a motion and second that
25 this be accepted.

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All in favor say aye.

(Chorus of ayes.)

DR. MARGULIES: Opposed?

(No answer.)

DR. PAHL: In recognition we are fast approaching lunch hour, let me say a few items are for your information only.

I don't think they require any particular discussion except that you may well be interested in the regional evaluation survey which was completed a while back and has to do with the present state of evaluation and of resources and activities in the regions, together with a document which points out how we plan to use our evaluation funds in fiscal '73 in very specific ways as well as a listing of contracts which are funded by us both in the kidney program and otherwise.

These documents -- we will be pleased to answer questions should you have one.

There is one last point of business which I think is important and that has to do with the kidney guidelines and I would ask Dr. Hinman to please present this point of business.

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1 DR. MARGULIES: We will ask Dr. Hinman to go over
2 these kidney guidelines. We will adjourn for lunch. After
3 lunch, we will proceed to some updating on the Cancer Construc-
4 tion Facility, and move from there to a review of the block
5 actions on the supplementary awards for emergency medical sys-
6 tems, health maintenance systems, and for the education acti-
7 vities.

8 So you can sort of set your timing accordingly.

9 DR. HINMAN: Thank you.

10 On May 3rd, this document was mailed to all of you,
11 the coordinators of the Review Committee. It incorporated the
12 discussions which had been held with this discussion over the
13 past two meetings, and discussions in the field over the last
14 eight to ten months.

15 The prime emphasis had been to try to begin to move
16 the kidney supported activities into the regional medical
17 program activities at a local level, and yet still maintain a
18 certain amount of program direction so there would not be over-
19 lapping and under-utilization of expensive facilities.

20 The emphasis here is upon the development of a
21 regional plan for the treatment of resources for ^{end} instage,
22 kidney patients, which must be approved by the RAG. And, then
23 applications from individual RMPs or investigators must meet
24 this regional plan. We have emphasized there would be a local
25 technical review that would be performed by three experts in the

1 field who do not reside or work within the region submitting the
2 application, and that they must be approved either from our
3 list of consultants maintained here, or a curriculum vitae,
4 sent to us for approval by the RMP; the written comments of
5 these reviewers would be presented to the regional advisory
6 group who would disapprove or approve the project and sent
7 it into headquarters.

8 There would not be an additional review at the
9 Washington level. It would be presented to the Review Committee
10 for priorities concerning funding.

11 This was discussed after the last Review Committee
12 Session. There was a question on one part of it which I
13 will bring up in a moment. I am wondering if you all have any
14 questions concerning any element in the document so far?

15 DR. MARGULIES: For the benefit of those who are
16 now on the Council, let me say very quickly, that the dialysis
17 and transplant program for kidney disease in RMP, has been
18 operated on a different basis from the other activities.

19 Our intent, over the long period of time, is to
20 establish on a kind of national network basis, a method of
21 investing RMP funds that will lead to an orderly development of
22 centers for dialysis and transplant, so that we do not scatter
23 activities according to individual perceptions, but rather move
24 toward location and development of competent centers, located
25 in a geographically strategically way so that at the end of a

1 period of time, we get as close as possible to total access to
2 a very predictable number of individuals who will require
3 dialysis and transplant.

4 As a consequence, we need a separate set of guide-
5 lines which has been up for discussion from time to time. This
6 is the final phase of that discussion. These were distributed.
7 We have had no negative comment that I know of from the regional
8 medical program, and there was, as will be indicated in a
9 moment, some question raised by the Review Committee.

10 DR. DE BAKEY: One question I wanted to raise about
11 it. I think it has confusion. In paragraph Six (b), it says,
12 "Assure maximum utilization of full-time transplantation surgery."
13 I think there is some confusion about what they mean by full-
14 time.

15 DR. HINMAN: The intent was that this would not be
16 a general surgeon doing it as a ten percent activity, but an
17 actual surgeon devoting the full percent of his time to trans-
18 plantation, not trans -- kidney transplantation, alone.

19 DR. DE BAKEY: it has been interpreted differently
20 in different places. In our region, it has been interpreted
21 two ways; Full-time in the sense of financial full-time, and
22 in the second sense that he would not do nothing else. That,
23 to me, you know, important to clarify because it has created
24 a lot of difficulty within our own program for this reason.

25 I think, you know, you have no idea what words like

1 this will do when you get out in the periphery of where they
2 can be interpreted differently and sometimes, they are inter-
3 preted differently because the people who are involved in the
4 interpretations want to interpret them their way, you see?

5 DR. MARGULIES: This also -- you picked up a very
6 critical point.

7 DR. DE BAKEY: I am always doing that.

8 (Laughter.)

9 DR. MARGULIES: It was very extensively deliberated
10 because the question was centered around whether you can get
11 an effective transplant activity going without a true basis
12 of commitment for the surgeon and the surgical team involved
13 and in some of the proposals we had, the attitude was, "Well,
14 of course, you know some one can come along and do it," which we
15 find highly unsatisfactory.

16 We are trying to make a clear-cut commitment and
17 support to that commitment.

18 DR. DE BAKEY: I think that is desirable. I agree
19 with you completely that there be in a sense a commitment to
20 the program. But, this can be done in a number of different
21 ways and different places. I am not at all sure -- I had been
22 entirely happy myself with a patient -- as a patient with a
23 man who is a full-time transplant surgeon.

24 DR. HINMAN: Dr. De Bakey, a question was raised as
25 to whether a person spending 75 percent of his time, whether

1 this represented full-time. We interpreted this representing
2 full-time.

3 DR. DE BAKEY: Yes. But you see, it is being inter-
4 preted differently. That is what I am saying. For example,
5 we have in our own group, all of us are full-time, you know.
6 We are regarded as full-time. That does not mean we give kid-
7 neys full-time or curettage full-time. We have had a team that
8 is well integrated.

9 DR. MARGULIES: I think we can do better with it
10 by referring it more to a full commitment, rather than full-
11 time, which is really what we are after.

12 MRS. MARS: Could one say, fully-qualified?

13 DR. DE BAKEY: No. I think the intent is not the
14 qualification because you can get that established. The intent
15 is -- important, but it is not being interpreted that way. It
16 is desirable to make this intent a commitment.

17 DR. HINMAN: Absolutely. We have one region that has
18 a number of places calling themselves transplant centers in
19 which the transplant is less than ten a year. We do not feel
20 this is adequate to warrant our RMP support.

21 DR. DE BAKEY: I think it is important to encourage
22 the expansion of the program. The need is greater than is
23 being met so to speak.

24 DR. MARGULIES: I think we can send out a clarifying
25 statement without changing the document which has already been

1 circulated.

2 I can do that and make the point that what we are
3 after is some method of assuring there will be ~~some one there~~
4 ~~who will devote enough time to it, to develop the team,~~ the
5 confidence, without depending upon the appearance of enough
6 patients to make it possible which is another kind of approach.
7 We can follow that.

8 MRS. WYCKOFF: Is Section 910 something we are using
9 for any of these, yet?

10 DR. MARGULIES: We will be, yes. And we will be
11 using 910 in this review cycle.

12 DR. HINMAN: If there are no other questions, I will
13 share with you the concern of the Review Committee. During the
14 discussions at the last Review Committee Meeting, the question
15 was raised concerning our statement on page three, Item Two,
16 the Second Paragraph in which we stated that should the RMP
17 desire to choose its own Review Panel, the names and curriculum
18 vita must be clear to the Division of Professional and Technical
19 Development.

20 After considerable discussion, they made a motion
21 that recommended to you all, that the wording be changed, and
22 require that the local RMP only utilize consultants whose names
23 are furnished by us, without them having an opportunity for
24 input.

25 This, from my personal standpoint, the document has

1 only been out for one month and we have not had an opportunity
2 to see if any problems will arise from this. So far,
3 any of the RMPs that have been reviewing kidney proposals have
4 called and asked for suggestions of names; we have given them
5 at least one or two more than they have wanted, and they have
6 been very comfortable with this arrangement.

7 DR. MARGULIES: The Review Committee felt very strong-
8 ly about this. Their argument was if you are going to use
9 outside consultants, and try to obtain objectivity, you have
10 a much higher level of security by doing it by a national panel
11 with the assignment or at least, the request for professional
12 assignment coming from RMPs rather than from a panel
13 from which the RMPs made their selections; and felt there was
14 in the later sources, the source of some bias.

15 I do not think it would do any harm -- Len, do you
16 have any further comment you would like to make?

17 DR. SCHERLIS: I think what you have stated fairly
18 reflects the review. We felt there is no reason for having a
19 kidney project than there is to allow a region to select its
20 on-site visitors.

21 I think you should have some national standards and
22 the best way to have them is by having a national panel and
23 that automatically, when they stated that they had a real
24 project, this should be looked at by a national panel.

25 I do not believe in having a panel selecting those

1 groups they wish to select.

2 DR. MARGULIES: That was really the axis on which
3 the argument went on, George?

4 DR. SCHREINER: I think you should give them that
5 flexibility. There are two problems with having a closed
6 national panel. One is that it is true that it does guarantee
7 a certain amount of standard quality, but it also is true that
8 generally speaking, people who go in such panels, activities
9 are -- have other attributes besides their competence.

10 One is they have the time available, and two, is that
11 they are often selected on the basis of a certain kind of
12 breadth that you might not find in all technical consultants.
13 Whereas when you are putting together a program from scratch,
14 you might want a technical competence that you are not going
15 to find in the older, more established panelists, who are on
16 the registry.

17 It seems to me that the RMP can utilize that. If
18 they are going to have three regional renal authorities -- if
19 the trouble is with the AV fistulas, that are breaking down,
20 you might not want a renal guy. You might want a very good
21 peripheral vascular surgeon. As long as they are subject to
22 some kind of a veto power, it seems to me that the document as
23 it exists, gives this added flexibility.

24 I also think it would be bad to change things. We
25 change them too often.

1 DR. MC PHEDRAN: Could you have the best of both
2 worlds by adding a member that would be on everyone of the
3 site-visit items?

4 Have a national group always represented in the site-
5 visit team, plus special technical advice which was suggested
6 by the particular program that was being sight-visited?

7 DR. SCHREINER: These really are not site-visits.
8 These are site-visits. (indicating.)

9 DR. MC PHEDRAN: I am sorry.

10 DR. SCHREINER: The region is putting together a
11 program and obviously, it is to its best interests to get the
12 most expert people.

13 DR. MARGULIES: It is partly that, but it is also
14 partly to see what they have put together.

15 DR. SCHERLIS: It is my interpretation the work will
16 be done by the individuals selected. From there, as I listen
17 to what you said, as I recall our discussion, the rest of the
18 Review Committee would not be related to the technical aspect.
19 This is not just relative.

20 It is when it comes in, it would have the stamp of
21 approval on it, saying the technical review is excellent, but
22 the people who did the technical review will have been selected
23 by that group of individuals putting together their own program.
24 This is a technical review.[?]

25 DR. SCHREINER: When the region is visited, the site-

1 visitors will look at who did the technical review.

2 DR. MARGULIES: I think -- the thing is that it is
3 a question of degree. We would restrict them to a group of
4 consultants whom we have selected for that purpose. The real
5 discussion is whether it is adequate to have them select from
6 that restricted group, or whether we should assign from that
7 restricted group.

8 The paper which has gone out already, has made that
9 that they could select from that group.

10 MRS. MORGAN: This is a group you have selected prior
11 to this.

12 DR. MARGULIES: Yes. That we have selected or that
13 have been suggested to us. We have agreed they should be a
14 part thereof.

15 Now, if you wish to change it in deference to the
16 Review Committee's objectivities, we can do that. Or we can
17 leave it as it stands, and see how it functions, and review it
18 in the future to see if it needs to be altered. Either way.

19 DR. DE BAKEY: In the document here, you make it
20 quite specific that the RMP's Review Committee will not review
21 on a technical basis, the merit.

22 DR. MARGULIES: That is right. It is to be done
23 by the consultants.

24 DR. DE BAKEY: So in a sense, you are putting the
25 responsibility for the technical aspects on the consultants?

1 DR. MARGULIES: Yes.

2 DR. HINMAN: We do not do technical review of the
3 RMP applications on a project by project basis anymore, except
4 in the EMS round.

5 (Laughter.)

6 DR. MARGULIES: This is the one in which we wish
7 explicitly build in technical review.

8 DR. DE BAKEY: Wait a minute, you do on your project
9 visits. You have technical review on project site visits.
10 I think there is a lot to be said for keeping it the way it is.
11 I would be inclined to leave it the way it is in spite of
12 the strong feeling of the Review Committee.

13 I think there are some good reasons for leaving it
14 this way.

15 DR. MARGULIES: Any further discussion?

16 DR. DE BAKEY: ~~Secondly, I do not see why there is~~
17 ~~such a big point made by the Review Committee.~~

18 DR. MARGULIES: Well, like with any other discussion,
19 you sort of have to be there to get the feeling of it.

20 Would anyone like to make a motion on this?

21 Want to ponder it further?

22 DR. SCHREINER: You want a motion for approval of
23 the guidelines? I would so move.

24 MRS. MORGAN: Second it.

25 DR. DE BAKEY: With clarification of the full-time

1 time business.

2 DR. SCHREINER: Right.

3 DR. MARGULIES: Moved and seconded, the guidelines
4 be approved as they have been distributed with a letter of
5 the clarification of the meaning of full-time surgeon.

6 All in favor, say "Aye."

7 (Chorus of Ayes.)

8 DR. MARGULIES: Opposed.

9 (No answer.)

10 DR. MARGULIES: We will reconvene at 1:16.

11 (Whereupon, at 12:35 p.m., the hearing was recessed,
12 to reconvene at 1:16 p.m., this same day.)

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AFTERNOON SESSION

(1:35 p.m.)

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3 DR. MARGULIES: You will recall that part of the
4 unfinished business of the last meeting had to do with the
5 action of the Council regarding the application for a
6 construction grant for a cancer center in Seattle.

7 There was a motion by the Council which was passed to
8 provide the grant award if certain conditions were met. As you
9 know, this was a specific action which had been made by the
10 Appropriations Committee in the preceding fiscal year,
11 identifying \$5 million for this purpose.

12 There were very careful reviews of the applications
13 including the primary one which came from Seattle. There has
14 been a series of events following that which Mr. Russell, who
15 is the head of the western group of programs will summarize
16 for you.

17 We have not awarded the grant and if it is to be
18 awarded it must be awarded within this fiscal year because we
19 had to make sure that all of the requirements were met and give
20 the Council the opportunity to see whether or not they would
21 accept the application in the modified form.

22 So, if you will bring us up to date?

23 I should add that the amount of work which has gone
24 into this on the part of the staff has been extraordinary and
25 it's been very carefully correlated.

1 We won't detail all of that. You can assume that's
2 been the case and Dick will take over from there.

3 MR. RUSSELL: As most of you will remember, the
4 award was contingent upon the applicant's meeting a number of
5 specific conditions. There were four major conditions.

6 The first one was that all relevant federal, state
7 and local requirements concerning expenditure of federal funds
8 for the construction of the proposed type of facility -- this
9 includes all needed licenses, permits, approval, et cetera -- be
10 met.

11 The applicant has satisfied this condition.

12 The second condition was that the University of
13 Washington and Swedish Hospital formalize their relationships
14 with the Fred Hutchinson Cancer Research Center through written
15 agreements.

16 There now exist formal affiliation agreements
17 between the Fred Hutchinson Cancer Research Center, Incorporated
18 and the Board of Trustees of the University of Washington and
19 between the Center and the Swedish Hospital Medical Center.

20 The third condition was that all conditions
21 contained in the Council's November 10, 1971 statement on
22 cancer center to serve HEW 10 are satisfied.

23 In February, you remember Council received the report
24 of the January site visit to the Fred Hutchinson Cancer Research
25 Center and found that most of the conditions set forth in the

1 November statement of Council had been satisfied.

2 Those conditions which were not satisfied at that
3 time were covered by the conditions placed on the awards.

4 The fourth condition was that the provision of space
5 to accommodate 20 beds which would be isolated from the Swedish
6 Hospital Medical Center be reconsidered with further justifica-
7 tion for review and approval by the National Advisory Council,
8 RMPS.

9 This condition stemmed from Council's concern that
10 research patients in isolated units often receive inadequate
11 general care. The placement of the beds in the Fred
12 Hutchinson Cancer Research Center it seemed would separate the
13 research patients from the general medical services that they
14 would require.

15 Further it appeared that adequate emergency services
16 might not be available to the research unit since there was
17 no indication that the professional attention and facilities
18 required for emergencies would be available immediately.

19 Now, you have before you the applicant's response
20 to Council's concerns. This is the letter dated April 22nd,
21 signed by Dr. Hutchinson, President and Director of the Fred
22 Hutchinson Cancer Research Center, Dr. Lobe, Medical Director,
23 Swedish Hospital Medical Center and Dr. Donald Thomas, Head of
24 Medical Encology at the University of Washington.

25 This states the consideration of the bed has been

1 reconsidered and the plan to place the beds in the center was
2 reaffirmed, the primary reason being if the beds were not placed
3 in the center, the regional concept in the Northwest area would
4 be seriously jeopardized.

5 What the letter does not say, but is a fact, is that
6 if the beds were placed in any other facility except the center,
7 one of the major institutions in Seattle which is heavily
8 involved in cancer programming will not participate in the
9 center.

10 Therefore, the entire regionalization concept will
11 go down the drain.

12 The letter as you know states that the center will
13 have complete medical staff ranging from house officers to
14 fellows to a senior staff of 24-hour coverage seven days a week.

15 The beds in the center will not interfere with the
16 excellence of treatment and care given to the patients. Since
17 the center will be connected to Swedish Hospital by a short
18 tunnel and elevator, the patients will be in immediate
19 proximity to all hospital services.

20 The applicant believes that any emergency measures
21 could be promptly instituted and the treatment facilities
22 available will be closer than in many large hospitals.

23 In summary, then, the Fred Hutchinson Cancer Research
24 Center has responded to all of the conditions placed on the
25 award. Through administrative and previous Council review, it

1 has been determined that to date all forms of these conditions,
2 the issue of the bed locations, have been satisfied.

3 Since this requires Council consideration, this is
4 what we are placing before you now.

5 MRS. MARS: First of all, I would like to make a
6 motion that the money be awarded with the condition that the
7 fourth condition be taken out of the motion that was previously
8 made. I think that the -- it's very necessary that the beds be
9 in the research center. I think we would be doing them a great
10 deal of harm and defeat the purpose of the entire center, for
11 what it stands for, not only in regionalization, but it is going
12 to stop teaching; it is going to stop research.

13 It becomes part of Swedish Hospital; the patients
14 become under the supervision of Swedish Hospital and having met
15 the people involved, the caliber of the type of individuals
16 involved in the Fred Hutchinson Center, I just cannot see that
17 there would be any question whatsoever as to the treatment and
18 the type of care that would be rendered patients under their
19 supervision.

20 So, therefore, I think that we are doing them a
21 great injustice by insisting that these beds go into Swedish
22 Hospital. I think the whole purpose would be defeated
23 entirely and, as I say, a great injustice created.

24 I met these people; I talked to them. I think this
25 letter explains - I think everything that is said in this letter

1 would be carried out and they could be completely trusted.

2 DR. MARGULIES: There is a motion to approve the
3 grant award and accept the placement of the hospital beds as
4 proposed by the applicant. Is there a second?

5 DR. DE BAKEY: I second.

6 DR. MARGULIES: Be moved and seconded. Further
7 discussion?

8 DR. OCHSNER: I presume -- they say the Swedish
9 Hospital will supply recovery room. Will that mean that the
10 patient will remain in the recovery room in the Swedish
11 Hospital?

12 MR. RUSSELL: I do not know, sir.

13 DR. OCHSNER: The supplying of the recovery room
14 doesn't mean anything unless the patient remains there.

15 MRS. MARS: I think this is a fact. This would be
16 carried forward.

17 DR. DE BAKEY: I don't see how they can possibly
18 duplicate in the center a recovery room and intensive care unit.

19 MRS. MARS: I don't think there is any attempt made
20 to do so.

21 MR. RUSSELL: Dr. Ochsner, I believe Mrs. Mars'
22 observation is correct. Having looked at the schematic plans
23 and not being an engineer, I can't say for sure, but I don't
24 see plans for a patient recovery room.

25 DR. OCHSNER: I wondered whether they were going

1 to leave the patient there because they were so adamant about
2 not leaving the patient there.

3 DR. SCHREINER: On this scheme where are the
4 elevators?

5 MRS. MARS: There's a tunnel, you see, which goes
6 underneath and this tunnel is very short. Actually, we walked
7 the ground distance above and it's not very far.

8 DR. OCHSNER: Ninety feet.

9 DR. SCHREINER: I presume the building is somewhere
10 inside.

11 MRS. MARS: I can't remember where the elevators
12 would be.

13 DR. SCHREINER: It would make a difference if the
14 elevator were at the other end of the building. Not that I
15 would predict that hospital architects could be that stupid,
16 except I haven't worked in one yet in which they haven't been.

17 MRS. MARS: I presume there will be some such errors
18 made.

19 DR. MARGULIES: They have had extensive architectural
20 consultation. They have not had legal consultation to the
21 extent you heard this morning, George.

22 Any further discussion?

23 DR. DE BAKEY: How many beds in the center?

24 MRS. MARS: Twenty. And there is space, adequate
25 space to increase that number at some future date.

1 The one thing that we fought them particularly on
2 was the fact that so much space was relegated to parking areas.
3 This in the end obviously was not necessary and that space
4 can be utilized and at some point can be utilized for more
5 beds if necessary as well as laboratories.

6 So that all this, every inch of ground will be
7 utilized for the research center. As I said before, the
8 caliber of people involved, there's just no question in my mind
9 that care, proper care would not be instituted and carried out
10 to the nth degree.

11 DR. DE BAKEY: To what extent will the University
12 of Washington participate?

13 MRS. MARS: They will participate as far as
14 teaching and their students coming over, supportive faculty.
15 I believe part of their faculty will be involved in it. They
16 would use it for their own teaching purpose.

17 DR. MARGULIES: I think all of the affiliation
18 agreements, they are not only signed but I think there has been
19 a real effort to work out the usual kinds of sticky details
20 when you have research grants in one activity going on in
21 another.

22 I think they are probably as far along as one can
23 get before the building is completed.

24 DR. SCHREINER: I can see where we are under a lot
25 of pressure here. I don't think we should gloss over it, no

1 matter how competent anybody is in the cancer field. That is
2 a long way from a complete medical staff.

3 It's fine if you are not dealing with very sick
4 patients, but if you need a pulmonary machine in a hurry and
5 there are a couple of them across the street, it's going to pose
6 real problems in the thought that you could have a totally
7 competent emergency service serving 20 patients.

8 It means one of two things: Either they are not
9 going to be complete or its going to be very expensive. You
10 can't get around the logistics. You can't provide a complete
11 medical staff for 20 people.

12 MRS. MARS: No. But the facilities are completely
13 available within 90 feet so to speak.

14 DR. MARGULIES: If there is no further discussion, the
15 motion is to approve the grant award with the conditions which
16 you have established and which have been met, dropping out the
17 requirement that the beds be moved out of the center.

18 All those in favor say aye.

19 (Chorus of ayes.)

20 DR. MARGULIES: Opposed?

21 (No answer.)

22 DR. MARGULIES: Thank you, Dick.

CR 6499

End #13

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BEGIN¹³⁴EMS

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We will now move to the consideration of the special actions which are going to be presented as bloc actions, one on emergency medical services, the other on health maintenance actions.

Len, do you want to come up to the front?

By way of introduction, these are carried out as supplementary reviews because we were, at the time of setting up the review processes, unsure of the total amount of funds which would be available to us in June. This is June and we remain unsure of the total funds which will be available to us. At least that part of it was correct. What we therefore decided to do was to provide regions the opportunity to respond to a special supplementary award concept.

We had in the course of doing it to set up some very specialized procedures. Obviously, the best thing to do would be to combine review committee and council membership to carry out these review processes and that we have done.

With the emergency medical systems, we asked Dr. Scherlis to act as chairman of a group which included Dr. Bessen and Mr. Toomey and Drs. Roth and McPhedran from the council. They did participate in that review. We also had some consultants in emergency medical systems to come in; Dimmick from Alabama, Kenrick from Ohio.

The subcommittee activity was headed by Dr. Rose whom you met earlier.

nb-2

1 The only other thing I want to say before Dr. Scherlis
2 makes the presentation is that there are two activities in
3 the emergency medical field which are undertaken at the present
4 time. One of them is a contract activity which is managed
5 out of the office of the administrator and which provides with
6 a total of \$8 million for five demonstration contracts to be
7 carried out by those applicants who within the contract award
8 in a national competition. That competition is under way at
9 the present time.

10 The contracts submitted, the responses to proposal
11 have all been in. They have been through review. Site visits
12 have been conducted. We do not at this time know which of the
13 applicants will receive the contract.

14 Now, because these contract requests came in at
15 the same time as our emergency activities and this was delib-
16 erately planned, we have set up a mechanism for keeping a day
17 by day information flow between the contract activity and RMPs
18 activity so there is no possibility that we would be awarding
19 to RMP funds which are also being awarded through contract.
20 There won't be any duplication.

21 Back of this effort lies the desire which I feel
22 rather strongly about to make sure that anything which is done
23 in the emergency field through major demonstrations does not
24 simply remain five interesting demonstrations as is so often
25 the case.

nb-3

1 We hope that we can follow the earlier thrust of
2 RMPs towards emergency medical services by setting the stage
3 for a much better integration of emergency medical care than
4 has been present in the past and by establishing an environment
5 by anything which comes out of the major contract demonstrations
6 will have meaning for fuller utilization across the country.

7 We have generally followed the same principles as
8 the contract has followed in its review processes.

9 Len, if you would like to introduce what you have
10 done.

11 DR. SCHERLIS: First I want to thank you for the
12 opportunity of presenting the findings of our subcommittee.
13 I particularly want to thank Dr. Roth who was here, because
14 I had been impressed until I read the review in the American
15 Medical Association Bulletin.

16 The committee was faced with what to me is one of
17 most formidable tasks that a review committee can have and it
18 would have been impossible without the help of staff.

19 I will allude to that in a moment. We had some 35
20 projects submitted from the various regions and some of these
21 projects really existed have not just one but six individual
22 projects. This itself said something to us as far as the
23 review was concerned. Each region had received some very well
24 detailed guidelines as far as what was hoped there actual
25 application would include and it is interesting to note that

nb-4

1 some of them went right down the line and almost rephrased
2 the grants, exactly what the application planning had indicated.
3 Others indicating a high degree of independence paid no
4 attention to what the guidelines were. Some were inbetween.
5 Some of the applications really addressed themselves to the
6 total system of care which is what the committee was basically
7 interested in. Unlike the contract funds which in some
8 instances look at specific aspects of emergency care, the
9 applications we were most interested in really related to a
10 total system which involves not an excellent project on
11 trauma or one on coronary disease, but one which put all of
12 these together.

13 This had to be part of our consideration because
14 they are talking about a total system. One couldn't begin
15 at this stage to front part of the system which was so highly
16 categorical that it could not come to terms with what could
17 be a total system of care. At the same time there had to be
18 some realistic limitations in our consideration, not just
19 because of the function constraint, which we don't know about
20 because we are operating in a vacuum here as far as knowing
21 what funds are available, but because of the constraint too
22 that any system being proposed now might begin with a small
23 bite of what can be done but yet it had to pay attention to the
24 fact that whatever bite was now supported would be part of an
25 overall planning process.

nb-5

1 The staff work that I have alluded to briefly, was
2 an excellent one because what had been done was to go through
3 all of these projects in some detail looking for actual page
4 references in terms of the guidelines set out. The reviewers
5 had six or seven programs for primary review and another six
6 or seven for secondary review.

7 You know the thickness of these grants, particularly
8 when there was a time limitation on the applicants, what was
9 done was to give us three or four pages of material which were
10 relevant and then everything else which was of background
11 material.

12 The background material, as you know, becomes more
13 and more extensive as the program becomes more and more
14 limited. I for one ended up with many dry figures. The volume
15 of the material was unbelievable.

16 The review meeting was an all day affair. We did
17 not adjourn for lunch, we did not adjourn for coffee, just
18 to give you an idea of the problems we had.

19 We reviewed the 35 projects in some detail trying
20 to, as I indicated, trying to look at a total system of care
21 to make sure that all of the community components were
22 involved with plans, looking for demonstrations of needs.

23 It is simple to come up with a project that says
24 finance 50 ambulances each one of which is a coronary care
25 vehicle and to list all the hardware for -- telemetry and to

nb-6

1 go into a system of communication. But what we tried to find
2 out was if this related to a system of care which got involved
3 with existing emergency rooms, hospital facilities. In great
4 measure the work of the Interagency Society -- ICHD -- these
5 reports helped us particularly the one on the stratified system
6 of care.

7 A lot of the emergency care in the area of heart
8 disease relates to it. As I said that is not the categorical
9 support.

10 The type of evaluation we had from the staff is
11 a highly detailed report which we paid great attention to. At
12 least it gave us a sense of what was included and what the
13 rating was.

14 Dr. Rose is to be congratulated for the work his
15 group did on this.

16 In total we reviewed 35 projects. The amount
17 requested came to a total of \$14 million for a grand total of
18 three years of \$33 million.

19 Five of them we gave recommendation of disapproval
20 to: the remaining 30, the first year where 14 million had been
21 requested, we recommended a funding for the amount of \$5,788,000.
22 For the second year, 3,302,000.

23 Some of the recommendations are in terms of taking
24 what had been a large request, sometimes totally several
25 million dollars and grading it down to what we requested that

nb-7

1 they were funded for planning. In some instances the plans
2 were excellent. In terms of the involvement of community
3 groups which would have to be a part of the program, we felt
4 this was a glaring enough omission that we would recommend
5 no funding or minimal amount for planning.

6 There was a wide variation as far as the content
7 of these proposals. In one or two instances, indeed a total
8 system of care was set up involving training of the necessary
9 medical and allied health groups, transportation which was
10 on a broad base not just dedicated vehicles, emergency medical
11 services, lay education, professional education, and a whole
12 gamut of care involving trauma, heart disease, psychiatric
13 care, and so on.

14 The others which were packaged for hardware, out
15 of the blue, without there being any indication or support what-
16 soever. The levels of support vary markedly. We graded them
17 as best we could, giving a priority grading, five being the
18 highest. In natural fact only, a few fours were present.
19 Some you will note were zeroes. In some instances the appli-
20 cations we received really weren't sent to us. I say that
21 because it was apparent from dates and from letters of
22 approval that they had been prepared in the past for other
23 sources of funding and because some were duplicates of what
24 had been sent for the contract funding and as such really
25 didn't address themselves to systems of care, only looked at

nb-8

1 very small parts of the package.

2 The members of the committee here, Dr. Roth,
3 Dr. McPhedran will vouch for the fact that if we had difficulties
4 it was in terms of wading through what looked like systems of
5 care until you got down to the fact that these had really a
6 lack of wide community support, a lack of evidence of accept-
7 ability in the total community.

8 Some states which submitted two or four or six
9 different applications weren't related. Thus a variation
10 as far as levels of support which were suggested.

11 My own feeling is that emergency medical services
12 is one of the very few opportunities which the regional medical
13 program has of setting up cooperative ventures in systems of
14 care and actually addressing RMP to the problem of strati-
15 fication of care, reference centers for types of care, and
16 putting the various individuals involved with emergency care
17 into committee or planning group, probably involving what I
18 think is a very important aspect of regional medical activity.

19 Thank you.

20 Dr. Roth, Dr. McPhedran?

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End of #14

CR 6499
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dh 1

1 DR. ROTH: I think that he has given an excellent sum-
2 mary of the dilemma or the problem that we had before us. It
3 was perfectly obvious as I had occasion to say earlier this
4 morning, that presented a problem that we have run into many times
5 in RMP:

6 If need qualifies you, certain areas automatically
7 get a top priority, and if resources meet those needs, you're in
8 trouble. So we did the very best we could.

9 I think the council should be aware that when you
10 look on this summary page, you almost don't have to look over
11 the last two columns to see what happened. The programs that
12 got rated five and four made out reasonably well in the finan-
13 cial dealings, recommendations.

14 The people with the threes and the two and a half and
15 so on, have made out less well. But this is merely a reflection
16 of the concensus of the resources those extremely poor in many
17 of these places where the need is so tremendous to at least give
18 them money to go on with further planning and try to get a show
19 on the road.

20 It may be far more important than just its reflection
21 in emergency medical services, because this may be the very first
22 bit of honest to goodness impact of RMP in any respect in these
23 areas.

24 DR. MC PHEDRAN: The only thing I have to add is that
25 Dr. Scherlis prepared his own material and made intelligent

dh 2

1 comments. I move to accept his recommendations.

2 DR. ROTH: I second.

3 DR. MARGULIES: It has been moved and seconded that
4 the recommendations of this special review committee be approved.

5 Let me say again that in this, as in other kinds of
6 applications, we -- whether we know exactly the amount of money
7 available or not is incidental. We do try to look at the qual-
8 ity of the proposal rather than the funds available and try to
9 match the two together.

10 There are practical reasons for doing that, and
11 quality reasons for doing that. They worked hard. It was an
12 extraordinary exercise, and the comments have appreciation, I'm
13 sure the staff endorsed totally.

14 Is there further discussion of this recommendation?

15 DR. ROTH: Only to give an order of magnitude to Dr.
16 Scherlis' comment about the bulk of the material, since it arrived
17 one day before I left on a 10 day trip around the country. I
18 weighed it. Sixty pounds of it.

19 DR. MARGULIES: We had planned on your cancelling
20 that trip.

21 (Laughter.)

22 DR. MARGULIES: Any further discussion?

23 DR. DE BAKEY: I would like to ask one question in
24 regard to this program. It seems that as Dr. Roth said, this
may have potentially great impact and I'm wondering if the

dh 3

1 council wouldn't do well to give some thought to assessing
2 this in terms of its total priority of funding in this area?

3 DR. MARGULIES: I don't know if you all heard Dr.
4 DeBakey. He was commenting and agreeing that the emergency med-
5 ical area is one that is particularly appropriate for RMP, and
6 rather than merely taking action on the motion, he wonders if
7 it might not be appropriate for the council to comment on the
8 kinds of priority it would give for funding on the assumption
9 there may be competition for funds.

10 DR. ROTH: Well, it probably is important for the
11 council to recognize, maybe everybody does, but for example,
12 you will nothing that Florida which typifies, one problem was
13 turned down completely, zero, disqualified. Not because it
14 wasn't one of the best programs in the whole bunch, but because
15 it had been previously fully funded through a formal RMP grant.

16 I just bring this up as evidence of the fact that
17 this is not an exclusive program. This is using some money. We
18 don't even know how much, really.

19 DR. MARGULIES: There are two complications for any
20 kind of action you might take on the priority. One has to do
21 with whatever we do between now and the end of the year, and
22 the other has to do with the level of encouragement we give to
23 programs either that meet our needs and could not be funded, or
24 programs that need further development and refinement during
25 the coming year.

dh 4

1 I received a note just now that the house has --
2 the committee actually of the -- subcommittee on appropriations
3 has reported out a recommendation of \$150 million in grants
4 contracts, etc., for RMP's. At least we have one stage of the
5 discussion under way.

6 I don't bring that in because it means anything spe-
7 cifically, but it calls to mind the fact we have another year
8 coming up and priority considerations which the council is
9 concerned with.

10 DR. DE BAKEY: I think it has appeal, too, in addi-
11 tion, so that I think it deserves considerable and serious
12 consideration. Possibly encouragement of the whole as expected
13 of the program.

14 I don't think this is being done well in most of the
15 programs.

16 DR. KOMAROFF: How does our action effect the council
17 approved level for a region and is there any flexibility for a
18 region that gets this awarded to take any of that money and
19 redirect it into other activities.

20 DR. MARGULIES: No. What we will have to do, when
21 we are through with those special actions, is request of the
22 council a motion to adjust the level of the RMP to accommodate
23 whatever has been approved by supplementary grant.

24 But the exacty way in which these awards are going
25 to be handled is -- we still have to negotiate because it

dh 5

1 depends in part on the language attached with any release of
2 the 7.5 million and any language with the release of the remnant
3 of the ~~MHC~~^{HMD} money.

4 If they say we can spend it but not raise the level
5 of commitment, we may have to release funds for more than one
6 year. If not, then we can work it out over a period of time.
7 So if you take the action to allow the region to adjust its
8 level, it can do any internal manipulation which it needs.

9 It does imply a raised level of commitment on paper.
10 Any further discussion? Does anyone want to take
11 further action, or did you want to amend the motion?

12 DR. DE BAKEY: No. I really didn't mean it that way.
13 I thought it was just wise that we take cognizance of the im-
14 portance of this program, for one thing, and secondly, to --
15 as an -- express some kind of sense of power on it. I didn't
16 want to get into the establishment, but rather than to express
17 a sense -- in the sense that council wishes to express that,
18 then if that's all I was intending to do.

19 DR. MARGULIES: Well, without going through the
20 motion process, may I feel free in stating or in taking this as
21 a sense of the council, this emergency medical activity is of
22 high priority and should be given full consideration in any
23 executive funding?

24 I see nods. All right.

25 If there is no further discussion, all in favor of

dh 6 1 the motion say aye.

2 (Chorus of ayes.)

3 DR. MARGULIES: Opposed?

4 (No answer.)

5 DR. MARGULIES: Thank you.

6 DR. MILLIKAN: I have a question. Somebody like
7 Tristate now, two and a half million, what will the phasing be?

8 DR. MARGULIES: That's part of the problem. If OMB
9 says you can use it, the money, but you can't raise the commit-
10 ment level in the second and third year, we may have to devise
11 a method of either scaling it down or doing what is effective
12 forward funding of it to make sure it is made available.

13 That kind of acting process has not been selected
14 yet. We are still trying to get it clear. We have a few days
15 left.

16 DR. MILLIKAN: I'm also looking at it from their end
17 of the line. If they get 2.5, what kind of continuity is going
18 to be established at the other end? This is quite a change?
19 How much will they need to continue, what's the second year
20 level, third year level?

21 DR. MARGULIES: If we find that the potential level
22 at stake is higher than they can reasonably expect to reach by
23 rejuggling , we will not get them involved in that kind of
24 spiral because there is that danger.

25 DR. SCHERLIS: That has to be a very carefully

dh 7

1 monitored program.

2 DR. MARGULIES: This is what we can determine when
3 we know our total funds available and make some kind of guess,
4 with luck, this month on what the level will be in the subsequent
5 year. We are really walking a tight rope on this. The recom-
6 mendations we need, the final action will be very complicated.

7 DR. DE BAKEY: Chances are it won't be less than one
8 fifty?

9 DR. MARGULIES: I wouldn't think so.

10 DR. KOMAROFF: Could there also be a sense of council
11 that any requests come through the formal process?

12 DR. MARGULIES: There is no question about that.
13 They will. This number of us like, and there was no choice we

14
15 The next item for discussion will be the applications
16 for health maintenance organizations which will be -- Dr. Mak
17 Leod here?

18 Jerry, would you like to join us up at the front table?
19 Mr. Riso is now with us.

20 We will go through the HMO applications, through the
21 education applications, and then we will do our very best to get
22 to those requests for action which depend upon the presence of
23 individuals who are here only for this afternoon. We will try
24 to keep things moving as effectively as possible.

25 For this portion of the presentation, in just a

dh 8

1 moment, I will turn it over to Dr. MakLeod. There are three
2 members of the council who participated in the final review
3 process of HMO applications. They are present here today.

4 Dr. Komaroff, Mr. Watkins, and Dr. Cannon.

5 DR. MAK LEOD: I want to thank you for the opportunity
6 to present this part of the application process of the HMO ser-
7 vice. As I indicated this morning, this was my intent for the
8 day, and I'm glad to have the opportunity to go over it with
9 you.

10 I thought it might helpful just to briefly review the
11 -- where the HMOS is today and some of it has been mentioned
12 earlier today. I think it would be helpful to summarize just
13 for the record.

14 We have in reserve here a copy of the pink sheets that
15 were prepared for the interprocess and they can be brought in
16 if you wish. Rather than clutter up the process, we have them
17 outside on a table. If you wish to have them brought forward,
18 we would be happy to do so.

19 The ad hoc group does have copies of the pink sheets
20 in front of them. They are the yellow colored books with the
21 green binders.

22 Mr. Carfin, do you want to bring those books forward?

23 DR. ROTH: Would it be possible to have this deferred
24 to the next council meeting? I'm not prepared for the stuff in
25 books?

dh 9

1 DR. MAK LEOD: Let me just say what has happened to
2 date is that the review process was intended, at the session
3 last week, was to really -- actually review the review processes
4 itself. Instead of having the ad hoc group and the other mem-
5 bers of the financing project review group go over in detail all
6 the applications. Let me explain briefly where the process
7 starts, and where it is at the present moment within this par-
8 ticular sequel.

9 A request for applications for continuation support,
10 no new support, of existing grant applicants to the HMO service
11 were sent out during mid April and at that time, it was announced
12 that the review process would be essentially decentralized to
13 the regional health directors offices throughout the country.

14 The processes involves a review at the regional level
15 involving the Social Security Administration, the Social Rehab-
16 ilitation Service, and various programs within HSMHA. In some
17 of the regions, there are special advisory counsels to the
18 regional health director as in California, which is composed of
19 the California Medical Hospital Association, the regional med-
20 ical program in that area, the organized labor sits in on that
21 committee, and other members of council summer groups are rep-
22 resented on that particular advisory committee.

23 It was our feeling that nod to have cross contact
24 between the central office and the regional office that the --
25 that their should be a representative from the central group

dh 10

1 sitting in the regional review process. At the regional review
2 processes each of the applicants were asked to make a presen-
3 tation approximately two hours in length before this composit
4 group. We then turned it around and asked the -- for a central
5 review that involved different programs within HSMHA, including
6 the regional medical program, comprehensive health plan, plus
7 regional representatives to come in and to provide continuity
8 now from the regional level back to the central level.

9 The central review is more highly technical. I think
10 it's fair to say the regional review reflects many of the local
11 programs that exist and a regional action with respect to a
12 deferral or a disapproval, would be considered by our standards
13 as a mandatory action.

14 At the central level of actions, we would review
15 those actions which have been approved regionally, and to the
16 extent that we approved them, which was usually with conditions,
17 the action would then be generated one further level. That level
18 was to a -- what we have used in the past which was an outgrowth
19 of a policy coordinating committee that was made up of the Soc-
20 ial Security Administration, NIH, OEO, and to this group, we
21 asked the ad hoc group from the regional medical program national
22 advisory council to join in the discussion.

23 At that time we presented the -- generally the
24 service to date with a -- the grant activity during the first
25 sequel, the second sequel, and at the present time, and showed

dh 11

1 the trends that had taken place and the proposed -- the past
2 expenditures and past all locations of money. The dialogue was
3 active and vigorous and several proposals which made and incor-
4 porated into the award proposals which we are not presenting
5 before this particular council for an even block action.

6 I would at this point in time perhaps turn it over
7 to a representative of the ad hoc group to ask for their reactions
8 and responses.

end 15

9 DR. CANNON: I would say that the review process was
10 certainly adequate --

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Take 16

dw 1

1 DR. MARGULIES: Could you use the microphone?

2 DR. CANNON: So far as the review process, as
3 Dr. MakLeod has described to you, we thought the review
4 process was certainly adequate, in some places too much,
5 perhaps, being confusing.

6 There were several points which we discussed that
7 council would be interested in.

8 We did rehash again the absence of any reference
9 to an ongoing educational process which the council previously
10 had stated in its minutes as being necessary if we were
11 going to be charged with any responsibility of quality -- for
12 assessment of quality.

13 Likewise, on some occasions, we found that there
14 was inaccurate information on whether or not certain
15 groups were officially signed up for HMOs.

16 But if you will turn to -- you don't have this --

17 (Laughter.)

18 DR. CANNON: If you have it, you would see that
19 there is a diversity of groups applying in quite -- I can't
20 find it myself.

21 (Laughter.)

22 DR. CANNON: In which the medical schools, about
23 9 percent, and the physicians groups and foundations,
24 total about 30 to 42 percent and the hospitals about 10
25 percent and the consumer public, 20 percent, and insurance

1 companies and private, about 20 percent.

2 Now, if you put the physicians groups, medical
3 schools, and hospitals into one category, you would see that
4 they do have the potential of developing an educational
5 component.

6 The last two, which consisted of about 40 percent
7 of the consumer public, insurance company, and private,
8 we did not see the evidence of it.

9 Now, I have no further comment.

10 I will pass it on.

11 I think Dr. MakLeod and the group did an excellent
12 review.

13 Where the council stands in its involvement in
14 HMO is the question and that will probably be discussed
15 later.

16 DR. KOMAROFF: I think with regard to assuring
17 quality of care standards, the one provision that we spoke
18 about being sure to incorporate if it wasn't possible to
19 have a formal linkage with a medical center was some
20 evidence of a functioning peer review system within the
21 HMO, union based HMO, so that there would be some device
22 for assessing quality of peer.

23 Otherwise, any RMP involvement would be very
24 difficult for this council to support.

25 Basically, I supported the council's awarding the

1 bloc support of the review procedure as it has been defined by
2 HMOS and will support that later.

3 DR. MARGULIES: Dr. Watkins?

4 DR. WATKINS: We all agreed on the review process
5 and I support this also, but Dr. MakLeod detailed the
6 quality care especially based on the fact there will be
7 internal and external audit and surveillance.

8 One of his staff explained the educational com-
9 ponent in our opinion fairly satisfactorily.

10 We think this procedure should be approved.

11 DR. ROTH: I hate to be so ignorant about this thing,
12 but I am still totally at sea in respect to statements made
13 this morning that there was as yet no single RMP dollar
14 involved in HMO funding and I believe that was a statement
15 this morning.

16 We are now considering RMP involvement in what I
17 now see is a second group -- third cycle, but, at any rate,
18 the present cycle is to consider 37 of those whose fundings
19 had run its course.

20 Now, are we talking about RMP money or aren't we?

21 I can't seem to find anybody that will give me
22 that answer.

23 DR. MARGULIES: This is the first request for
24 RMP grant money to go into the support of HMOs. There is at
25 present no RMP money which is going into contracts.

dw 4

1 There is under consideration as a part of the
2 \$16.2 million some funding which will be used by the contract
3 mechanism, not to support HMOs but to support collateral
4 activities which will enhance the HMO development.

5 This will still leave a residual of approximately
6 \$7 million.

7 So what we are talking about is a first request
8 to this council for grant support for HMOs for a total of
9 \$4.3 million, whatever the sum may be.

10 We are going to have approximately \$5 million
11 of RMP money for collateral contract activities in HMO and
12 approximately \$7 million remaining for general RMP
13 activities of the 16.2 that we have been discussing.

14 DR. ROTH: And this is the first time this entire
15 subject has been on this table before this council, is
16 that correct?

17 DR. MARGULIES: That is right.

18 And the first time HMO funds have been requested
19 of the council.

20 DR. ROTH: I rest my case.

21 DR. MARGULIES: We have talked about HMOs in
22 previous meetings but not in such terms.

Jerry, would you like to comment?

24 MR. RISO: The HMO has three sources of funds.

25 It is true that to date there has been no use of RMP money.

dw 5

1 That is not the first time the issue has been
2 addressed because we identified earlier at the beginning of
3 the year the three sources of funds for HMO funding and we
4 have reached the point where involvement of the RMP funds and
5 the RMP council, the RMP staff, is necessary.

6 Our intentions have been clearly indicated, three
7 kinds of ways, I might add.

8 It has been clearly enunciated from the start, all
9 during the fiscal year, that our intentions were to fund
10 the RHMO activity from three sources, RMP being one of them.

11 We identified our intentions in front of
12 Congressman Rogers and his committee as to use of RMP funds
13 for continued HMO activity, to continue further the work
14 we had started with the -- some 110, not all of which would
15 qualify, but the 110 grants made about a year ago.

16 We repeated our intentions on this subject before
17 Senator Kennedy.

18 So there has never been in our minds, at least, any
19 question as to the use of RMP money, never a question in our
20 mind we would go the grant route and never any question in
21 our mind we would follow the conventional council procedures
22 in doing this and that is what brings us here today.

23 DR. DE BAKEY: Why didn't you?

24 As far as I am concerned, you haven't followed the
25 Congressional procedures.

1 This is the first chance I have received to hear
2 anything about the grant applications, yet you ask me to come
3 up and participate in a decision about the applications.

4 MR.RISO: We did have a subcommittee acting
5 hopefully on behalf of this council to review the materials.
6 That is the way we have always done.

7 We believe we were following a process we would
8 follow in other kinds of activities previously.

9 DR. DE BAKEY: I want to challenge your statement
10 about that. In the first place, you are taking for granted
11 the same kind of procedure we have used on all others.

12 You made the decision that this was a part, that
13 RMP could be interpreted as a means of supporting HMOs.

14 Congress didn't make it and this council didn't
15 make it.

16 The council did go along with the idea of supporting
17 one aspect of it, the educational aspect.

18 This is administrative decision, not a council
19 decision.

20 You are now telling me you followed the same
21 procedure when you haven't. This is the point I am trying
22 to make.

23 This is a new subject matter for this council to
24 consider completely in terms of its responsibility to advise
25 regarding the disbursement of funds of regional medical

dw 7

1 programs.

2 That is the point I am trying to make and tried to
3 make earlier today.

4 DR. MARGULIES: [REDACTED] the council
5 met, it was apprised of the fact that we intended to use
6 the funds this way. It agreed that it would appoint -- would
7 allow me to appoint a subcommittee which could act in your
8 absence and the fact we did not do that was based upon the
9 lack of need and the lack of timing for it.

10 But the council fully discussed it.

11 DR. DE BAKEY: I wasn't here when it did.
[REDACTED]

12 DR. MARGULIES: But it did. It met and acted and
13 agreed to do that and appoint a subcommittee to do that.
[REDACTED]

14 DR. DE BAKEY: Maybe so. I didn't agree to do it.
[REDACTED]
15 This is an interpretation.

16 DR. CANNON: I would like to say as a member of the
17 subcommittee, when we were asked to come up here on short
18 notice and speedy action, we were asked to approve the
19 review process. That was our request and that is what we were
20 told.
[REDACTED]

21 DR. MARGULIES: What we had expected would occur.
22 As I indicated to you earlier this morning is that there
23 would have been action in the spring, early spring, on HMO appli-
24 cations. There would not have been time for the council to
25 meet again prior to that action, so in fact, what the council

1 did was to delegate final authority to a subcommittee.

2 It was not necessary for us to exercise that action
3 because the review process for HMOs that we are considering
4 now was delayed allowing us therefore the freedom to
5 bring it back into full council.

6 If we taken literally the action of the council last
7 time, we could have used that subcommittee to complete action.

8 We thought we shouldn't.

9 DR. CANNON: I think you are right about it.

10 I remember your delegating it, except the authority
11 of the review committee is to review and comment on the review
12 process, which we did, not on the question of whether or not
13 funds from RMP should be used to establish HMO.

14 DR. MARGULIES: Quite right.

15 DR. CANNON: That wasn't the question put before the
16 subcommittee.

17 I think that is -- now, this thing has been
18 discussed in council for many, many months.

19 Vern Wilson discussed it with the council a long
20 time ago. I think the final decision as to whether RMP funds
21 would be put into HMOs -- I don't recall the minutes of the
22 action.

23 DR. MARGULIES: You are absolutely right.

24 What we wanted was to bring to this council, council
25 members' judgment on the validity of the review process.

1 DR. CANNON: You have got that.

2 DR. MARGULIES: Yes.

3 The question before the house now is whether this --
4 that this review is an appropriate basis for any action you
5 can take and the collateral question then is does this
6 council wish to utilize a portion of the funds set aside for
7 the HMO activity with the understanding that it is a one-time
8 grant award to continue the planning and development of HMOs.

9 There is no time excepting now to do it because
10 this is the end of the fiscal year and that is the issue.

11 DR. CANNON: In other words, find nothing wrong with
12 the review process.

13 The question before the council, the subcommittee
14 having acted in their behalf, that there is nothing wrong
15 with the review process.

16 The question now before the council is do you wish
17 to devote the funds to this project or not.

18 MRS. WYCKOFF: Is RMP being used as a kind of pass-
19 through for funds to HMO?

20 DR. DE BAKEY: This is one of the sources of
21 funds, that is all.

22 MRS. WYCKOFF: It isn't RMP money, is it?

23 DR. DE BAKEY: It is partly RMP money.

24 MR. RISO: It was in fact earmarked at one point
25 in time for use. When some 16.2 was released, it was released

dw 10

1 with the thought -- the report of the Senate indicates using
2 16.2 to "try out" the HMO concept. The issue, to be perfectly
3 candid, you have two things:

4 One, you have it as a source of funds.

5 I think you have to face that as a fact.

6 Secondly, we feel it is a legitimate source of
7 funds.

8 It is a necessary and important involvement for
9 RMP in the HMO program.

10 MRS. WYCKOFF: Even though it is a one-time kind of
11 thing?

end 16

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1 [REDACTED]
MR. RISO: It is a one-time for '72.

2 DR. DE BAKEY: I challenge your statement about that
3 too. You may think it is necessary for us to get involved in
4 it, but that does not mean that we have --

5 DR. SCHREINER: Would you speak into the mike?

6 DR. DE BAKEY: He says he regards it as a -- what
7 did you say?

8 MR. RISO: If you want to take issue with the term
9 "appropriate"?

10 DR. DE BAKEY: I take issue with it because I do
11 not think we have had a chance to discuss it in relation to the
12 appropriateness of using it for this purpose.

13 One thing, I think it is important to define what
14 you mean by HMOs and what they are going to do and at what
15 extent they are able to do something for the regional medical
16 program which the regional medical program cannot do.

17 I do not think we have had a discussion of that
18 at all. I am not convinced this advances the regional medical
19 program. I made statements earlier that I had to admit we have
20 not advanced the regional medical programs, particularly with
21 the intent of Congress, and I have to say so, officially in
22 a public record.

23 I think there is good reason and good evidence for
24 it. You are now coming along with another program that you
25 think does. What is the basis for your thinking of it? You

1 have not convinced me of that.

2 Your word is not enough for me.

3 MR. RISO: You raise two issues, Doctor. You raise
4 the issue of lack of discussion. I find that difficult to
5 accept, that there has not been discussion about our intent or

6 DR. DE BAKEY: No. I raised the issue of lack of
7 discussion in terms of the substance of the program, not in
8 relation to whether or not we should be involved in it. That
9 is the point I am making.

10 MR. RISO: I can only tell you about my involvement
11 with this council. I suggest it has been minimal. I do not
12 know what conferences you have had, to date, among yourselves.

13 DR. DE BAKEY: As far as I am concerned we have had
14 no discussion of the substance of HMO programs in advancing --
15 As a matter of fact, we were supposed to have -- this is what I
16 understood was the role of this delegation in determining the
17 review processes.

18 Now, you are coming back to us now, and wanting us
19 to approved funding. That is the point I am making. You can
20 do it by contract, or you can do it with -- with or without
21 my vote, but I am expressing my own feelings about that. That
22 is what I am trying to make in terms of my responsibility.

23 DR. ROTH: I would like to say for Mr. Riso's bene-
24 fit, because he was not here when it was said earlier this
25 morning, that some of the important, extremely important

1 material in this whole issue has just come to us in the
2 distributions that we got at home, and that we have here before
3 us in the black book.

4 I would point out for example, the General Counsel
5 Opinion, dated May 3rd, which raises a very significant ques-
6 tion, as far as I as a member of this advisory committee is
7 concerned; that is the question was, do we have the legal
8 authority to use RMP money and the legal counsel answer is to
9 the extent that proposed HMO activities fall within the pur-
10 poses of Section 910(c), we do.

11 Then, reading 910(c), the connection between HMOs
12 and what is actually being done with the monies that have been
13 given for HMO development and any of the words in 910(c) seems
14 to me to be unrelated.

15 I think we ought to have a chance to discuss this
16 in this council. That is all I am saying, is that it seems
17 to me perfectly clear that the members of this council have not
18 been sought, and that we sit here approving grants, having them
19 unfunded because some of our monies, particularly because 910
20 money, are being diverted.

21 If this is the way it is to go, I think we should
22 at least have a chance to express our opinion about it. It
23 may prevail. Maybe that is the way the council wants to go.
24 But, I think the council should have a chance to say so.

25 DR. MARGULIES: Russ, in fairness to the other

1 members of the council, this was discussed at the last meeting.
2 I brought it to the attention of the council that the funds
3 were going to be used for that purpose, that it would be done
4 in such a way that it would direct those funds to HMO. I made
5 the point that the council which it understood that the review
6 would be by the HMO service, and that this was a method of
7 getting activated, a program of health maintenance organizations
8 which was considered of significance.

9 During that discussion, there were potentialities,
10 particularly in the development of methods for monitoring the
11 value of care for RMP growth, which were identified which were
12 considered worthwhile.

13 It is always true in any council action, that some
14 members are present and some are not. It is also true
15 that any council action is subject to reconsideration. But
16 the council then made -- passed an action in which they said,
17 if it is necessary for these funds to be used for grant pur-
18 poses prior to the next meeting of the council, we will delegate
19 full authority to a subcommittee of the council to act in
20 our behalf.

21 This was done with full understanding. It does not
22 mean you have to stick with it but it did occur, and there was
23 discussion.

24 DR. ROTH: I was present when a substantially
25 different statement than that was adopted, and reprinted as an

1 Attachment F to the minutes. This was not the original state-
2 ment and we had a lot of discussion about it in the council and
3 we did not like the way the thing was originally proposed, and
4 we came out with something that I think none of us really saw
5 in writing.

6 My impression of what we did is almost reflected by
7 this Attachment F, to the minutes where it says, the council
8 shall discharge its -- by delegating to a subcommittee of the
9 council actual authority to work with the Director of RMPs.

10 It was not my understanding they were authorized to
11 approved grant applications and this was the first time that
12 this was brought up before the council, which is what has led
13 me to do a little bit of homework on where RMP grant money, I
14 mean where HMO grant money has come from, which I reported to
15 you this morning.

16 I think the council has been beautifully railroaded
17 on this one.

18 DR. MARGULIES: I am sorry you think so, but in
19 any case, the council is here to consider it. The grants have
20 not been approved, they have not been awarded. We have come
21 as closely as possible to what we thought you should do. In
22 fact, there was so much attention to the wording at that time,
23 that there was a group which met separately, reworked the
24 wording of that action, brought it back into the council, and it
25 was passed by the council after it was reworked.

1 But you are not bound by that. You are here to
2 consider what action you want to take on this particular HMO
3 Grant award.

4 DR. PAHL: Before we proceed, Tony, let me say, the
5 conditions under which that Attachment F were developed, you
6 may recall, were somewhat time-limited because individuals
7 were leaving the council.

8 Staff developed that statement and as I recall, got
9 two or three of you to look at it, most momentarily, before
10 leaving the council room. So the fact that it appears in the
11 cold light of day not to be what you thought you had read it
12 to be, is quite possible and I think that if that is the case,
13 and if it is not the sense of what you formerly thought you
14 had approved, it would be most appropriate not to approve the
15 minutes, but to make an amendment to that.

16 This is part of the problem of trying to get the
17 business down with leaving, but also staff should have gotten
18 this Attachment out to you, prior to your coming to the council
19 meeting this morning. So. I think that should be a consider-
20 ation of the council if the minutes are to be changed from what
21 the action taken this morning was.

22 Tony?

23 DR. KOMAROFF: I did not put the period after RMPs,
24 but to approve applications for HMO Grants. When you are
25 called down to look at the review process, I have ambulant

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1 feelings.

2 We were looking at the grants and we had to take

3 secondhand, any assurances about the adequacy of the review

4 process. I was assured and I would like to move that we

5 have expressed our feeling about the way this was handled and

6 the way council has been treated, but I would like to move

7 block approval action in support of the HMO Grants as approved

8 by other level review processes.

9 DR. MARGULIES: Moved.

10 Is there a second?

11 MR. WATKINS: Second.

12 DR. MARGULIES: Moved and seconded.

13 Further discussion?

14 DR. SCHREINER: Did you say something about forty

15 percent of these not coming under the umbrella of quality

16 control? I thought I heard something like that.

17 DR. CANNON: What I said, was that council in its

18 minutes, not once, but several times, even to preparing a

19 statement saying that if the -- if it became involved in HMOs,

20 especially the quality of any health care program; that it

21 would insist on an educational component in an effort to main-

22 tain quality, and that educational component should be funded

23 not out of the costs of the medical care program.

24 I do not know where the minutes are, Harold, but I

25 am sure somewhere we went through that, because they wanted to

1 assess quality in the program. When we met, we were not asked --
2 I did not understand we were asked to go any further than
3 approving the review process, what it was, and making suggestions
4 about the adequacy or inadequacy, and the review process was
5 certainly adequate, but there were things that were left out;
6 and one was the educational component.

7 This was discussed, and I have here, a report that I
8 wrote -- that John wrote for me, as an addendum to what should
9 have been the charge of any organization that wishes to start
10 a HMO. Of those organizations which had applied for grants
11 already funded, there were those with a hospital, medical school,
12 the foundation, the physicians' groups.

13 They easily could incorporate an educational com-
14 ponent, continuing education or the process of training man-
15 power. There were 40 percent or rather 38 percent, 18 and 20
16 of either insurance company or consumer-base sponsorship
17 which we did not see that that was assurance that there would
18 be an educational component for -- to initiate at least on
19 the front end, some quality control.

20 DR. DE BAKEY: I think it is one thing to approve a
21 review process, but I think it is another thing to ask for the
22 approval of funds to support a program, the nature of which in
23 terms of its relation to the advancement or let us say, the
24 achievement, accomplishment, of the regional medical programs'
25 intent and goals, and objectives, is yet to be determined and

1 certainly it -- as far as I am concerned, there has been no
2 convincing evidence to provide us with the conviction that
3 this will further the regional national medical program, and
4 yet, we are asked to approve monies on that basis, and on the
5 basis, that the review process has been satisfactory.

6 Well, now, there is a lot of difference between a
7 review process that is satisfactory or adequate, and a pro-
8 gram that needs to be funded to advance the cause of the regional
9 medical program.

10 I think in terms of the responsibility of this council
11 for the approval of funds for these purposes, it should be
12 provided with that evidence, not just with the evidence that
13 the review proces is satisfactory, or that we should participate
14 in the program.

15 That is the point I have been making all along that
16 each one of us as a member of this council, has a definite
17 responsibility, authorized by the law, to provide advice on
18 funding of programs, that will advance the cause and intent
19 of the law.

20 Now, here you come with a HMO organization, the
21 exact nature of which is still not clear, and how it is to
22 be operated or anything else, these are funds you want to
23 support the development of. Now, just how that is going to
24 advance the cause of this, and therefore, the monies by which
25 we determine the approval of funds is not presented.

1 I know we have talked about it. I know all that you
2 have said since early January. I know all of that. But, we
3 are coming now down to voting on the funds. This is where I am,
4 and this is why I cannot really, in a sense, participate in
5 voting on a motion of this kind.

6 That is the only point I am making.

7 *JM* MR. WATKINS: Six months ago, I had the opinion that
8 the council had held jealously, the educational component.
9 When I was asked to come down for the review process, I assumed
10 the input had been assumed already. This is the method by
11 which we were going to allow the funds to be involved.

12 *So* we have six months of this discussion. Perhaps,
13 I made a mistake and misunderstood the intent. I thought the
14 intent of council was to have this input educationally, and
15 funded so when we are asked to come down for the review proce-
16 dure, we are coming down to let down now, how the review
17 procedure was set up to fund. This was the final task.

End #17

18 I got this over the last six months.
19
20
21
22
23
24

Tae 18

dw 1

1 DR. ROTH: I would like to second what Dr. DeBakey
2 has said and make it clear if there is any misunderstanding,
3 that I think it would be a disaster, I think it would really
4 be flushing money down the drain if we carried 114
5 developmental experimental projects up to this point and
6 then refused to fund them, somehow or other, to see how they
7 work, how they fly, what they show, and what we should learn
8 from them.

9 My point is that to involve this council I think
10 has not been well done, at least, as I interpret the
11 reactions of the council members.

12 There seems to be a substantial difference of
13 opinion between council and staff on how well they were
14 clued in on these things.

15 I hope there will be ways and means. There must
16 be ways of continuing the funding of these 114 demonstration
17 projects until they are able to demonstrate something.

18 I don't want anybody to think we are against that.

19 I do think there is a very serious question of
20 the appropriateness of the RMP money and certainly no question
21 if it is divorced from the ^{educational?} evaluative factors Dr. Cannon
22 has talked about.

23 DR. MAK LEOD: I would like to address the issue,
24 Dr. Cannon raised and Dr. Watkins, too, that is health
25 education and continuing education, that it should be a part

1 of HMO activity.

2 One of the problems that we face to date is that we
3 have not funded ongoing service organizations.

4 The criteria for that phase of HMO development have
5 not been developed todate.

6 What we have funded has been the planning and the
7 developmental aspects and out of this we have found any
8 numbers of different ways that different organizations have
9 proposed these kinds of activities.

10 We have used the coordinating committee concept
11 with a project review work group and now added to this particu-
12 lar session with the groups from the national advisory group to
13 develop the policy for HMOs and to incorporate those suggestions
14 into funds that would be used for HMOs activities.

15 It would be our action and our recommendation that
16 the proposal made by Dr. Cannon and drafted here would be
17 included as part of the policy development within the HMO
18 service for those applications that are -- those fugure
19 applications which will be considered for obligational
20 support.

21 DR. SCHREINER: This isn't the form of a motion.
22 We have a motion on the floor.

23 DR. MARGULIES: No, no.

24 DR. SCHREINER: There are a variety of reasons why
25 I might vote against the motion but I will single out only

dw 3

1 one for discussion.

2 Regardless of confusion about prior comments at
3 this council meeting and transmission of information and bits
4 of news, et cetera, there has been one core item that I
5 personally recall as having run through all our discussions
6 and that core item was that if the RMP was going to be
7 related distantly or closely to HMOs, it was going to be in
8 the area of potentially furnishing and helping out with
9 quality control.

10 I see a few nods.

11 There may be a little bit of memory about some of this
12 having gone on around you.

13 Continuing that thesis, the idea of quality control
14 got exemplified by the business of "educational component."

15 Quality control might be put in a number of dif-
16 ferent fashions, I presume. However, I just heard from
17 our own review committee, regardless of what they thought
18 they were reviewing, I have just heard that 38 percent of the
19 items recommended for bloc action did not have that component
20 in them.

21 I am going to have to vote against the motion.

22 DR. MARGULIES: Clark, the responsibility for
23 developing effective methods for monitoring the quality of
24 medical care in HMOs does remain in the regional medical
25 program and there is little question in my mind that the RMP

1 is going to be the most vigorous arm in the monitoring of
2 HMOs in the Federal service.

3 Regardless of the other features of the HMO
4 activity, that represents an opportunity to develop techniques
5 and to measure them and evaluate them for which we have no
6 alternative.

7 Our thinking has been along those lines.

8 I would like to add one thing to this discussion,
9 for whatever it is worth.

10 As you might infer from the conclusions, the
11 development of the HMO activity has not been one of the most
12 brilliant in bureaucratic history.

13 It began with the assumption of legislation which
14 would have been passed about a year ago, with repeated assurances
15 and, as I indicated to you this morning, if everybody had sat
16 around waiting for the HMO to develop, suddenly had a bill
17 passed and an appropriation at about this time of the year
18 and nobody had done anything, the criticism would have been
19 the same.

20 You have a group of people running the risk of
21 mounting an activity to prepare for something which will take
22 place, doing what they can, acting in what they consider the
23 best interests of all, to develop momentum, staff, doing
24 whatever is required to squeeze money here and there to get the
25 job done, and this always does carry with it the likelihood

dw 5

1 of being caught with your drawers down.

2 Well, that is where we are. The fact is that we
3 needed money from any source which was available to get this
4 job done.

5 It was not the last time this will occur.

6 There are possibilities in the future that
7 somebody else's money will be used for RMP.

8 If that occurs, I will bring it to your attention.

9 Where we are now, as I laid out to you fairly
10 nakedly is in the need for money to get something done which
11 has got to be done.

12 You are in a position of saying "aye" or "nay"
13 to that idea here.

14 MRS. WYCKOFF: We said at the last minute that
15 many of the RMOs are already involved. I assume we were
16 funding it.

17 Secondly, it is quite clear that RMPs will have a
18 role in development of HMOs as quality of care monitoring
19 and health manpower.

20 This looks as though we were already in right up
21 to our necks.

22 How were those funded?

23 DR. MARGULIES: These are RMP encouragement.

24 MRS. WHCKOFF: They were not being funded?

25 DR. MARGULIES: Not through a central source, no.

dw 6

1 DR. MERRILL: I was looking at the same paragraph
2 Mrs. Wyckoff was but I was thinking of some of the remarks
3 of the previous sentences. There is a clear understanding
4 that review would not follow the normal RMP pattern.

5 I gathered there was some question about that?

6 (Laughter.)

7 DR. MERRILL: I would also like to know how firm or
8 how much substance we can attribute to the remarks of
9 Dr. Wilson on page 2.

10 I ask this because if it is true that there has been
11 considerable misunderstanding about whether or not HMO should
12 be funded through the normal RMP mechanism, and this is indeed
13 a one-year activity, then we have made a five million dollar
14 misunderstanding which hopefully will not be repeated.

15 I think as Tony has suggested, it might be more
16 damaging having set these things up and reviewed them not to
17 fund them at this point if we can be assured that the problem
18 will be very well clarified.

19 DR. DE BAKEY: As I understand it, that one year
20 activity is based upon legislation that has not come about and
21 certainly, from what I see in the Congress taking place right
22 now -- may I get off the record?

23 (Discussion off the record.)

24 DR. ROTH: Is it fair to ask -- so far, no RMP
25 money has gone into this in the '71-72 appropriations. Are

dw 7

1 we now being asked to take it all? Is it all going to come out
2 or will there still be Section 1110 money from SRS?

3 If so, what is the breakdown?

4 DR. MARGULIES: We are asked to contribute at this
5 round 4.3 for continuing planning and development.

6 Whether there is additional money which is going to
7 be used during the rest of this fiscal year from other
8 sources, I don't know.

9 Gordon, can you answer?

10 DR. MAK LEOD: This grant activity is with
11 respect to the HMO service, is the only one that is going on
12 at the present time. SRS is involved in extending some of the
13 activity in their evaluative projects that are going on.

14 Part of the hundred and ten, but it is a limited
15 program, limited funds.

16 MR. RISO: The HEW policy, I think I have to
17 restate it again, because -- I think we are talking to one
18 another, the policy is to fund -- the ones that have been
19 funded, that we would undertake, until legislation is passed,
20 whenever that would be, we would, one, fund no additional
21 grantees and, two, we would not provide funds for direct
22 service, and we would confine our activities to assisting
23 those among the hundred and ten who were determined by an
24 appropriate review that they had made significant progress
25 and deserved to be carried further into the program development

1 stage.

2 This is what was intended to be done with the RMP
3 monies right now.

4 Our plans for next year will be to work with those
5 that have been funded.

6 We have not identified 1973 in the absence of
7 legislation, anything like the earmarks that were established
8 in '72.

9 In addition to which, even if we had intentions
10 of additional funding, we have gone on record as estimating
11 about the level of planning and development funds needed to
12 carry forward a mature and appropriate applicant to the
13 point when he should begin to open his doors and forget about
14 the planning and development work.

15 We will have reached with many of these that point
16 in levels of funding early in '73.

17 So we have two kinds of constraints on us:

18 One, the fact we don't have funds, that is a very
19 real one.

20 The second constraint is that at some point in time,
21 we will have exceeded what we think is a normal amount of money
22 to spend for planning and development and it would be just
23 a waste of time to continue funding planning and development
24 activities of an organization that should have reached the
25 point of either being viable or forgetting about it.

1 That is the two constraints I think we have.

2 MRS. MARS: What exact figure are we talking about?

3 MR. RISO: 4.3.

4 MRS. MARS: 4.3 is how much money in figures?

5 DR. MAK LEOD: It would be 29 of the 37 applications
6 that were submitted and approved for funding. Eight of them
7 were disapproved at this point in time.

8 So it would be among the 29 that the 4.3 million
9 would be distributed.

10 DR. MARGULIES: We would probably illuminate the
11 situation considerably by more discussion, but we do have some
12 constraints on Warren Perry, who has to leave and he has a
13 bloc group on the education activities.

14 If you feel you are ready to take a vote on the
15 motion, we can do so but we can continue the discussion.

16 DR. SCHREINER: There is one philosophical thing and
17 that is whether more is to be lost from leading somebody
18 down the primrose path to nothingness or more is to be gained
19 of sponsoring somebody to a salvage point.

20 I haven't heard anything from the review subcommittee
21 or from anybody to indicate how they feel about these.

22 If you will look at these critically as a triage
23 problem, what do you have to lose?

24 DR. KOMAROFF: A significant triage was done at
25 the lower level. It was reduced by 40 percent. Only the most

1 viable made the grade.

2 Is that fair, Gordon?

3 DR. MAK LEOD: I think it certainly is fair.

4 The other thing that might be said in that regard
5 is that some of the activities going on in parallel would
6 be to assist these applicants to address themselves to the
7 obtaining of money from private sources so there will be activity
8 supplementing Federal support money.

9 MRS. MARS: Did we include a one-year limitation in
10 the motion?

11 Could we hear the motion again that was made?

12 Did we include a one-year limitation of funding in
13 the motion?

14 ~~DR. MARS: I would be willing to do that and I~~
15 ~~ought to make that formal, that some assurance of quality~~
16 ~~of care plans, whether that means medical school linkage or~~
17 ~~not must be built into all of these.~~

18 I had assumed it would be since the guidelines the
19 subcommittee was given -- it says on page 5, that the
20 proposed quality care assurance must be a part of each of
21 these applications.

22 We had assumed it was.

23 DR. DE BAKEY: I am going to say I find it a little
24 difficult to understand the basis for our approval of the
25 money.

dw 11

1 We have a committee that is delegated the authority
2 to participate in the review process, to determine the
3 adequacy of the review and to be assured that there is going
4 to be a quality control.

5 Now, I haven't yet heard whether or not in their
6 opinion these grants will advance the course of the medical
7 program.

8 This has been given to us ex cathedra, as far as
9 I can tell.

10 I have yet to be convinced it can do that.

11 You should be able to say the plans include
12 evidence that the objectives and the intent of the legislation
13 for regional medical programs, for which this money was given,
14 is going to be furthered by these plans and by the HMOs.

15 Up to there, I haven't been convinced of that.

16 This is the whole point I am making. You know, I
17 expect ex cathedra, but not to the extent of voting these
18 millions for this purpose. I haven't been given that
19 evidence.

20 DR. CANNON: Let me say that you can't pass that
21 over to the subcommittee because we weren't asked whether or
22 not this would advance the goals of the regional medical
23 programs.

24 Our charge was the adequacy of the review process.
25 I was told by Harold a few minutes ago that the RMP staff,

1 RMPS, was the ones that were doing the review.

2 That is exactly what they did. We came here and
3 started about 9:30 or 10:00 and left at 1:00. During that
4 period of time, our first two hours were taken up in
5 describing the review process and what they have been through,
6 where they are from.

7 At the last, there was a spot check of certain
8 grant applications and these spot checks, with a discussion of
9 certain points, such as the educational component in which we
10 disapproved grants that didn't have the educational component
11 clearly set forth as an example.

12 My understanding, when I was called, rushed to come
13 up here, and I did so at considerable inconvenience because
14 apparently no one else on the council would come, they
15 told me I was about the last one.

16 (Laughter.)

17 I am just kidding. You can't pass that responsibility
18 on to a subcommittee, the decision you are asking.

19 The question is whether or not they made it in the
20 past or whether they never made it and should make it today.

21 I personally feel -- and I think we are down to being
22 personal -- my personal feeling is that I think the
23 council should fund anything that has to do with the educational
24 component that will maintain quality in any program that we are
25 charged to be involved in but I don't think our funds should

1 be used for other than that charge.

2 I feel that that is our responsibility. We are --
3 concil is supposed to look from the viewpoint and maintain
4 quality and transfer knowledge and all those things.

5 DR. DE BAKEY: Are you ready to say to the tune
6 of, what is it, four million or so, you are doing that in
7 this program and should fund the program for that purpose?

8 DR. CANNON: Would you say it in the microphone
9 so I might hear it?

10 (Laughter.)

11 DR. DE BAKEY: I thought you were a lip reader.

12 I said are you prepared to say on the basis of
13 what you have seen so far that it is achieving that objective
14 to the tune of four million dollars?

15 DR. CANNON: No, but that is not what I was asked
16 to do.

17 DR. OCHSNER: The thing concerning me most about
18 this is the fact Clark has already spoken about it.

19 Apparently there are 38 percent of these people and
20 we have no assurance that they are going to have quality
21 control. There might be every reason to believe they might
22 not.

23 DR. MARGULIES: You might compare that with the rest
24 of the health care system. At least in the HMO you have the
25 opportunity to try to do something about it. It is a little

dw 14

1 more difficult elsewhere.

2 I am more attracted to the idea of doing it in an
3 HMO.

4 Mike?

5 DR. BRENNAN: My problem with this is that an
6 invalid process has been generated and there is only one prob-
7 lem. Whereas we are now sure we have a process, but we don't
8 have it aimed at a target.

9 The problem for me in spending -- seeing that we
10 should spend RMP funds here is that I don't yet to this day
11 have any clear notion of what the content of that term HMO
12 is.

13 We had a council member who drew a cartoon for me of
14 an HMO greeting the dawn, which I would be happy to
15 disseminate at some future time.

16 He was a humorist. He had a sort of fantastic
17 bird that looked like an extinct rock or something of that
18 sort and I think that is what our real problem is.

19 If somebody were talking about a clinic, detection
20 program, an educational scheme, we would all have a pretty
21 good idea in our minds of what the terminoloty meant, but
22 we don't have, with respect to HMO, have that content.

end 18

23

24

25

1 DR. MARGULIES: Russ?

2 DR. ROTH: One other thing I would like to get
3 straight in my own mind, this committee has reviewed and I
4 gathered from what Dr. Cannon has said, you have disapproved
5 some grant applications, among those 114 that were approved --
6 you haven't approved them all automatically?

7 DR. CANNON: We didn't go through it like that. I
8 tried to describe it. The review process had already gone
9 through and written approval or disapproval, but we spot-checked
10 certain ones for certain features to see how the review process
11 went about getting the information to make such a decision.

12 In doing that we came up with a decisional change
13 on a couple of the applications. That's in essence the service
14 that this committee rendered.

15 DR. MAC LEOD: At the present time the -- we have
16 funded during the first funding cycle which was in fiscal
17 year '71, 39 grant applications.

18 Again, the second funding cycle in December of '71,
19 involved another 46 applications. In addition to that there
20 were 15 from SRS, six from SD's and four or five from generator
21 type contracts, such things as the American Association of
22 Medical Colleges, American Association of Medical Clinicians.

23 These were all part of the 110 that were used for the
24 funding cycle up until the present time. When this particular
25 cycle was announced, invitations -- these 110 were asked if they

1 wished to come in for continuation support. Of this group, 37
2 asked for continuation support and 29 -- all 37 were reviewed
3 and 29 were approved in the process that was put before this
4 composite group which I mentioned.

5 DR. BRENNAN: I would like to call for the question
6 and then we can make another motion if we have to. I think we
7 have discussed this until we are blue in the face.

8 DR. MARGULIES: As I understand it, the motion is to
9 provide the grant funds for those HMO's for planning and
10 development which have survived the review process with the
11 understanding this is for one year only and there will be
12 adequate input to maintain a good level of quality of care in
13 the HMO's.

14 All those in favor, please raise your hands.

15 (Show of hands.)

16 DR. MARGULIES: Opposed?

17 (Show of hands.)

18 DR. MARGULIES: It carries.

19 I age greatly during these discussions.

20 If there is no further reason to discuss that motion,

21 I would like to get on --

22 DR. PERRY: I think everyone needs a break. I'll
23 take a later plane.

24 DR. MARGULIES: That's kind of you. I think a ten-
25 minute break would be fine.

1 (Recess.)

2 DR. MARGULIES: Could we reconvene, please?

3 We had a request after the last vote, which I think
4 is highly desirable, for a recording of the -- of those who
5 voted for, those who abstained and those who voted against.
6 I do think we need that for the record.

7 If I -- if we may, let's go around the table
8 beginning with Mrs. Wyckoff.

9 MRS. WYCKOFF: I voted for. ✓

10 DR. MARGULIES: Sewell Milliken, for. ✓

11 MRS. MORGAN: For. ✓

12 DR. MARGULIES: For the recorder, give your name if
13 you will and your vote.

14 MRS. MORGAN: For. ✓

15 MR. WATKINS: For. ✓

16 MR. MEYER: Against.

17 DR. ROTH: Against.

18 DR. BRENNAN: Against.

19 DR. MC PHEDRAN: For.

20 DR. MERRILL: For.

21 DR. CHASE: For.

22 DR. KOMAROFF: For.

23 DR. MILLIKAN: Against.

24 MR. HIROTO: For. ✓

25 DR. SCHREINER: Against.

*10 for
8 against
1 abstention*

1 MRS. CURRY: I abstained but I would like to say
2 against if I can change.

3 DR. MARGULIES: You can't.

4 MRS. CURRY: I abstained.

5 MRS. MARS: Against.

6 DR. DE BAKEY: Against.

7 DR. MARGULIES: Cannon's vote was against.

8 The vote was nine to seven.

9 DR. MC PHEDRAN: Where are the abstentions?

10 DR. MARGULIES: One and seven shown.

11 DR. BRENNAN: Mr. Chairman, I think it's
12 inappropriate for a Council member to abstain on a vote to
13 spend \$4 million.

14 DR. MARGULIES: It may be but that's what the vote
15 was.

16 DR. BRENNAN: Then I would like to ask for another
17 vote.

18 DR. DE BAKEY: I think you can move parliamentarily;
19 you can make a motion about the vote.

20 DR. MARGULIES: I think you may do it if you want,
21 Mike, but two of the people who voted are no longer here.

22 DR. BRENNAN: My opinion is on large expenditures
23 like this everyone ought to be comfortable.

24 DR. MARGULIES: Do you want to make a motion?

25 DR. BRENNAN: I make a motion to the effect that the

1 Council vote without abstentions on this question.

2 DR. MARGULIES: Is there a second?

3 MRS. MARS: Second.

4 DR. DE BAKEY: Could we discuss that.

5 DR. MARGULIES: I am a little lost parliamentarily.

6 DR. DE BAKEY: I am not sure that ought to make the
7 final decision about what we should do. I think what is much
8 more important is a decision that the Council feels secure with,
9 for one thing, and certainly is -- feels that in the sense of
10 making the right decision.

11 I think it's important for us to recognize that this
12 is a precedent-setting type of procedure we are engaged in here
13 and I really think that it really required more deliberation
14 and consideration than we have given it.

15 There was a great deal of discussion in terms of
16 the appropriateness and so on but, take, for example, you see
17 I feel very strongly personally that I am not really able to
18 vote on this issue in a truly honest way in discharging my
19 responsibility because I have never had presented to me the
20 evidence that I think is needed. It may be available; it may
21 be available.

22 Secondly, I -- we have used the procedure delegating
23 authority or delegating in a sense our responsibility and I am
24 perfectly willing to do that and I know this is the proper
25 procedure and we have done it effectively on numerous

1 occasions.

2 Now, here, instead of really delegating our
3 responsibility, we have delegated in a sense another type of
4 responsibility which was not related to the expenditure of the
5 funds. I am not really sure that the committee that -- let's
6 say participated in this on the basis of our request was able
7 in itself to determine whether the Council could be advised as
8 to the appropriateness of spending this money for this program.
9 They have provided no evidence to this extent at all.

10 This is why I think it was quite inappropriate for
11 us in a sense to vote at this point. I voted against it not
12 because I am against the program, because I don't know what the
13 program is, and I am asked to vote on -- to provide money for
14 a program that -- I really don't know the nature of in terms
15 of responsibilities, let's say, we have for the regional
16 program.

17 As I said before, it's all very well and good for
18 the administration, let's say, to determine ex cathedra it does
19 belong in this, but then in terms of the Council, the
20 appropriateness of the Council's decision-making, this is not
21 enough. It is certainly not enough for me to accept that and
22 this is the reason I had to vote against it.

23 If I had the evidence before me or it was sent to
24 me in some way so I can be persuaded that it is, I would vote
25 for it. This is why I think that it's a mistake.

1 DR. MARGULIES: I certainly think the points you
2 have made in the sense of discomfort which the Council has in
3 taking action on something which has not been properly
4 deliberated should be a prominent part of the record. There is
5 no question about that and I think everyone is assenting to
6 that.

7 There was no sense of comfort on anybody's part
8 in voting aye or nay on this.

9 MRS. WYCKOFF: This is the price you pay for
10 accepting earmarked funds.

11 DR. DE BAKEY: They weren't earmarked.

12 MRS. WYCKOFF: I thought they were. I thought the
13 16 million was earmarked.

14 DR. DE BAKEY: That's a very important point.

15 Congress earmarks money from time to time for
16 specific purposes. This money has never been earmarked except
17 by the administration. This is the point I am trying to make.

18 MRS. WYCKOFF: I thought it was earmarked and we
19 were given the responsibility.

20 DR. MARGULIES: This is an administration decision
21 on funds, not a congressional decision.

22 We have a motion which is to make the vote on this
23 subject one in which abstentions are not allowed. We can vote
24 on that if you would like.

25 DR. DE BAKEY: I would like to amend the motion. And

1 what is I would like to amend the motion to move that we set
2 side the vote that we have just passed in terms of the
3 decision and -- in order that we may have some evidence provided
4 each one of us to deliberate further this matter and then bring
5 it to a vote.

6 If you want, set another meeting, quite all right.
7 or make it a mail vote.

8 DR. BRENNAN: I am afraid, Mike, that is another
9 motion. That's hardly an amendment. If you can defeat mine,
10 you can make yours if you want.

11 DR. DE BAKEY: It's a substitute motion.

12 DR. BRENNAN: That's a substitute motion.

13 DR. ROTH: I'll second that.

14 DR. DE BAKEY: The substitute motion?

15 DR. MARGULIES: It's been moved and seconded the
16 vote be set aside and some other process be found for reaching
17 a conclusion.

18 DR. MILLIKAN: No.

19 DR. MARGULIES: There will either be another meeting
20 or a mail vote.

21 DR. DE BAKEY: The motion includes the need to
22 provide some material to each one of us relating to the HMO's
23 and the program and how in a sense this does provide, let's
24 say, an advancement of the program giving us the opportunity
25 to make the interpretation as well because it is our

1 responsibility to vote the money. I want to be in a position
2 to make this interpretation.

3 I am really asking that this vote be set aside and
4 delayed until we have this opportunity to do this, whether it
5 be done by mail or whether you want to call a special meeting
6 for this purpose is all right with me.

7 DR. MC PHEDRAN: Not a special meeting.

8 DR. MARGULIES: I see no alternative to a special
9 meeting.

10 DR. MC PHEDRAN: I just think when so many people
11 have views that coincide on so many features about this that
12 we split almost evenly on voting on this question, it must be
13 because we don't have good grasp. The only way we can get at
14 that is by going over the material, I would guess. I think
15 that -- I just never have seen the Council get split like this
16 before. It means that there is some real misunderstanding,
17 real difficulty, and you probably ought to get at it by
18 reviewing material.

19 So, that's why I would support it although I voted
20 the other side of the question.

21 (Discussion off the record.)

CR 6499
End #19

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1 DR. BRENNAN: I would like to point out that it is
2 my understanding that Social Security funding of this program
3 is currently under Congressional investigation.

4 Secondly, that I believe that if we have had a
5 motion or if it were possible for us to have voted to support
6 the educational, the quality control, the interinstitutional
7 and the prior relationship planning components which are our
8 responsibility that I would have felt better. But I simply
9 cannot understand the present circumstances which the Congress
10 is clearly in doubt about the program, where previous funding
11 for it is currently under investigation, I should hate to see
12 our program put in any jeopardy by attachment to the spending
13 of another four million something about which there is no
14 Congressional unanimity particularly in view of the fact that
15 one of the sections of our act calls upon us to be very chary
16 about moving to radical changes in the health care system in
17 this community.

18 DR. MARGULIES: If we are to change the motion which
19 you presented, it will require the approval of the seconder of
20 the motion which was -- Mrs. Mars.

21 MRS. MARS: Yes. For the first motion.

22 DR. MARGULIES: That has your approval?

23 MRS. MARS: Yes.

24 DR. MARGULIES: The motion is changed to one which
sets aside the previous vote and which asks for further

motion W 197
reconsider

1 information to demonstrate the way in which the grant funds
2 would contribute to the purposes of RMP and which calls for a
3 subsequent ballot on the same question either by mail or another
4 meeting of the Council.

5 Any further discussion?

6 MR. HIROTO: What kind of timing is required for the
7 continuity of the HMO program?

8 DR. MARGULIES: We would have to take action on this
9 before the last ten days of this month.

10 MR. HIROTO: Could I say something off the record?

11 (Discussion off the record.)

12 DR. MARGULIES: Fred, do you have any comments to
13 make?

14 MR. STONE: To tell you frankly, I don't know
15 whether anything I would have to say would help or not. You
16 obviously have a council here that is very disturbed on the
17 basis of certain information they feel they should have, that
18 they do not have.

19 This being true, it's inappropriate to expect the
20 Council -- if this is true and I must accept it as true, it's
21 inappropriate for the Council to take action under those
22 conditions.

23 On the other hand, the Council it seems to me in
24 its obvious effort to help the staff must upon the receipt of
25 this information be prepared rapidly to accept a mail vote.

1 I think that the -- I know the staff has done all
2 that the staff could be expected to do. These are matters which
3 have been discussed and actions have been taken at a very high
4 level for which the staff is not responsible; neither is the
5 Council.

6 On the other hand, it's perfectly obvious that under
7 the law that Council has certain responsibilities which the
8 Council is attempting to discharge.

9 I think the Council, feeling as it does, has a
10 right -- a responsibility to request the information it needs
11 to come to a decision. It seems clear to me in listening to
12 this as an outsider, because as you all know, I haven't been
13 here very long, the Council is trying to find the basis on
14 which to help the staff get out of this impasse.

15 I accept this as -- I myself accept this without any
16 mental reservations as an attempt on the part of the Council
17 to find a legitimate way to be as helpful as possible in this
18 matter.

19 Now, is this a reasonable explanation of what the
20 Council is trying to do? As you know, I came in in the middle
21 of the discussion. Does this seem right?

22 DR. SCHREINER: I think that's a very, very concise
23 and accurate summary. People are bothered and none wants to
24 pull corks and watch them for the sake of seeing the water --
25 we are trying to get --

DM
1 MR. STONE: I hope I didn't add to your problems.

2 DR. MARGULIES: I don't believe there is any room.

3 (Laughter.)

4 DR. DE BAKEY: Would it be better to try to have a
5 meeting of the Council by the end of next week?

6 DR. MARGULIES: Dr. De Bakey raised the question of
7 whether it would be more practical to have a special meeting
8 by the end of next week. It's awfully difficult to get this
9 many people together.

10 MRS. MARS: How quickly can you get material out to
11 us?

12 DR. MARGULIES: Very quickly, but the risk of having
13 a low attendance on such a critical issue frightens me.

14 DR. BRENNAN: Mr. Chairman, is there any
15 administrative method open to the Director of HSMHA whereby he
16 may within the allocations to HSMHA rebudget some of the
17 funding on his authority? In other words -- one of my problems
18 were this is not wanting to identify at this point because the
19 thing seems to me to be so vague in outline and so loaded with
20 many complications that I can't clearly foresee at the present
21 time.

22 I'd rather not attach the Council to what is
23 essentially a rebudgeting authority. If the administration
24 were to do this, and explain itself to the Congress, in that
25 regard, it wouldn't seem to me to be quite as harmful as it

1 would be if we were asked to do it.

2 DR. MARGULIES: I think that's an interesting
3 suggestion. We should move on.

4 I think probably we should take a vote on the motion
5 which I think you all understand now. I think we will have a
6 show of hands.

7 All those in favor of the motion, please raise your
8 hand.

(Show of hands.)

9 DR. MARGULIES: Opposed?

(No show of hands.)

10 DR. MARGULIES: The vote on this is unanimous.

11 MR. WATKINS: No.

12 DR. MARGULIES: Oh, I am sorry. One negative. The
13 [REDACTED]
14 rest for.

15 This means we will get to you material which will
16 attempt to relate the HMO activity to RMP purposes so that you
17 can take a vote on the material which was presented to you by
18 ballot and we will ask for a very quick response.

19 Keep us informed of your movements so that we can
20 get in touch with you.

21 DR. MERRILL: Will you include specifically the
22 working of that?

23 DR. MARGULIES: I doubt that we can get that. Are
24 there specifics beyond the RMP purposes which you feel need to
25

1 be addressed?

2 DR. BRENNAN: In principle I would like to suggest
3 that the funding taken from RMP should be funding in part of
4 activities which plan for the necessary educational and quality
5 control components for inter-institutional arrangements on the
6 part of the HMO's and for the definition of relationships
7 between a -- the providers and the HMO's and the means by which
8 those providers might negotiate with the HMO's for the level of
9 their orientation.

10 DR. DE BAKEY: I think that's fine except for one
11 thing. That is that we then would have to have an assessment
12 so to speak of the amount of the HMO that would go into that.

13 In other words, we would have to have -- we are asked
14 in a sense to expend \$4 million or something of the total. As
15 I understand it, it is the total amount for these HMO grants.

16 DR. MARGULIES: I think it's impossible for us to
17 deal with anything other than the substance of the motion which
18 is presented which is that following this review process the
19 grant will or will not be made for the support of the HMO's.

20 Your question is what does this have to do with our
21 RMP. That's the question we will try to respond to.

22 DR. DE BAKEY: I would like to do a little of the
23 interpreting myself, Harold. I don't want the interpretation
24 given to me, handed to me. I feel that I have enough knowledge
25 about, you know, the HMO criteria, having at least participated

1 in authority to know something about the framework structurally
2 of regional medical programs.

3 I think I know the criteria of the characteristics of
4 the regional medical program. What I don't know and that's what
5 I want to interpret, are the criteria and characteristics of
6 HMO in relation to what I will interpret are the regional
7 medical programs. I don't want you to give me another ex
8 cathedra opinion. That's the point I am trying to make.

9 DR. ROTH: That's sort of an impossible request.
10 Lord knows which one of the laws if any of the present bills
11 are going to be passed.

CR 6499
End #20

#21

12 DR. MARGULIES: I think we can do it on the basis of
13 what is being funded by the HMO service. That we can do and
14 lay it out for you so you know what the money is going to go
15 for. That's what we will do.

16 May we move on to the next agenda item?

17 As a part of our other activities for supplementary
18 grant awards, we did address the potentiality which began
19 earlier with the subject of area health education centers which
20 as I told you this morning were ruled out for RMPS and moved
21 from there to community-based educational activities which are
22 of a different character.

23 In doing this, we have worked very closely with the
24 Veterans Administration which has been interested in the same
25 activity and have identified with them in the review process

1 those hospitals which have been site-visited by the VA and
2 which they feel are an appropriate point for their support.

3 These have been identified in the review process
4 for these educational activities which were carried out in a
5 manner very similar to what we have described for the emergency
6 medical systems.

7 What we did, in order to make sure that there would
8 be an appropriate review process, is feed back to the regional
9 medical programs a description of an activity which is more
10 than anything else an enhancement and embellishment of what
11 RMP's have been doing in general to bring together community
12 resources to improve education of health professionals and the
13 relationship of that education to the delivery of services.

14 Because again we were uncertain of our funding, the
15 amount of that or the restrictions placed on it, we have
16 carefully separated this out from anything which appeared to be
17 the area health education center as currently defined and as
18 originally defined and we are talking about something else
19 which is a program that will be apparent as Dr. Perry reviews
20 what has been done.

21 In order to carry out this activity, then, we did
22 set up a special review committee which met a week ago Sunday;
23 again we had to act more hurriedly than we like. It was not
24 as difficult in this case as in many others because RMP's have
25 been involved in this kind of activity almost from the very

1 beginning.

2 Nevertheless, it did rush events and in the future
3 this will be part of the RMP process unless we get into a
4 strange and bewildering committee.

5 Dr. Perry was the Chairman and he will summarize it
6 for you. Miss Kerr from the same group; Dr. Hess from the same
7 group and Miss Anderson and Mr. Hilton both from the Review
8 Committee; Mrs. Wyckoff attended representing the Council;
9 Mr. Ogden had intended to but was unable to and we had also
10 Dr. Popna, formerly coordinator of the RMP and formerly a
11 member of this council.

12 The Review Committee was headed by Veronica
13 Cronley on the part of the -- to prepare the materials and make
14 them reviewable by this group.

15 It is that review process and the results that Dr.
16 Perry will report to you.

17 DR. PERRY: My flight isn't until 7:45. I made the
18 change. I hope we will be done in a very short time.

19 Certainly the review process as those of us
20 experienced at Sun Valley felt -- that it was indeed probably
21 the best review in the three or four years that we have been
22 a part of RMP that we have seen.

23 As had been mentioned when looking at the emergency
24 projects, the review from the staff and the assistance from the
25 staff was really exemplary as this assistance was given to us.

1 We in turn made them a most integral part of our
 2 process. As Harold has said, our projects and our program was
 3 not something entirely new. Many of the programs indeed are
 4 involved -- many of the projects indeed are not new and have
 5 been the kinds of projects that RMP has known in the past.

6 As Harold said, we were looking at supplements in
 7 programs, looking at those projects that had responded in the
 8 past in many ways to these kinds of educational programs.

9 All of us know that much of this had been stimulated
 10 by the Carnegie Commission Report and certainly the acceptance
 11 by the RMP's at Saint Louis of the coordinators of their great
 12 interest in moving and looking at the manpower development and
 13 utilization in various ways.

14 Through a consortium that many of us know is in
 15 operation in our own regions and those of us who have been
 16 looking at grants are familiar with, the providers, educational
 17 institutions, clinical institutions, and indeed in this case
 18 quite a community input in relation to these is looking at the
 19 goals to be achieved.

20 Thus from the Saint Louis meeting in January to a
 21 point where in a short span of five or six months we did have
 22 before us a large number of grants from 17 -- I am sorry, 19
 23 regions and over 75 projects had come in immediately on this
 24 area of community-based programs.

25 I think many of them, if we look at what did happen,

1 were greatly stimulated and indeed helped by the key concepts
2 paper that is in your material. That final paper that came out
3 of the Saint Louis meeting became a very important principle
4 kind of thing. That was immediately built into many, many of
5 the projects.

6 How was it possible to review such a number in one
7 day? We started Saturday night with Harold and Dr. Paul and all
8 the Review people that were there. Many of us were not out at
9 Sun Valley just for the trip. It was RMP's third allied health
10 conference and thus there were many coordinators and many people
11 from the staff at that meeting at that time.

12 The integrity of the review process in that period
13 of time I feel is a most important kind of thing to respond to
14 here. If you look in your folder, the -- I think RMP has
15 learned a great deal in the past few years.-- the review
16 criteria, the ways in which this was put together for this
17 project, with three or four pages of review criteria, with
18 recommendations from staff on these pages.

19 We had something to go at and look at together in
20 relation to this. Plus people from the regions and such that
21 were there with us.

22 For every project, every program we were reviewing
23 we had people who had indeed been in that region and could
24 respond to direct questions that we had.

25 So, these guides and criteria for review certainly

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1 Dr. Hinman, Dr. Conley, the staff did a fantastic job. We all
2 profited from it.

3 As an active part of the processes, I mentioned we
4 did indeed include the staff up at the table with us, to get
5 the totals here, and I want to refer to you four brief
6 summaries to give you an idea of some of the kinds of projects
7 we did look at here. From your totals you can note a total
8 requested amount of \$10,229,811, was requested in this total
9 amount.

10 The recommended figure for this amount by the
11 Review Committee, and we do have a change here that Mrs. Wyckoff
12 who is quite an accountant found in relation to this.
13 Intermountain is a 42,080 amount which changes the totals at
14 the bottom to 882,060 and a grand total then of 6,800 --
15 \$6,874,996.

16 In relation to this program, what about the
17 disapprovals and the large number we did look at? What was
18 missing? What were those areas that we considered were not at
19 this period of time effective for funding?

20 Certainly many and some of the programs -- I should
21 not say many but some of the programs we were still looking at
22 a very traditional pattern of continuing education and trying
23 to fit it in still in a continuing plan.

24 Although continuing education was an integral part
25 of many of the programs, it was the only kind of program in

1 some of them that had been put together.

2 The community input, we looked at very carefully as
3 we looked at the various groups that were a part of the
4 consortium of the program that was involved here. We were
5 looking at the needs of all of the health professionals
6 involved in this program and particularly the leadership role
7 of medicine as it related to some of the other health
8 professions in these areas.

9 There were individual parts of a consortium missing.
10 If there was community need in some cases, not the hospital
11 input or the educational institution input. We looked very
12 carefully at those pieces and parts of the total process.

13 We were very encouraged however at the excellent
14 applications that were among the review processes at the same
15 time.

16 Some of the consortia have already been in operation,
17 have already developed their bylaws beyond the planning phases
18 ready to implement.

19 These are the programs that were out there that
20 have been a part of this kind of development during the past
21 few years.

22 Let me read then just briefly, and I did ask the
23 staff to give me a few summaries of some of the projects that
24 have been approved so you can get a feel for the kinds of
25 consortia and since you do not have available to you the large

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1 stack that we had.

2 Project number 110 from Los Angeles East.
3 Their community-based manpower project proceeds from
4 intensive work by the RMP in that area in the medically
5 deprived areas of East Los Angeles. The LA East consortia
6 which has just been incorporated has a 25 member body
7 representing a consortia of 13 citizen consumers, three
8 students, and three representatives each from the health
9 professions involved in it with representatives from health
10 care facilities, health training and educational institutions
11 in that area.

12 The CBMP there would serve as an information
13 clearinghouse, will coordinate and look at all existing
14 training programs and will serve as a catalyst for the
15 recruitment and training relative to that community and
16 its health service needs.

17 It also hopes to act as a fund raiser for
18 future activities of this kind.

19 Also in California, number 107, which impressed --
20 certainly some of these I am reading are indeed the kinds
21 of projects many of us have been looking for, at times
22 as we look at those programs that "why discover the wheel."

23 Some of these indeed have some very important
24 kinds of things that have selected demonstration potential
25 for other areas. This is great variety in the different

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1 kinds of projects we have, but some are so well put
2 together we can profit by looking at these.

3 San Fernando Valley, an already existing
4 consortia in the San Fernando Valley will be expanded to a
5 CBMP extending to several surrounding counties. The first
6 year will be devoted primarily to the refinement of the
7 administrative structure of the nonprofit coordinating
8 governing body. High level of interest and commitment of
9 all relevant educational health care institutions as well
10 as the health practitioners and consumers will enable this
11 new corporate body to serve as the primary vehicle for
12 planning all health manpower training activities in their
13 service area.

14 Long-range plans call for the development of
15 long-range curricula in the California system. The plans,
16 RMP community manpower project, is considered a most
17 important model and certainly geared to that area.

18 A careful data base aimed at ascertaining
19 needs and establishing priorities has already been
20 accumulated for this project. The program is conceived
21 as a truly cooperative effort of the health care resources
22 and represents an integral arm of the RMP.

23 The range of cooperation extends from the RMP
24 to consumers, health planning groups, to the university
25 and community colleges, professional societies, public

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1 schools, health care provider institutes, health care agencies,
2 and the Veterans Administration, which is indeed a part
3 of that project.

4 The ultimate goal of that program and the program
5 projects is that of meeting the demands and need for health
6 care needs of the region, a range of operational activity
7 such as university-community coordination of health care
8 programs, pediatric and nurse associate programs, evaluating
9 home health team training programs, cooperative inter-
10 institutional in service educational program and so forth.

11 Again, in this case, financial support of the
12 program will come not only from the RMP, it will come from
13 the VA, from participating institutions, the state, TB and
14 Heart associations.

15 Unlike some of the programs, a unique effort
16 here is that they are at this very moment identifying sources
17 of continued financial support following the period of
18 both the RMP and VA federal funding.

19 I could go on with South Dakota, with some of
20 the other projects we did review. There were really some
21 very strong programs that have come out in this review process.
22 One area that you do not have on your listing there is a
23 priority listing that has been done in addition to what you
24 have. You have the total requested and you have a total
25 amount. We were informed that in all likelihood, as Harold

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1 mentioned this morning, the necessity of being unable to
2 fund everything, that it would be extremely important to
3 do a priority listing here.

4 Evolved from that listing are nine regions, and
5 I will be very happy to read these off to you as priorities
6 in this listing, if you wish to take your own page here
7 under number five and check these off, I can list for you
8 those that have been given priority attention by staff and
9 by the committee.

10 Alabama project number 45; California project
11 104, 107, 110, Lake Erie's project 28 through G and J
12 through N, Maine projects 27 through 37, New Jersey project
13 30, Northeast Ohio, project 15, Northlands project 68
14 through 74, South Dakota number 2 and Tristate number 19.

15 This amount and figure at this point is
16 \$5,218,795 at this point.

17 I think you know for the future as we look at
18 this kind of programming, as we look at this kind of planning,
19 as we look at the community-based projects here, there is
20 certainly great future as one looks at RMP, as a part of
21 looking in a shared way at some of the new systems developed
22 by the relationship of many of the health professions working
23 together, of the accessibility of health care that is showing
24 up in quite a few of the projects from the standpoint of
25 rural projects, projects in inner city and so forth. These

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1 are all, I believe, very indicative of some strong, strong
2 input for the future.

end 21

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1 If there is one area that we watched carefully, and
2 one area that I believe RMP must indeed strengthen in every way
3 in relation to those projects and look at cautiously, and that
4 is the evaluation of out put of these projects for, indeed, if
5 there are models here that are important, we must evaluate them
6 and have this to share with others because the projects, as we
7 saw them are indeed some of the strongest we have seen in this
8 area. For the accessability of health care, some of the pro-
9 jects in some of the more rural states as they are looking in
10 these areas, let's evaluate them, let's be certain that we have
11 a good record of evaluation on whether or not it is coming out
12 of these.

13 The subcommittee was delighted to have Harold and
14 Dr. Pahl with us throughout the entire meeting, and he is
15 especially happy to have Mrs. Wyckoff sponsored on behalf of the
16 council. We were very pleased to have her with us.

17 MRS. WYCKOFF: Thank you.

18 DR. MARGULIES: Mrs. Wyckoff?

19 MRS. WYCKOFF: This was a very thrilling meeting in
20 many ways. I had been on this council for some time. I never
21 -- I want to compliment the staff on the wonderful preparation
22 work they did in digging out the data that we needed. I feel
23 it is very important for us to get off the ground with this new
24 community-based program with projects that are good models so
25 we will have something to point to with pride here and be an

1 inspiration to the rest of the program.

2 I would like to move approval of the report of Chair-
3 man of the Review Committee and also to recommend the priority
4 list that he gave in case we have to use it.

5 DR. DE BAKEY: I would second the motion, but in some
6 way I think it is important that we express our sentiments --

7 DR. COMAROFF: Can't hear you.

8 DR. DE BAKEY: I think it is important to express our
9 sentiments. I think this is a very important program, and it is
10 true that it may take a while to assess the full impact, but I
11 have the feeling that as the -- as a programmatic activity, it
12 can be extremely important in furthering the goals of the region-
13 al medical program, and so I would urge, insofar as it is
14 possible to do so, that we avoid having to lean on the priority
15 listing, and that we give this total program a very high priori-
16 ty.

17 DR. MARGULIES: Okay. Dr. Chase, would you like to
18 comment any from the V.A. point of view?

19 DR. CHASE: Yes. This has been a very useful experi-
20 ence for us. On the many applications submitted on this first
21 go around, there were four from the hospitals we identified to
22 provide initial support. We -- from the applications, we iden-
23 tified again some difficulties which we will have to address
24 ourselves to. Specifically, that in spite of the guide lines
25 which have been provided and meetings held in the field in

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1 Washington with these coordinators and the V.A. Hospital direct-
2 ors, we had some difficulty identifying the components within
3 the application which were relative to the V.A., so among those
4 four, three of them we were able to provide on this first go
5 around on the basis of only a small amount of money. That
6 largely was in the realm of continuation of planning activity;
7 in other words, an annualization of funds which we had already
8 provided.

9 On the other hand, the main application got the
10 message pretty clearly, and we were able, on an eighteen-month
11 basis, to permit \$317,000 of V.A. money to that application; the
12 point being that now we will have to be back and work closely
13 with these sites to help them, if you will, in terms of grants-
14 manship, so we have the documentation to use our legislative
15 authority.

16 Counsel may be interested in knowing that we, too,
17 are enthusiastic about this approach for the future, and we are
18 again committing for the '74 budget year another three million
19 dollars for our contribution.

20 DR. MARGULIES: I think this has been a very reward-
21 ing working relationship between two usually quite separate
22 agencies, and it is getting stronger as we go along.

23 Any further comments?

24 MR. HIROTO: Yes. I am a member of this East L.A.
25 task consortium. Should I excuse myself?

1 DR. MARGULIES: No. By taking block action we are
2 avoiding the embarrassment of everyone but two leaving the room.
3 We had to use those use those for illustration, but to get
4 around that difficulty, we are asking for a block acceptance of
5 a review process.

6 For the record, anyone who was involved with a
7 region did leave the room during the review process. Mrs.
8 Wyckoff was out during California, et cetera, et cetera. That
9 part was kept unsullied

10 MRS. WYCKOFF: Can I make a motion?

11 DR. MARGULIES: You have made it, and it has been
12 seconded.

13 Further discussion?

14 All in favor say aye.

15 (Chorus of ayes.)

16 DR. MARGULIES: Opposed?

17 (No answer.)

18 DR. MARGULIES: Thank you.

19 We have to take one other collateral action. Because
20 of the action taken on the emergency medical systems which we
21 feel is of high priority, we do need to get a motion from the
22 council allowing us to readjust the level of commitment of the
23 various regions so that they are appropriate to these actions.
24 I would like to do that separate from another action on RMP
25 levels which raises a slightly different issue.

1 DR. DE BAKEY: So move.

2 DR. MARGULIES: Is there a second?

3 MR. HIROTO: Second.

4 DR. MARGULIES: All in favor say aye.

5 (Chorus of ayes.)

6 DR. MARGULIES: Opposed?

7 (No answer.)

8 DR. MARGULIES: We also have another action on chang-
9 ing council action of approved medical programs, a list of which
10 we have available somewhere. Partially, this is based upon the
11 obligation we have by Congressional action in this case to main-
12 tain pulmonary pediatric centers at a level of the previous
13 year. In order to do this, there are some regions which will
14 need to have their commitment level evaded above where it is at
15 the present time.

16 There are also so many regions which are so close or
17 right at the level of the council approval that they do not
18 really have any turning-around room and cannot develop any new
19 activities. I will hand this list out to you, and while I am
20 doing it I will read the --

21 DR. DE BAKEY: Would you clarify that just a bit?

22 DR. MARGULIES: I will go back over that. First, let
23 me identify those in which there is a pediatric pulmonary issue,
24 and then we will look at the two in which other action has to be

1 taken.

2 In Colorado, Wyoming, in metro D.C., in New Mexico
3 region, and in South Carolina, if we are to support pulmonary
4 pediatric centers and maintain our oevels of commitment at 1.7,
5 there will have to be, as you see listed before you, a new annu-
6 alized national advisory council level. Now, the other two have
7 different justifications, and I would like either -- Bob do you
8 want to speak to this or Judy, the actions on Florida or
9 Tennessee, mid-south, which propose an elevated level?

10 DR. DE BAKEY: Let me ask one question in this regard.
11 Congressional action was taken upon this. Was it within the
12 current budgetary --

13 DR. MARGULIES: Yes, it was the action of the Appro-
14 priations Committee of the past year. We are getting to it
15 later than I would have liked, Mike, because again we could not
16 feel free to commit 1.7 without knowing we were going to get all
17 the funds available. Now it appears we are close to it, and we
18 think we should.

19 DR. CHAMPLISS: Specifically in the case of Florida a
20 request is being made of council to increase their level in the
21 amount of \$321,000 to take care of the fact that in their previ-
22 ous application there was the amount of -- for \$321,000 to cover
23 emergency medical service activities so this is an effort to
24 provide -- they were ahead of the whole movement here. This is
25 an effort to provide them with a restoration of the amount that

1 they had already committed for that activity.

2 In the case of Tennessee/Mid-South, you will note
3 that that they are right at the analyzed approved council level,
4 and the additional funds in the amount of \$263,000 would permit
5 them to have expansion of their ongoing activities, and, there-
6 fore, request is being made to have that council -- that level
7 approved by this council.

8 DR. DE BAKEY: Does that include pediatric pulmonary?

9 DR. MARGULIES: No, it does not.

10 DR. DE BAKEY: So they are really talking about two
11 actions?

12 DR. MARGULIES: Yes. Well, if you want to take them
13 together or if you want to separate them, you can.

14 DR. DE BAKEY: I just want to be clear.

15 DR. MARGULIES: There are one, two, three, four that
16 involve pulmonary pediatric, and the others involve levels of
17 RMP development which we feel is reasonable for the progress of
18 the region.

19 DR. CHAMPLISS: The 321,000 -- specifically that is
20 to cover additional program activities that they wanted to get
21 underway. I am not specifically aware -- Judy?

22 MRS. SILSBY: This is a request to raise the level.
23 It is not a request to give them the funds. All of these funds
24 are allocated, and it is a matter of going in before their next
25 application comes in. We would expect a full request to come in

1 to delineate what it is they want to do. Some of the regions
2 got extended 15-16 months.

3 DR. MARGULIES: You see, when we extended the pro-
4 grams by several months, some of them were in a very uncomfort-
5 able position of wanting to initiate something new in the
6 extended period, but not knowing what kind of continuing support
7 they could plan on. So we had to give a reasonable level of
8 assurance to keep things moving. All this does is give us the
9 opportunity to respond to what is legitimate. It is not
10 necessarily going to be associated with further plant support.

11 DR. SCHREINER: My credibility is strained by being
12 able to predict wiggle room to the closeness of 13 dollars.

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1 DR. MARGULIES: That's the left small toe.
2 This is obviously based on what they think they can
3 develop over a period of time and gives us an opportunity to
4 respond or not depending upon the availability of funds. You
5 see what will happen, if the action of the House holds up or
6 is higher than that, and we want to develop programs within an
7 anticipated level of funding and they can't do anything for
8 nine months to a year, we are strapped again into the mobility
9 of a program.

10 DR. DE BAKEY: That's why I was going on creditability,
11 really.

12 DR. MARGULIES: They have not applied for it but
13 they are anticipating doing so.

14 DR. MILLIKAN: How do you decide who isn't going to
15 have this.

16 DR. MARGULIES: We have gone through a process of
17 renegotiation of budget with all of the programs that have had
18 their fiscal year extended.

19 This is a by-product thereof.

20 DR. DE BAKEY: I would like to move block approval
21 of this.

22 MRS. WYCKOFF: Second.

23 DR. MARGULIES: Moved and seconded. Any further
24 discussion?

25 All in favor say aye.

jr 2
1 (Chorus of Ayes.)

2 DR. MARGULIES: Opposed.

3 (No answer.)

4 DR. PAHL: Mr. Komaroff?

5 DR. KOMAROFF: I guess I don't understand.

6 It seems to me we are approving a supplement without
7 a request for supplementary funds.

8 Were these just prorated on the basis of the approved
9 level?

10 DR. MARGULIES: No, they were not. All of the
11 regions which were extended were given 12 months funding only
12 and they had to renegotiate their funding for the 15 or 16
13 months, whatever is necessary and provide justification for
14 that.

15 In the process some of them were able to justify
16 higher levels, same levels, or lower levels. This is what
17 finally came out of it.

18 DR. KOMAROFF: So in approving this supplement, they
19 are not operating at a month three higher level?

20 DR. MARGULIES: They are still in the same range
21 but this gives them a chance to do more.

22 DR. PAHL: Recognizing that it's somewhat late and
23 we don't have too much time to delve into specific
24 applications, we will have to take up at least two today because
25 the principal reviewers will not be here tomorrow.

jr 3

1 So with your indulgence at the end of a somewhat
2 lengthy afternoon of discussion, I would appreciate it if we
3 could discuss the Northeast Ohio application.

4 That is in the red covered ring binder and we have
5 Dr. Millikan as the principal reviewer. Dr. Schreiner is the
6 back up reviewer and Mr. Ashbee, staff and Mr. Milliken --
7 the record will show Mr. Milliken has absented himself from
8 the room.

9 Before we have a discussion of the appli-
10 cation, I should like to say that you will notice, those of
11 you who have been looking at staff materials and council books
12 for some time will notice new color sheets and new formats
13 and as Dr. Margulies indicated this is an attempt to have
14 somewhat greater uniformity and reduction in paper work.

15 The important thing for the council to know is that
16 the blue sheets in each of these sections are the summaries of
17 the review committee's consideration relative to that applica-
18 tion.

19 MRS. MARS: You said we were going to take up two.
20 You just said Ohio. Who was the second?

21 DR. PAHL: Ohio itself. Northeast is first, and then
22 Ohio will be the second application this afternoon.

23 Mr. Baum has also asked me to indicate that we will
24 be passing out for your consideration if you need them, the
25 computer print-outs, a compilation of all of these.

jr: 4

1 Those of you who were principal or back up reviewers
2 did already receive the print-outs he will be distributing.
3 These are just for reference sake at the table.

4 While I am on that topic, Mr. ^{JOHNOWSKI} ~~Lekniasso(?)~~, who is
5 chief of our office would appreciate any kind of -- Frank,
6 you should indicate they are not compelled to read these at
7 this point in time or you will have a rebellion.

8 He would appreciate receiving comments from you as
9 was indicated by his letter relative to how these print-outs
10 may be made more helpful in your consideration.

11 We will be ready in a moment. I am afraid taking
12 up the applications out of order. We have caught Dr. Millikan
13 somewhat unaware here and he has to get his materials in order.

14 DR. PAHL: Is Dr. Millikan not here? We got too far
15 along. We are not going to have him.

16 I thought he was looking for his material.

17 Dr. Schreiner, I think the ball has fallen into your
18 court. Would you please discuss Northeast Ohio application?

19 DR. SCHREINER: Is he not coming back?

20 DR. PAHL: It appears Dr. Millikan will not be
21 returning. It's just that our HMO discussion lasted longer
22 than the plane departure time.

23 We will turn to Dr. Schreiner comments for Northeast
24 Ohio.

25 DR. SCHREINER: I am afraid I can't give as much

jr 5

1 detail as I would do if I were primary reviewer.

2 The Northeast Ohio region embraces about 12 counties
3 in, as you might imagine from the name, the northeast portion
4 of the state of Ohio and represents what is left over after
5 the council's coalition efforts of the past year and centers
6 primarily around Cleveland and the university contained therein
7 Case Western University which has a medical and dental school
8 and there are a number of nursing schools and allied health
9 schools in the area.

10 Principally rather heavy in medical technology and
11 in radiation and so forth. There are, for example, 60 schools
12 of medical technology -- I thought in reviewing the materials
13 that the review --

14 DR. PAHL: Would you use the microphone, please,
15 so our recorder can hear you?

16 DR. SCHREINER: I thought that the site visit data
17 gave a pretty reasonable insight into the operation in the
18 area and that one is really faced philosophically with two
19 kinds of judgment and that is one could put a great deal of
20 pressure on the group to join the Ohio area which I think most
21 of the site visitors felt eventually should be the evolution
22 of this particular RMP and that there are various ways of
23 accomplishing that.

24 One would be to disapprove it totally and wipe them
25 out.

jr 6

1 The other would be to continue them for a year of
2 support and that attention be given to a new deputy coordinator.

3 I am at a disadvantage not having been on a site
4 visit. Is anyone here who was on a site visit?

5 MR. ASHBEE: I was on the site visit.

6 The report that Dr. Millikan gave at the last
7 council -- was a copy of that in with the materials that you
8 had --

9 DR. SCHREINER: No.

10 MR. ASHBEE: Let me read. First is recommendation
11 on Northeast Ohio.

12 He said it appears the impact of Dr. Hudson's
13 leadership or intimidation of some personnel in Northeast Ohio
14 changing the position of the Northeast Ohio Regional Medical
15 Program will be one of simply refusing to cooperate or relate
16 to or combat any of the regional programs since the Northeast
17 Ohio Regional Medical Program has a full time coordinator. It
18 would appear wise to fund this program at its current level on
19 a year to year basis, possibly having an in depth project site
20 visit during the next few months.

21 Under the present circumstances, it is recommended
22 that a triangular review is not appropriate at this time.

23 He went on to say that activities to combine the
24 northeast with Ohio State should be carried forward.

25 DR. SCHREINER: My own superficial view was that

jr 7

1 \$600,000 is quite a bit for continuation of something that we
2 are a little bit uncertain about, but I expect the site visitors
3 who were on the scene and I think about all you can say is that
4 you have a new program director, you have a RMP that hasn't
5 moved in the direction that the council would like to have it
6 move in, and essentially you are treading water and what's
7 the price for treading water. If everyone thinks that's a
8 reasonable price for treading water, I would be in favor of it.

9 DR. PAHL: Mrs. Silsbee informed me that Dr. Millikan
10 prior to his departure accepted and was in accord with the
11 recommendations of the review committee which would support then
12 your statement, Dr. Schreiner. Would you care to make a motion
13 or further comments?

14 DR. MARGULIES: Bob, do you want to comment?

15 DR. CHAMPLISS: I think the council should know
16 that this is a region on very high priority for assistance.
17 We realize the inherent problems there from a staff point of
18 view and we have rescheduled our technical assistance and
19 management assessment visits to that region so as to take
20 them out of phase. We anticipate that the management assessment
21 team and the site visit will be made next month.

22 We think this is a region that needs a great amount
23 of help and that is already being put on our schedule.

24 DR. PAHL: Dr. Schreiner, would you care to make a
25 motion?

jr 8

1 DR. SCHREINER: I move approval at the recommended
2 level.

3 MRS. MORGAN: Second.

4 DR. MARGULIES: Motion made and seconded to accept
5 the recommendations of the review committee.

6 Further discussion?

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1 MRS. MARS: What is the hope of merging it in the
2 very near future with the rest of Ohio? What prospects are there?

3 DR. MARGULIES: I think they are very vague at the
4 present time, Mrs. Mars.

5 The -- part of it depends upon the strength that
6 emerges from the Ohio merger which appears guardedly promising
7 but they are at the point now of trying to decide what they
8 really should be.

9 I think the existence of some outside people in
10 Ohio like Dr. Cashman, who is the State Director of Health
11 there, is going to be a very useful force.

12 They are talking with one another in much more regu-
13 lar terms than they were in the past and we in turn are going
14 to encourage them to talk together more in the future.

15 I could not hold out any promise for anything more
16 than an effort to move in this direction. It's still very un-
17 certain. It's too bad, really, because the resources in Cleve-
18 land are tremendous for developing a good program.

19 If they can get over some of the personality blocks,
20 I think they may find that coming together will be good for
21 them in the long run. It's still very, very uncertain so far
22 as the total merger is concerned.

23 DR. BRENNAN: I think in that regard our experience
24 over the years has been that these programs are really grass
25 roots programs if they have any health to them at all, and we --

jr 2

1 every time we try to doctor them too much, bring them around to
2 what we think they ought to be before they have an idea of
3 themselves, that we generally end up with a long period of dis-
4 ruption and discouragement and no activity.

5 If it's valid to have programs that are founded on
6 those issues, I think you have to leave room for a great deal
7 of patience with respect to how they are going to come along.

8 It just seems that this thing has been going on so
9 long in Ohio that we might have to say to ourselves, "Well,
10 Ohio is peculiar and let it find its own way to the water
11 fountain because we have been trying to hold it up and make it
12 drink and haven't been able to do so for a long time."

13 DR. PAHL: Further discussion.

14 MRS. WYCKOFF: Maybe the community based education
15 program there will have an effect.

16 DR. PAHL: The motion has been made to accept the
17 review committee's findings.

18 All in favor of the motion, please say aye.

19 (Chorus of Ayes.)

20 DR. PAHL: Opposed. (No answer.)

21 DR. PAHL: Motion carried.

22 DR. PAHL: Dr. Schreiner, we are going to have to
23 call on you to start the discussion on Ohio. Mr. Jewell will
24 be here as our staff representative.

25 DR. SCHREINER: I think those of you who have not

jr 3

1 read the report will be interested in the sentence a site
2 visit was not performed. A great many of us had difficulty
3 in considering this application.

4 That does not make my task easier. This has to do
5 with support for the remainder of Ohio which depending whether
6 you live in Cleveland or not is the merged or the unmerged
7 portion. It contains a number of proposals.

8 First, let me address the areas in which I do have
9 some insight and that is the two renal transplant programs
10 which were rejected and I think quite rightly so.

11 The organ procurement effort does not have anything
12 in the way of very specific -- for example, it says that a
13 patient is placed in a waiting pool and tied up with various
14 registries.

15 You don't just do that with a piece of string.
16 There is a specific way and it's very, very difficult actually
17 to get plugged into the registry.

18 There is no functional or national registry that
19 actually needs the exchange of kidneys and some of the regional
20 programs, the most formal one is in the mid-Atlantic area and
21 there are a few others that are informal arrangements.

22 I think we have to have specifics so we know where
23 is the terminal and who runs the computer and how do the
24 matches get made. Who calls up whom after you make the match
25 and so forth.

jr 4

1 This isn't something you do by committee or get a
2 letter in the mail three days later that they had a kidney last
3 week.

4 It has to be something operative on an emergency
5 basis. I think that the technical reviewers did a very appro-
6 priate job in that.

7 The same thing is true of the proposal of organs re-
8 cruited by paramedical personnel. The experts in this field
9 are debating whether doctors should do it.

10 A successful recruitment of organs has been in the
11 areas where there is a committed transplant surgeon and where
12 the surgeon himself is out harvesting kidneys.

13 Dr. Koontz set the pace on this in San Francisco
14 where he harvests all the kidneys he transplants and he has
15 the -- he is the only person in the country with an adequate
16 supply.

17 Right now it seems to be funding technicians who
18 will go around to hospitals and explain to people that their
19 relatives' kidneys are going to be taken out, is shooting at the
20 wrong level. I don't think it's going to be acceptable.

21 I think that it has some very serious problems
22 associated with it, and I think for this reason the review
23 group turned it down.

24 So essentially what they are recommending is that
25 the merger be consumated in the real world and that about ten

jr 5

1 percent more than the previous combined funds be given and that
2 a site visit.

3 I don't have any other basis for -- any other recom-
4 mendation than that so I would move approval of the review com-
5 mittee's recommendations.

6 DR. PAHL: Is there a second to the motion?

7 MRS. MARS: Second it.

8 DR. MARGULIES: Motion made and seconded.

9 DR. HINMAN: I would like to make a comment about
10 the third kidney project he recommended for disapproval.

11 There were three kidney projects and the local re-
12 views did not support them because of the fact that --
13 Dr. Schreiner commented on the first one. The third one had
14 to -- had to do with a pediatric necrology setup --
15 it had local turnout and was supported by --

16 DR. SCHREINER: I was lumping the two with the gen-
17 eral Ohio program.

18 DR. PAHL: Could you speak up a little bit?

19 DR. HINMAN: This will change the funding level you
20 were recommending. There was a \$900,000 recommendation for
21 program staff which is unchanged and a \$500,000 recommendation
22 for operational activities if the kidney was approved.

23 Since the kidney was disapproved this reduces it,
24 rounding it off to \$300,000 for the 01 year, \$315,000 for the
25 02 year.

jr 6

1 DR. PAHL: Further discussion on the Ohio application?

2 All in favor of the motion, say aye.

3 (Chorus of Ayes.)

4 DR. PAHL: Opposed.

5 (No answers.)

6 DR. PAHL: Motion carried.

7 DR. MARGULIES: This seems to be enough to have

8 accomplished for the day.

9 We will adjourn until tomorrow morning, although
10 Ken Baum has an announcement to make regarding the activities
11 in between.

12 (Discussion off the record.)

13 (Whereupon, at 5 p.m., the meeting was adjourned.)

End 24

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