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June 21, 1975

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TO: Members, Executive Committee, Council on Epidemiology.
FROM: Leonard P. Cook
SUBJECT: President's Biomedical Research Panel

*Reply on 28 June
Japs
File A/A
Conf.
to my reply*

On behalf of your Chairman, Dr. Nemat Borhani, I would like to amplify a recent letter sent to you by Dr. William Kannel on the above mentioned subject.

Nemat was most anxious to stress the importance of the issues at hand. He wanted you to know that AHA's President, Dr. Elliot Rapaport placed so much importance on them, that he attended the recent meeting of the Council Chairmen in Dallas to personally ask Council Chairmen for their assistance in obtaining input from the Executive Committees of Councils on the 13 questions raised by the Research Panel and the three additional ones posed by Dr. Ringler of NHLI (see enclosures). Nemat felt sure that you would agree with him that each of us are obliged to give serious thought to these questions and prepare thoughtful responses. Responses should be well documented because Dr. Rapaport will be confronted with intensive questioning at the oral hearings to be conducted by the Panel.

Nemat suggested that you might wish to exercise the option of addressing yourself to only the questions that fall within your area of expertise or interest.

Finally, he asks that you send your comments directly to him by July 18 at his Davis address along with the telephone number where you can be reached the last week of July. This will allow him time to summarize the responses and get back to you for clarification if need be and perhaps to share with you his summary before sending it on to Dr. Rapaport by July 31.

Dr. Borhani's Davis address is as follows:

Nemat O. Borhani, M.D.
Professor and Chairman
Department of Community Health
School of Medicine
University of California
Davis, California 95616

Have a pleasant summer.

cc: Stanford Wessler, M.D.
Mr. William Turko

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THIRTEEN QUESTIONS POSED BY THE PRESIDENT'S BIOMEDICAL RESEARCH PANEL

1. For the purposes of mission responsibility, is there a useful definition of the domain of "biomedical and behavioral research" as applied to the NIH and the ADAMHA?
2. Are there operationally useful distinctions between "applied or "clinical" research and "basic" or fundamental" research?
3. If such distinctions can be developed, what are they? Is there an appropriate or optimal mix of such research in a general research setting such as a medical school or research institution?
4. Is relevance to a "disease" an appropriate expectation for basic or fundamental research either empirically or as a basis for federal funding?
5. Is the funding of basic, biomedical research efforts influenced by attempts to establish "relevance?"
6. Do investigators in fundamental research modify goals to which they are intellectually committed in order to qualify under the rubric of relevance? If so, is such self-imposed modification harmful to the creative process upon which science depends?
7. On the basis of the results of the state-of-the-science reviews by the Inter-disciplinary Clusters, would you recommend changes in the current method of allocating resources to the basic biomedical sciences. If so, what changes would you recommend and how would you suggest that these changes be implemented?
8. If you do recommend changes in the distribution of resources among the basic biomedical sciences, how long would it be before any anticipated results would become apparent? Then, on a continuing basis, how would you evaluate the efficaciousness of the reallocation of resources? If the reallocation proved to be ineffective, what would the next alternative be?
9. On the basis of the results of the state-of-the-science reviews, can judgements be made as to how these results relate to the preservation of human health? On the basis of a list of human needs required for the preservation of health, prevention of disease, or cure of morbid states, would you recommend changes in the allocation of resources?
10. Is the current method of appropriating funds (largely in relation to diseases) appropriate for support of the basic biomedical sciences?
11. If the disease-oriented appropriation procedure is an alterable political reality, could the procedure be modified to reflect the scientific complexity of the disease rather than morbidity, mortality, or some other commonly used measure of need? How?
12. How can the Congress and the public be educated to the basic realities of the total scientific endeavor that leads to detection, treatment, cure or prevention of disease?
13. Are there methods for strengthening the interface and information transfer process between fundamental research and clinical application?



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July 2, 1975

MEMORANDUM

TO: Nemat O. Borhani, M.D.
FROM: Henry Blackburn, M.D.
RE: President's Biomedical Research Panel

Because of the unfortunate continuation of the academic-pragmatic adversary positions in the AHA Council Chairmen letters addressed to Eliot Rapaport on this matter, I suppose there is no other alternative but for our council to be partisan concerning the necessity for empirical research.

A strong point must be made that "good empirical research is as essential to the public good as is good explanatory research". Though one would prefer to hear Pasteur quoted as below*, those of our scientific colleagues who feel their contribution and their interests challenged by directed research have always been in the majority and ascendancy at NIH, and nationally. The consequence of a lack of effect of unfettered basic research on major public health problems might be emphasized by data at hand, and the cruel cost of the technologically top-heavy disease care system pointed out.

It is obviously the directed and pragmatic and preventive area of research which requires protection, rather than the fundamental, which has been in the forefront since NIH started and which has only felt itself threatened in the last two or three years by growing attention to compelling priorities for empirical research. Consequently, I think our council should agree that fundamental research should not be subject to reduced funding, but should advance proportionately to the growth of available national resources. Whereas, at certain times in history, emphasis needs be on applications and empirical research, which our Council has clearly seen to have greatest relevance to the existing health level of this country.

* "There are not two sciences. There is only science and the application of science and these two activities are linked as the fruit is to the tree."

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Should we try to define a minimal proportion of energies and funds for this area of research so that it can never again be relegated to the extremely minor role of the years prior to 1970? Should we recommend flexible policy to accommodate shifting priorities depending on probabilities of return for investment (though I agree with Dr. Remington that the probabilities of "break-throughs" in fundamental research are not ascertainable).

I sincerely regret that our Council must take an adversary position to some among the leadership in the American Heart Association and the American College of Cardiology who do not understand the contribution of empirical research; some that think it is far "better to understand nature than to conquer it". This intellectual elitism leads us to be one of the most unhygienic, purposeless, flabby, unhealthy nations on earth, in the presence of the highest technology. Unfettered, so-called fundamental research is totally free of moral priorities. Perhaps we have seen considerable evidence that it can become amoral. The breakthrough mentality and the Holy Grail Syndrome have been responsible for important contributions to disease care, but almost none to health care, and very certainly have given rise to politization of the National Institutes of Health. Our Council runs the risk of being considered anti-intellectual, but I'm inclined to feel that the lack of a broad, intelligent approach to society's ills by some distinguished basic and clinical scientists, or recognition of the obvious truths and complementary contribution of the preventive approach is the real anti-intellectual element; the one which unfortunately pushes us into this adversarial role.

I'm also not particularly happy with the jargon-filled bureaucratism of some of the questions posed by the President's Biomedical Research Panel, but I believe that we can respond to them individually and should.

1. Definition of biomedical and behavior research:
The investigation of those aspects of physiological function and human behavior which relate to disease and health.
2. Operational distinctions between basic and applied research:
It is useful to distinguish between these without drawing the lines too fine. It is necessary to guard a certain proportion of national energies for the applications of science, lest we become the most superior technological culture while at the same time being the most unhealthy. Applied, pragmatic or empirical research involves considerations of design, analysis and evaluation fully as skilled and complex as those of explanatory basic research. The results of each are necessary to complement those from the other; neither is inherently superior to the other. A useful distinction might be: applied research is that in which the goals are distinctly and clearly measurable in terms of the improved quality and quantity of life.

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3. The optimal mix of applied and basic research:
I do not believe that it is possible to establish the optimal mix in any individual academic institution as such institutions cannot well pursue excellence in all directions. I do believe that it is desirable and feasible to set general guidelines for such a mix at the national level. I believe that the mix may vary somewhat according to availability of ideas and probability estimates. However, I believe that a minimum portion of resources should be suggested so that 1) continued applied research of excellent quality is possible to assure appropriate applications of scientific knowledge, and 2) so that scientists in the explanatory versus the empirical areas of investigations should not have to waste so much time and energy fighting each other (and us) for priorities.
4. Relevance to disease:
Perhaps an Institute for Basic Biological Research similar to the Institute for General and Medical Sciences might be considered as an appropriate mechanism for research freed from categorically directed applications, though the basic structure of the institutes should probably not be changed. This extends the arbitrary division of basic and applied, when in reality we are talking about good science, good ideas, good hypotheses and good methods. Because one works in a microscopic field doesn't necessarily make first class research, and because one works in the community doesn't necessarily make second class research.
5. Relation of funding to "relevance":
I believe there is a relationship and some influence on applications though I'm inclined to think that the influence is exaggerated and that few good investigators choose to do studies in fields outside their real interest simply to maintain support.
6. This question is very similar to question 5 and I do not believe that the scientific community is seriously prostituted by the categorical nature of the institutes.
7. Though I don't know what "Interdisciplinary Clusters" are, I have made a suggestion above concerning allocating resources to basic biomedical sciences.
8. Evaluation of the impact of basic biomedical science:
You've got me there! But this is one of the reasons why basic biomedical science cannot, like other basic science, be totally unfettered in its galactic expansionism without some evaluation of its impact.
9. Unquestionably the Council on Epidemiology can make recommendations concerning human needs required for the preservation of health, and prevention from disease in the allocation of resources, and should do so.
10. Yes, with the questionable suggestion above of a basic Biomedical Science Institute.

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11. I would find it very hard to allocate resources based on scientific complexity rather than on the social human and economic burden of a disease process as a basis of need.
12. Public education, along with that of Congress, should be the subject for recommendations by our Council. I find myself without any stimulating ideas right now.
13. Facilitating, and strengthening the transfer of information between fundamental knowledge and application is important. This Council has felt the severe effect of the long lag time required for this, which in some ways has jeopardized the appropriate testing of prevention hypotheses in cardiovascular diseases. I'm not sure, however, that a reasonable period of delay in digestion and thoughtful scrutiny before the expensive and mass testing or programming of the broader applications of fundamental knowledge is entirely a bad thing. At any rate, I see no definite steps other than an alerted administration and active advisory councils to consider this question.

Dr. Ringler's questions:

- 1) I do believe that expenditures of biomedical research money are now related to perceived societal needs. I think this is healthy except when it leads to politization of categorical disease institutes.
- 2) Improvement of the structure of NIH: I have no brilliant suggestions for this area, except that an evaluation should be made of the function of advisory councils to individual NIH branches to determine whether they do improve and expedite decisions, priorities and directions in biomedical research.
- 3) It is not clear what the questioner regards as the new problems of public health, but I feel that there is a broad recognition in the Institutes of Health for environmental problems and drug dependency problems. There is inadequate awareness of the need for behavioral research in these areas, both at the individual, professional and the societal level.

pc: J. Stamler
R. Remington
L. Cook

P.S. I find, as do you, that my increasing use of the dictaphone has resulted in deterioration of my syntax, sorry.