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EDITORIAL

An Overview Statement on the National Conference on Health Research Principles

On October 3-4, 1978, DHEW Secretary Joseph A. Califano, Jr., convened a National Conference on Health Research Principles. At this Conference, five panels — selected by the Secretary from nominees of all of the DHEW health agencies — heard testimony from many public witnesses concerning a draft set of principles developed by the agencies. At the close of the Conference, the panels presented preliminary reports. These were edited by the panel chairmen, given to all panel members for comment, and in some cases revised before submission as the conclusions of the panels. The Conference staff then analyzed these final reports and prepared a revised set of draft principles based upon the panels' recommendations.[1]

In accordance with the Secretary's policy of seeking public advice throughout this process, these documents are being presented now for evaluation by the Institute of Medicine and for public review. As this next phase of comment and revision proceeds, however, the DHEW agencies need not delay their consideration of the preliminary results of the process initiated by the Secretary last May. The present DHEW support and conduct of health research merit review in light of a number of the major conclusions of the Conference.

Health research in the United States has reached a stage of highly complex organization, fairly remarkable achievement, and heavy dependency upon government support — all in the space of a few decades. The promise of the enterprise still far exceeds its failings; and some perceptions of the latter are misconceptions of what science ought to be able to do and cannot do (at least now). Most of us number ourselves among the strong supporters of health research, but our reasons are highly diverse. Thus, any distillation of the essence of health research — the important principles upon which its public support and conduct should rest — must yield a diverse mixture. And such was the product of the Secretary's Conference. There was, however, one important control in the process not present in all similar deliberations. All participants had a common reference to consult, from which they could select certain qualities to be preserved or rejected, and from which they could also choose among initiatives to be encouraged; and finally they were allowed to add such principles as consensus seemed to permit. The resulting new fabric was to be rewoven on the warp of the original draft.

The revised principles are subjective and uneven. They are in need of further refinement, reordering, and transmutation to goals — the next phase in the process which the Secretary announced should be completed by next spring. The principles are, however, a more thoughtful and valuable beginning than many observers expected. They reflect *angst* of different kinds: that fundamental research not be sacrificed to expediency, that access to scientific help not be denied to any of the health missions, that an essential pluralism of health sciences not be stifled by monolithic creations, or that budget displacements not substitute for skillful management rearrangements designed to assure effective interaction and collective responsibility among the health agencies. Some of the panels were reluctant to accept as given the concept of austerity — the requirement that any change be met through fiscal redeployment. However, this reluctance was accompanied by reasoned arguments on what alternative sources the commentator would use.

The Conference reports provide a litmus to test the status of certain concepts and definitions. The term "basic research" seems to have become too ambiguous to bear its important burdens. "Fundamental" is used in the reports and clearly implies research that is either laboratory- or clinic-based, aimed at

mechanism, and not yet targeted toward specific, practical application in health care. The "Science Base" term now being tested by NIH in allocation definitions appears throughout the reports because it covers not only fundamental research but certain resources essential to that enterprise. Another area of much concern, health services research, was deliberately given a limiting definition of "scientific inquiry into problems associated with the actual organization, financing, and delivery of health care services." Categorical clinical investigations, sometimes grouped with health services research, were advisedly aggregated under "applications" research, a category including multiple kinds of developmental research of importance to numerous agencies. The NIH is now using Applications Research as a second major allocations category. The third is Technology Transfer, a useful description for a research agency to define its activities closely complementing the service, health promotion, or regulatory missions of some sister agencies. The fourth category is Training or Manpower Development.

The SATT system — *Science* Base, *Applications* Research, *Technology* Transfer, and *Training* — could be adapted to analyze all DHEW health research or science activities. The importance of some such rationalization lies in the recognition of strong recommendations that emerge from the Conference reports and revised principles calling for different ways to carry out the distribution of resources among these different categories. Thus, it is suggested that the processes of selecting and financing "science base" and "applications" activities, whether within one agency such as NIH or across agencies, should rest on different principles, with needed funds perhaps coming from different purses.

The conferees offered concrete suggestions while reaffirming the essential federal contribution to building the "science base." All five of the panel reports contain suggestions for protecting and improving the knowledge-development capabilities that facilitate the health and survival of man and his world. Consideration of these proposals by both the Administration and the Congress is merited. They include potentially useful components of a multi-year budget strategy. The most frequent assertion of commentators was that DHEW support of the science base should be stabilized to the extent possible during the period covered by the multi-year strategy. As the Secretary noted in his address before the Annual Meeting of the American Federation for Clinical Research in April 1978 and reinforced at the Conference, the building of our current capacity of knowledge development represents a 25-year investment of the American people, and to jeopardize this investment so carefully assembled over the years would not be in the public interest.

The panel reports also suggested budgetary and organizational changes. Some of these address areas where reorganization is under consideration by DHEW. On the important issue of creating knowledge to meet the needs of regulators, the panels, while not endorsing the concept of "mission-oriented fundamental research," did nevertheless, support the need for effective capability in each agency to conduct research aimed at its immediate needs. The National Toxicology Program, recently formed to unite research and regulatory agencies along a common front, was not known to many of the conferees. In some aspects, it goes beyond any design proposed at the Conference.

A bold suggestion was made for establishment of a type of health research council at the Secretarial level to unite the agencies for collaborative efforts in applications and health services research. This is a level and degree of interaction greater than now exists. Two fairly radical suggestions were made in relation to this proposal. One was that health services research be conducted by an agency under the joint stewardship of such a council. Another was that a special (Secretarial) research fund be established from which searches for urgently needed new knowledge be funded. How such a fund might be administered, or how the Congress might view much of the proposal, is left to be considered. The structured interaction among all agencies that was proposed as a means to enhance the development and application of knowledge to all health missions deserves careful thought; many believe something like

this is overdue. Creation of an appropriate mechanism for this purpose might be one of the minimum goals arising from this search for principles.

The conferees did express the view that if present strengths are to be maintained and enhanced, new organizational arrangements should occur around unmet health needs of mutual concern. This is the preferred alternative to broadening the research missions to embrace regulatory or care functions, or expanding the latter to include major research activity. Tomorrow's opportunities for improved health depend on research advances today, but such advances can only be impeded by a confusion of research and service. The ultimate goals of both are the same, but the short-term purposes, settings, skills, disciplines, and processes involved are not. More systematic ways of meeting regulation and health care needs could involve the resources of both the research agencies and the service and regulatory agencies, yet would not compromise the basic functions of either.

These highlights of the panels' conclusions indicate that a useful process has been started. Whether the promise will be realized depends upon our continued efforts within DHEW, as they are also guided by the further contributions of many outside the Department who have compelling interests in the biomedical, behavioral, and social science components of health research.

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Reference

1. National Conference on Health Research Principles: Conference Report. Washington, D.C., DHEW, DHS, NIH, January 1979.