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January 15-17, 1967 Washington, D.C.

U.S. DEPARTMENT
OF HEALTH,
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Public Health Service
National Institutes of Health
Division of
Regional Medical Programs

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#### Foreword

The "Proceedings: Conference on Regional Medical Programs" is a report of the matters to which the 650 participants who attended the meeting in Washington, D. C. on January 15-17, 1967 addressed themselves at this the first major conference on the new program authorized by the Congress of the United States 15 months before.

The presentations by the speakers. the discussions by the panelists, and the background papers prepared by staff and consultants are published in full. It was not possible, nor would it have served a useful purpose, to reproduce the discussions of the 25 groups which met for two hours or more on three separate occasions during the Conference. Nor did it seem appropriate to publish in full the more than fifty letters received by the Director of the Division of Regional Medical Programs from the participants who wrote to give him their considered views on the issues around which the Conference was structured. In making selections of materials for these latter sections we tried conscientiously to reflect the widely divergent viewpoints expressed. If we have failed in our effort to be impartial, the failure is a personal one rather than an effort to suppress views that might be regarded as less than helpful to "the establishment." Acknowledgement is due Dr. Jove Patterson, Publications Director at the University of Missouri Medical Center, and her colleague Mr. Normand Du Beau for their efforts in the initial organization and editing of this material.

We hope "The Proceedings" will be useful to the many persons who are now developing the more than fifty regional medical programs that have been initiated throughout the nation. We believe it will become a valuable document to those individuals who in vears to come may be interested in tracing the views of the persons most actively engaged in establishing a new and different mechanism for improving health care in our country. The volume will give a fair index of the views widely held during the year Regional Medical Programs were inaugurated.

Stanley W. Olson, M.D. Conference Chairman and Editor

#### Introduction

The Conference on Regional Medical Programs was sponsored by the Division of Regional Medical Programs of the National Institutes of Health, to provide a national forum in which this new concept in health could be discussed. Its dual purpose was to encourage ideas from a representative group of knowledgeable individuals that could be used in preparation of the required Report of the Surgeon General to the President and the Congress, and to provide an interchange of information on planning, activities, and goals for the Programs among all organizations, institutions and individuals concerned with the Programs, individually and collectively.

A sincere debt of gratitude is due all of those who attended the Conference. The record of the papers and discussions contained in these Conference Proceedings and the material contained in the Report of the Surgeon General to the President and the Congress, much of which was drawn from the Conference, form the historical base and the documentation for projection of Regional Medical Programs into the 1970's.

Medicine, or more appropriately health, in the next decade will become an increasingly critical national issue, economically, because the cost of health continues to rise more rapidly than other costs; sociologically, because of its relationship to other domestic issues including poverty, and urban affairs; and politically, because of the rising expectations of Americans, and the promise that these expectations may be more rapidly and nearly

realized in the future than they have been in the past. A major factor behind these movements is the accelerated advance of scientific knowledge in medicine and the need to relate this advance to the needs of people.

It is not possible to predict with any degree of accuracy the results of any one piece of legislation, like Public Law 89-239 which established the Regional Medical Programs for heart disease, cancer, stroke, and related diseases, or its eventual contribution to an area as complicated as health. Yet, it is the purpose of this report of the Proceedings of our Conference to record an attempt to evaluate and probe for dominant trends and pervasive forces that might be more clearly identified during the initial implementation of Regional Medical Programs. The accurate understanding of these trends and forces of society is an essential base for a Report to the President and Congress concerning extension of the law. As pointed out by Henry Sigerist, a medical historian, more than thirty years ago: "The characteristic features of the medical profession are determined to a very large extent by the attitude of society towards the human body, and by the valuation of health and disease. . . . There is one lesson that can be derived from history . . . that the physician's position in society is never determined by the physician himself, but by the society he is serving. . . ."

Already, in retrospect, some of the ideas, comments and conclusions of the Conference have proved unusually

accurate while the validity of many others are yet to be tested.

However, the Conference, like the Programs themselves brought together those of diverse background and interest to inquire how best to relate current resources to future potential and how to relate advances in heart disease, cancer, stroke, and related diseases to the needs of people on a regional basis.

There are a number of significant developments that have occurred during the six-month period since the Conference.

One important development has been the funding and initiation of the first four operational Programs. In addition, the number of Regions involved in planning activities has been increased to 48. These two facts indicate the increasing rate of forward movement of the Programs.

During this same period, the President submitted his Health Message and included the following definitive reference to Regional Medical Programs to support his request for a 1968 budget of \$85,314,000 for the Division activities:

"In 1968 we will: . . . Begin operating the new regional medical programs which will narrow the gap between the advanced methods used at university hospitals and day-to-day medical practice in the community." In this same connection, both the House and Senate Appropriations Committees have heard testimony to support this appropriation. In its report, the House Committee strongly supported the concept of the Programs,

and closed with the following two sentences:

". . . the committee is thoroughly convinced of the great importance of this innovative program to the health and welfare of every American. The concept of regional medical programs must be made to work, and no effort should be spared to insure that it does."

In accordance with a request by the Coordinators of the Regional Medical Programs at the Conference, a meeting of that group from both funded Regions and those still in developmental stages totaling some 53, was held in Bethesda on June 16 and 17. Additional meetings of this group are being planned for the coming year.

In late June of this year, based on the results of this Conference, the advice of the National Advisory Council. and an Ad Hoc Committee, Surgeon General William H. Stewart submitted his Report to the Secretary of Health, Education, and Welfare for transmission to the President and then to the Congress. As required by Section 908 of Public Law 89-239 it appraises the activities of the Regional Medical Programs and makes recommendations concerning the extension and modification of the law. This Report on Regional Medical Programs to the President and the Congress (Public Health Service Publication No. 1690) will be a basis for future legislative action.

Robert Q. Marston, M.D. Associate Director, National Institutes of Health, and Director Division of Regional Medical Programs

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# Section I-Papers Presented

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Representative leaders in the fields of medicine and health were invited to present papers reflecting their thinking on the subjects covered in the plenary sessions.

Charles L. Hudson, M.D.
President
American Medical Association

I am pleased to have this opportunity to add my voice and that of the American Medical Association to those who will participate in this meeting discussing Regional Medical Programs. I am sorry that previous commitments will not permit me to stay on with you in the succeeding days, but my interest will remain with you regardless of my absence.

As everyone here knows, scientific advances have tended to divide and stratify our profession, not only in what we do but in our principal interests. As we become more specialized and diversified, it should be recognized that we become more interdependent. To counteract this divisiveness we should set ourselves to the task of formulating plans to assemble dissimilar elements of health service into an integrated whole.

The problem posed in this endeavor is a mode of accomplishment of this task. How shall we do it? We in the medical profession tend to favor the retention of systems "that work" and do best within our resources, to proceed in an evolutionary fashion, perhaps more cautiously than suits the taste of everyone. While we are not "the last to lay the old aside", neither in clinical practice do we tend to be "the first by whom the new are tried."

Government, on the other hand, a financing rather than a service mechanism, with its great resources of money and influence, has the capacity, and I would say inclination, to effect rapid and major changes in patterns and procedures. Between the cautious

and the precipitant approaches there is often conflict, even though the objectives of both approaches be the same. We are present in this conference not to emphasize our differences but to determine as best we can how the resources of Government under the law can best be directed toward the health care system that is primarily serviced by the private sector.

The origins of Public Law 89-239 to my knowledge are to be found in the Report of the President's Commission on Heart Disease, Cancer and Stroke, from which document certain of its recommendations were selected for legislative implementation. As I understand it, it is extremely difficult to reproduce in the language of the law exactly what a narrative report contains. But it seems reasonable to assume that the sections selected for the Bill retain some relationship to that report from whence they originated. And thus the Senate Bill 596 was interpreted by the profession as recommending areas of service provision called "complexes" that described not only highly specialized medical and surgical treatments in a medical school center but also diagnostic and treatment stations in the periphery. We inferred that this, a closed entity of indeterminate size, excluding others already practicing in the area, was intended to demonstrate in a disparaging way perhaps the inadequacies of our physicians. A quantitative capability to replace these physicians or a visible means of improving their capacity to provide health care did not appear feasible under this plan. This we viewed not only as an unwelcome intrusion but also something extremely confusing to the public as well.

The raison d'être of such complexes, we learned, was the provision of services to people who were the target of the legislative thrust, based on the allegation that a barrier of ignorance of what was new impeded the flow of health care through current conventional channels.

Believing the premises upon whice these actions were based to be false and concerned that this was a revolutionary change in the system of health care not in the public interest, the AM did not support the legislation.

Then, later, several of us from the AM were on a mission to Washington 1 advise the Department of Health, Edication, and Welfare regarding the ne



P. L. 89-97. Hearing the passage of the legislation on heart disease, cancer, and stroke in the House of Representatives was imminent, we reported to President Johnson our belief that passing this, the Senate version, upon the heels of Medicare would be repugnant to the physicians of the country and would adversely affect their attitude toward any and all Federal support programs, especially Medicare.

As a consequence, a revised version of the Senate Bill was prepared with the assistance of the AMA. It passed the House, prevailed in Conference Committee, and became the law.

It is the AMA's interpretation of P. L. 89-239 and its regulations that services will be given incident only to the needs of education and research; that the program, rather than a geographic entity, is a sphere of influence, largely educational in intent and capable of exchanging information and personnel between the center and the peripheral institutions which are now called hospitals.

With this understanding—rather than with any definitive interpretation by the National Institutes of Health I must honestly add—I have recommended the program to the constituent and component parts of the AMA in counties and States, and they have responded not only as members of local advisory groups but also by leading in the application for approval of programs.

Our search for another mechanism in this country for postgraduate medical education and the adaptability of P. L. 89-239 as an excellent model for such a purpose have led me to give public support to the use of this legislation for educational purposes. I feel that the impact of P. L. 89-239, if used in this way, on the health care of the Nation will be infinitely greater than if implemented primarily in another fashion. The dissemination of the program's influence through the physician, especially those at the periphery, will be broader than if its substance is used up on services to a limited number of individuals.

To conclude on the note on which I began, I believe the assignment of roles in an integrated system will best be determined by a cooperative effort on the part of all segments of the profession rather than if it were made by legislative edict. It is true that differences in roles will be perpetuated by variations in breadth or depth of education and training, by the complexity of the skills required of us, and by the character of the occupations we elect to pursue.

The scarcest and probably the most essential element of the program is the educational and research center, where one might anticipate the most refined knowledge and techniques to be found. Inherent in this recognition is the hazard that judgments of high position in a vertical scale will disparage any other contributor to the whole scheme. Other contributions, while less refined perhaps, may be equally valuable. For that reason I hope communication within the program will be open, free, mutually respectful, and multidirectional.

We are meeting here today to focus on the future structure of Regional Medical Programs. We are seeking advice from those of you who will have to make the programs work. We are continuing to try to improve the formula for bringing all groups together to fuse the contribution of science, education, and service for the benefit of all of our people.

Many pressures and trends for change contributed to the health legislation of the 89th Congress, which was the most health-minded Congress in our history. More national health measures for providing the American people with the best possible health care were enacted in the 89th Congress than at any other time in the past century. The Regional Medical Program, Medicare, Medicaid, aid to medical schools, comprehensive health planning, grant support for training professional and allied health professionals, and increased support for medical research are just a few of the developments that aim for the delivery of comprehensive high-quality care. Today, as never before in history, you are being asked to help create the basic instruments to give people the kind of care they need, when and where they need it.

These programs represent a major new thrust—a new momentum in the field of health care. A whole continuum of the most economical and efficient forms of health care is being developed. Medicare, for example, has focused attention on ways to improve medical care, and the program itself carries major incentives to provide new and improved services. The program

has high-lighted the need for community planning of all its health and medical care facilities and manpower resources. Communities, many for the first time, have had to plan for an adequate number of facilities with a full range of needed services—extended care facilities, home health services, and outpatient clinics. Cooperative arrangements are being developed to assure that community resources are used to promote quality care with the most efficiency and economy.

We are entering a new era in health care—an evolutionary, almost revolutionary period. Our chief concern is the achievement of high-quality, comprehensive care for all Americans. We are keenly conscious of not only expanding medical services to many groups who have been without them in the past, but also with the provision of a higher quality of medical services for all of the population.

The achievement of our goal will not be easy because there are serious shortages in the health professions and in health facilities. The inherent nature of quality care rests with the health professions, their ideals, integrity, and vigilance. If they are going to meet the demands for high-quality care, improvements in the organization and the delivery of health and related services must be made. The Government can see to it that, in ever increasing numbers, professional competence is ever present in providing patient care. We are going to have to do a lot of rethinking about better ways of utilizing the personnel we have, how to train more personnel, how to rationalize our

services and how to create economy and efficiency in the organization and delivery of services.

Every community will have to reexamine how available personnel, institutions and equipment can serve to a better advantage. Business, labor, and civic leaders, under the leadership of the medical profession, can also help to introduce innovations and create new and improved methods of delivery of health care. Every member of the community has become involved in the organization and delivery of medical care in this country and shares the responsibility for its improvement. Effective community planning, active cooperation between the educational systems, health facilities and medical and other professional organizations are essential ingredients for implementing the new health programs.

While the new programs enacted by Congress in the past two years are national in scope, it is up to local groups to provide ideas and initiative in carrying them out and making them a success. These programs are an expression of "creative federalism." In discussing this concept recently before a Congressional Committee, Secretary Gardner pointed out:

"There is a great potential for innovation in the scope and variety of the Federal Government's partnership arrangements. Through these the Federal Government taps great sources of strength in American life. The private economy is the chief source of economic growth and vitality. The universities—State, local and private—harbor the bulk of the Nation's intellec-

tual resources. The professions provide the specialized talent without which no modern society can run. Non-profit or voluntary associations provide a significant means of harnessing non-governmental resources toward a public purpose."

The complexities of the problems we face in providing high-quality care require the best ideas and efforts of all the Nation's resources. Secretary Gardner noted:

"We have a multiplicity of institutions,

public and private (universities, hospitals, etc.) and we have no intention of submerging their identity in some rigorous master plan. The solution is to be found in new forms of cooperation among institutions."

No program better expresses this concept and approach than the grants for Regional Medical Programs. The very first words of the Act setting up the programs call for "cooperative arrangements" among the interested and affected organizations and agencies.

The main purpose of the program is to afford, through such cooperative arrangements, the medical profession and institutions of the Nation opportunities to make available to their patients the latest advances in the diagnosis and treatment of heart disease, cancer, stroke, and related diseases. And I would emphasize againas did the Congress in reporting on the Bill and the President in signing itthat our purpose will not be achieved until all medical practitioners and their patients realize the full benefits that modern science and technology make possible.

So now we reach the real test. After the new legislation authorizing grants for Regional Medical Programs was signed, it was up to you—the health leaders of the Nation, private, voluntary and public—to do something about it.

In April 1964 when President Johnson met for the first time with members of his Commission on Heart Disease, Cancer and Stroke he outlined their task in the following words:

"Unless we do better, two-thirds of all Americans now living will suffer or die from cancer, heart disease or stroke. I expect you to do something about it."

The President was talking directly that spring day to a small group in the White House Garden. But, indirectly he was setting a challenge for all persons concerned with the Nation's health. He was calling upon the practicing physicians who bear the heavy responsibility for diagnosis and treatment—the



health workers who assist and support the physician—the educators who train the present and future generations—the research scientists who are extending available knowledge and capability—the health officers who are concerned with preventing disease and disability—the volunteers and staffs of the private health agencies who are devoted to furthering the education of the public and the work of the professionals. To all of these, the President was also addressing his charge:

"I expect you to do something about it."

Tonight we can tell the President that a good deal has been done about it since April 1964. But while the job has been started well, there is still much to be done. Tomorrow and Tuesday, I hope you will tell us how the job can be done better.

Regional Medical Programs were designed to fit into the complete spectrum of needed health services and they represent the kind of innovative and experimental approach needed to achieve our goal. The authorizing legislation allowed three years for planning and pilot projects to gain experience. In order to provide an early opportunity for review and evaluation, the Surgeon General is required to report to the President and the Congress next summer on what has been accomplished and what changes are indicated.

You have been asked to come to Washington to help the Surgeon General prepare this report to the Congress. We need your reports on what has been happening in your localities in planning and developing Regional Medical

Programs. We need your advice on what more needs to be done so that we can help you step up the time between the discovery of medical miracles and their availability to the people whose lives may be saved by them.

Let us review the path we have traveled since April 1964.

The President's Commission, under the Chairmanship of Dr. Michael DeBakey, was convened on April 17, 1964 and made its report on December 9, 1964. The Commission contacted 60 private and professional agencies and organizations and consulted over 175 witnesses. The second National Conference on Cardiovascular Disease was rescheduled so that the Commission could have the advantage of its findings.

In looking back on the Commission's findings, we find eloquent testimony to the gains that scientific progress has made possible. But we also have documentation that the results of this progress is not being made available to the people who could benefit from it. The Commission Report pointed out:

"The rising tide of biomedical research has already doubled and redoubled our store of knowledge about heart disease, cancer and stroke. Yesterday's hopeless case has become today's miracle cure. We stand on the threshhold of still great breakthroughs in the laboratories and clinical centers of the Nation. Yet for every breakthrough there must be follow-through. Many of our scientific triumphs have been hollow victories for most of the people who could benefit from them."

The Commission asked: "How are we going to close the gap?"

The answer to this question was strikingly similar to the answer found by many others in related social fields in recent years.

Scientific progress has outpaced changes in human organization. As a society, we have more knowledge than we have know-how. As a result, the benefits of scientific progress are not accessible in equal portions to all the people of the Nation.

The Commission found that many agencies and institutions were working on overcoming these problems. However, these efforts were often being performed in isolation—and sometimes at cross-purposes.

The Commission found that its concern with the heavy price of fragmentation was shared by many others. Spokesmen of medical groups, medical schools and public health, among others, testified both about the penalties and problems of separated efforts and their willingness to explore new approaches and remedies.

On the basis of the extensive expert advice and its own staff studies, the Commission did something about it. It produced a 113-page report containing 35 major recommendations plus a reference document including over 600 pages of documentation and many subsidiary recommendations. The major recommendations covered a wide variety of proposals. Some were concerned with strictly categorical activities; others were aimed at the under-

lying problems of medical manpower and communications, which the Commission felt had to be met to effectively attack the so-called "killer" diseases.

Although the Commission's Report had many facets, there were two central themes. One was that people everywhere, not only those near great medical centers, should have the benefit of the latest medical scientific advances. The second was that this goal could only be accomplished by a fusion of science, education and service.

After the Report was issued, it was up to the Department of Health, Education, and Welfare to do something about it. And we did two principal things. First, the Department requested, and the President and the Congress approved, additional funds to begin to implement several specific recommendations of the Commission. Secondly, the Department, under the leadership of Dr. Edward Dempsey, Dr. Stewart, and Dr. Shannon, developed a legislative proposal to carry out that part of the Report which called for a joining of the worlds of scientific research, medical education and medical care. In formulating the legislation, the Department focused on the following recommendation:

"The Commission recommends that a broad flexible program of grant support be undertaken to stimulate the formation of medical complexes whereby university medical schools, hospitals and other health care and research agencies and institutions work in concert."

Perhaps the best way to recapture what the Department proposed is to quote from the President's message of January 7, 1965 on the legislative proposal:

"A plan to improve our attack upon these major causes of death and disability should become a part of the fabric of our regional and community health services. The services provided under this plan will help the practicing physician keep in touch with the latest medical knowledge by making available to him the latest techniques, specialized knowledge, and the most efficient methods. To meet these objectives, such complexes should be regional in scope: provide services for a variety of diseases: be affiliated with medical schools, teaching hospitals, and medical centers; provide diagnostic services in community hospitals; provide diagnosis and treatment of patients, together with research and teaching in a coordinated system. . . . Action on this new approach, will provide significant improvements in many fields of medicine."

The bill was introduced in Congress in January 1965 and enacted in October. During the intervening months, all interested groups had an opportunity to be heard and to participate once again in considering the best ways to meet the identified needs. Many viewpoints were heard. Testimony was received from representatives of the American Medical Association, American Osteopathic Association, American Public Health Association, American Dental Association, American Cancer Society, American

Hospital Association, American Academy of General Practice, as well as many individuals from medical schools, medical practice, hospitals and other concerned citizens.

As a result of the views expressed, numerous changes were made in the language of the bill which, I might add, taxed all the ingenuity I had gained from 30 years of legislative experience. As many of you know, the President joined personally in these efforts, in which Dr. Hudson participated, to find just the right words and concepts for bringing all the groups involved together in a common attack against these common enemies of man.

The Act that was signed in October 1965 was the result of these combined efforts.

The story of what you have done in a little over a year is exciting and auspicious. Under the able leadership of Dr. Robert Marston you have undertaken some of the most significant cooperative planning efforts in all our health history. Planning grants covering regions in which some 60 percent of the population of our country live have already been awarded. Applications for planning grants for the remaining regions are well along. Moreover, the proposals for the first pilot projects for operational activities have already been received and I trust grants for this purpose will be made within the coming months.

During 1966, innumerable groups of practitioners, educators, hospital administrators, health officers, voluntary

agency staffs and consumers met together all over the country to begin to plan Regional Programs. Many of these sessions, I am told, have not been entirely comfortable—for the participants have not been used to working together so closely in the past. But you have begun to work on something that is full of many problems and difficulties and you are working them out. That is progress and that is hopeful for the future of all medical care in our Nation.

Reports indicate that our faith in the ability of local groups to develop new approaches is proving to be wellfounded. We are also looking to the regional groups to find the best ways of fitting together the many related programs that touch upon these problems. The key problems of coordination must be solved at the local level. If the Federal Government tried to coordinate all its programs at the Washington level, it would end up imposing a pattern. More important, only State and local leadership has the knowledge of local needs and resources that will enable them to put all the programs together in a way that makes sense.

Regional Medical Programs have been described as having an obsession with quality. Nothing is more necessary—or fitting.

We are all aware of the tremendous investment that has been made in effort and resources over the last 20 years to advance the frontiers of medical knowledge. The advance of this movement has been one of our great accomplishments as a Nation. We intend to maintain and extend this in-

vestment in research. For we realized that only in this way can we achieve our objectives for the control of heart disease, cancer and stroke and other diseases.

Some have argued that there is an inconsistency, or even conflict, between high quality and widespread use. They believe that excellence is such a rare and tender flower that it can only bloom in special and carefully protected environments. They have suggested that we can lose everything by trying to mass produce what requires the most skilled craftsmanship.

This point of view, I believe, is contrary to our national history and commitment. I think we have the capabilities as a society to make the very best available to all our people. This is our national goal. It is this goal that inspires and integrates all the diverse programs for which the Department of Health, Education, and Welfare is responsible.

Regional Medical Programs have a unique and extraordinary contribution to make in this movement. Their essential purpose is to speed up the diffusion of knowledge—to bring together science and service for the benefit of all.

In the last year or so, the Public Health Service has reorganized itself so that under the leadership of Dr. Stewart it will be able to make its maximum contribution to this effort.

Regional Medical Programs are providing an opportunity and means for

#### With the Patient in Mind

Robert Q. Marston, M.D. Associate Director, National Institutes of Health Director, Division of Regional Medical Programs

health groups all over the Nation to take a somewhat similar look at their needs and potentialities. It is important but not enough for governmental agencies, either here in Washington or in State capitals, to examine how they can most effectively carry out their responsibilities. Nor is it enough for educational and research institutions to undertake similar examinations. Rather, as illustrated by the composition of this conference, all those concerned with these disease problems and better health must join in the process.

Happily this job has already been started in most parts of the country. We are doing something about it. But I trust you will not be satisfied—for we will not—until the best of health care is not only part of the continuing concern of health leaders and a preoccupation of some but is part of the daily life experience of all our citizens.

For the next two days you will be able to concentrate on these problems. We hope that you will give us your ideas and advice on how Regional Medical Programs can best be strengthened and facilitated. After you leave, we will welcome statements of your reactions and proposals as further experience is acquired in the planning and operations of Regional Medical Programs.

I can assure you that not only the Surgeon General but also President Johnson and Secretary Gardner, as well as members of the Congress, are looking forward as I am to your reports and recommendations. I am confident you will, once again, meet and exceed their expectations.

Regional Medical Programs have been launched at a critical time in American Medicine. The initial reception by the Nation has been far more enthusiastic than many supporters believed possible. Initial financing has been adequate. The program is now undergoing a process of analysis to determine whether the premises on which it was based are still valid; whether the initial implementation has been effective: and whether experience suggests that changes should be made for the years ahead. The fact that this audience is here to participate in these considerations and decisions emphasizes the fact that this program is indeed founded on local concern for the needs of those patients with heart disease, cancer. stroke, and related diseases.

Much of this paper and most of the meeting will be focused on the Report to the President and Congress required by the enabling law. Such a Report comes at a very early stage in the development of the program. Nonetheless, this Report will constitute the basic document on which the program for the period from 1969-1974 will be built.

In his Issue Paper on evaluation, Dr. Sanazaro has defined the several stages

Prepared in cooperation with Karl Yordy, Assistant Director, Division of Regional Medical Programs, and Stanley W. Olson, M.D., Chairman, Conference on Regional Medical Programs, and Coordinator, Tennessee Mid-South Regional Medical Program that characterize any new health program. He notes that in the first stage. available data is limited and decisions must be made almost entirely on the basis of the best judgments of responsible persons. This is where we have been during much of the past year. The focus has been on establishing mechanisms and approaches which promise better utilization of existing information and the collection of additional data which will form the basis for more confident decisions in the future. In considering proposals for extending the legislation, Congress faces the same difficulties that we have faced. Congress will value, as we shall, the best judgment of those who have acquired wide experience in the health fields and who have assumed responsibility for launching the individual Regional Medical Programs throughout the country. To reinforce the limited hard data that is available, the President and Congress will expect evidence of firmer commitments, clear purposes, and crisper definitions. These examples must be developed by you who are involved at the regional level on the basis of your actual experience and future plans. Since the very nature of Regional Medical Programs involves opportunities at the regional level to probe for workable solutions to complex problems, we in Washington cannot conjure the required realistic examples which indicate modifications are needed. Only your efforts and experiences can provide such evidence.

A major problem is related to the scope of the program. Gene Burdick's most pleasant book is one called the *Blue* of Capricorn. In a short story entitled "The Far Limits" he writes:

"The Pacific is enormous, plural, contradictory. One aches for limitations, for boundaries that reduce the sensation of awe. For each person the limits are different. For some people the Pacific is no larger than a tiny village, a strip of white sand, a reef. For a tiny group, that inquisitive body of oceanographers, the Pacific is illimitable. So great is their curiosity that their Pacific runs from the Bering Straits to the glittering ice cliffs of Antarctica."

The scope of Regional Medical Programs will certainly lie somewhere between Burdick's tiny village and the entire Pacific.

As the Nation begins an innovative and ambitious venture in improving the quality of health care for patients with heart disease, cancer, stroke, and related diseases, it is being watched intently by its neighbor nations. Lancet in a recent editorial refers to the Regional Medical Programs as "An American Catalyst." A description of the Connecticut program by Dr. Henry Clark at a Boerhaave Conference in Leiden, Holland, was of great interest to health leaders from Holland, Belgium, England, Sweden, and Turkey.

At one time I was chairman of the NIH Postdoctoral Foreign Fellowship Committee which brought young scientists from 40 countries for research fellowships in the United States. These young physicians and scientists uniformly praised our unique ability to bring together, for the purpose of the problem under study, the skills of those

from many disciplines. Our foreign colleagues who have observed this interdisciplinary achievement in research will be greatly interested to observe whether we can parallel this performance in the field of medical care. To bring this about, the primary focus must be not on the needs of medical schools, the needs of hospitals, the needs of health departments, or even the needs of physicians and other health workers. Rather, the primary focus must be on the needs of patients.

This Conference is framed against a series of difficult decisions facing American Medicine. We must decide how we shall provide health manpower for ever increasing needs and demands. We must decide how we shall provide particularly for these receiving the poorest care of all-the poor, the minorities, the isolated-both in the country and in the heart of cities. Severe economic pressures are being exerted on the entire field of health, particularly on America's hospitals. Urgency exists with respect to how we shall organize to best use the many new technologies that promise potential benefits if wisely and effectively used.

These problems and trends are powerful in their impact. They require that instruments of great durability and equally great sensitivity be structured so that medicine may be favorably influenced to provide the greatest service to those in need. We believe that Regional Medical Programs, with their emphasis on local initiative and local control, was created as such an instrument to help solve these problems and cope with these trends. To this end,



we are now in the process of testing the progress and capabilities of Regional Medical Programs.

STATUS REPORT. Secretary Cohen, last night, presented a splendid review of the historical development of the broad policy and philosophy that led to the establishment of Regional Medical Programs. The copy of a recent paper of mine forwarded to you in advance of this meeting summarized progress from October 1965 to October 1966. A few illustrated facts should suffice to up-date that data:

♦ The National Advisory Council has met six times. At four of these meetings applications for planning grants were reviewed.

♦ As a result of decisions reached at the April 1966 meeting, seven grants were awarded.

 $\diamondsuit$  At the June 1966 meeting, three additional applications were approved.

 $\diamond$  At the August 1966 meeting, eight more applications were approved and

♦ Most recently at the November 1966 meeting, the Council approved 16 applications, bringing the total of funded programs to 34.

♦ In addition, 14 planning applications which will bring the total population covered by planning activities to some 90 percent of the nation are expected to be presented to the February Council Meeting. The first four applications for operational phases will also be presented at that time.

There has been widespread involvement of individuals and groups in the development of all of these applica-

tions for Regional Medical Programs. Deans and faculty members of all of the Nation's existing medical schools and most of the schools under development have participated in this activity along with most of their teaching and affiliated hospitals. Representatives of State and local medical societies and health departments have been part of the discussions in almost every instance. In addition, area-wide hospital planning agencies and State and local hospital associations representing the Nation's community hospitals almost always have been represented. Members and staffs of cancer societies and heart associations have participated along with other public and private health agencies and representatives of the public such as elected officials, businessmen, labor leaders, and leaders of religious and ethnic groups.

A study of the backgrounds of the individuals who are assuming responsibilities as full-time coordinators and staff directors of Regional Medical Programs indicates that about half of these individuals come directly from the field of medical education. Another substantial number were formerly involved in key positions in hospital administration. The remaining came from leadership roles in voluntary health agencies, State government, and the private practice of medicine. The high caliber of person being sought and employed for these positions is impressive.

A study of the make-up of regional advisory groups indicates that on an overall basis . . .

- 21% are practicing physicians
- 18% are associated with medical schools and affiliated hospitals
- 13% are from Cancer Societies, Heart Associations, and other voluntary health agencies
- 12% are administrators of hospitals
- 8% are nurses and other health workers
- 8% are from public health departments
- 14% represent the public at large

HIGHLIGHTS OF ISSUE PAPERS. Let us now focus attention on the issues that are emerging. These have been described in a series of Issue Papers sent to you as background material for discussion at this Conference.

The first of these papers entitled, "The Development of Cooperative Arrangements," includes a fine statement by Dr. Charles Hudson, prepared four years ago, which expresses his views on the desirability of developing cooperative arrangements. We have been told that Regional Medical Programs have made considerable progress in developing genuine cooperative arrangements throughout the Nation. Groups in virtually every region have been probing to establish a workable basis for starting the planning process. However, the initial approaches concerning the size and shape of regions for planning purposes must be re-examined critically from time to time, especially when the region moves from planning into the establishment of an operational program. Let me be quite specific; questions have been

raised and will continue to be asked whether these arrangements developed for the purpose of starting to plan for a regional medical program will be the most effective arrangements for specific operational activities in heart disease, cancer, stroke, and related diseases.

Another issue suggested for discussion in the paper on cooperative arrangements is the nature of the local decision-making mechanism. The law requires that all operational grant requests must be approved by regional advisory groups. The question arises whether this approval shall be merely a pro forma endorsement based on confidence in the applicant organizations and institutions, or whether it shall represent a careful evaluation of regional priorities based upon sound knowledge of needs and capabilities. This issue is closely related to the problems of the review and approval process for operational grants to be discussed later.

In the second Issue Paper entitled, "Continuing Education and Regional Medical Programs," it is noted that continuing education has been accepted as an article of faith by the medical profession. Although it is regarded as an essential activity for the scientific and clinical renewal of the physician, the Issue Paper points out that this vital educational experience has often been characterized by lack of continuity. There are two key issues. First, how can programs be designed that effectively reach the physician and others in the health field; and secondly, how can self-monitoring aspects be incorporated into these programs to

determine which of them are favorably affecting the care patients have received, and to what degree.

I have often referred to the clinical pathological conference as a unique feature of medicine. It is here that even the most senior clinicians display their clinical judgment for all to see. It is a method for exposing error and thereby improving care. It and other established traditions such as the autopsy, the use of a case conference, and the wide use of consultants has firmly established medicine's commitment to constant scrutiny and critical evaluation of its judgment and techniques.

We are now entering a phase of medical care which requires that we do for populations of patients and populations of physicians what we have done so long and so effectively for the individual case and the individual practitioner. The techniques of epidemiology, medical care research, of community medicine must be adapted to personal health, as well as public health. To this end, we asked Dr. Paul Sanazaro to prepare the Issue Paper "Evaluation of Medical Care Under P.L. 89-239" and Dr. Vernon Wilson to discuss the problems in a subsequent talk. The issue is how rapidly the still-developing techniques for evaluation can be employed so that our effort to improve care will be logically rather than empirically determined.

THE REPORT OF THE SURGEON GENERAL TO THE PRESIDENT AND CONGRESS. The fourth and last Issue Paper is concerned with the primary focus

of this meeting and grows out of the fact that the Surgeon General of the Public Health Service is required by the law which established Regional Medical Programs to make a Report to the President and Congress on or before June 30, 1967. A subcommittee of the National Advisory Council on Regional Medical Programs and the Surgeon General concurred in our view that, in addition to the steps already taken toward the development of information for this Report, representative groups from the entire country should be convened. As a result, regional coordinators, representatives of regional advisory groups, and others identified as key people in the development of approved and pending grant proposals have been invited to this Conference. Major health organizations who have expressed an interest in this program were also invited to send representatives. Appropriate representatives of other government agencies including the National Institutes of Health, other bureaus of the Public Health Service, the Bureau of the Budget, and Congress were invited to attend. Also included are the 65 individuals who have served as consultants to the Division in helping define policy and philosophy. Specifically, these include members of the initial Review Committee, members of the ad hoc Committee for the Report to Congress, members of the National Advisory Council, and liaison representatives of other National Advisory Councils with related interests.

All of the members of the President's Commission on Heart Disease, Cancer,

and Stroke have also been invited. We are particularly interested in having them now refocus not only on the program as it exists today but on possible future modifications. Their background of competence and the experience they gained in producing the document which served to initiate the legislation establishing Regional Medical Programs will prove to be invaluable.

Public Law 89-239 specifies three things that the Report must accomplish:

It must appraise . . .

♦ The activities assisted by grants in the light of their effectiveness, and

It must deal with two issues . . .

- ♦ The relationships between Federal financing and financing from other sources of the activities undertaken on behalf of the Regional Programs.
- ♦ The extension and modification of the law.

We must give serious attention to the relationship of Federal and non-Federal financing. Congress will examine this issue carefully. For instance, activities once started are not easily curtailed. Yet the essential purpose of this program is to help bridge the gap between the advancing frontier of new scientific knowledge and the broad application to patient care. All funds cannot remain tied up in continuing program support of yesterday's advances. A significant amount must be available to encourage new programs at the cutting edge of science.

Although not required by the law, experience has indicated that the Re-

port must also speak to at least four other questions:

- ♦ In specific terms, the type of construction authority needed to achieve the goals of the program and the urgency of this need must be made clear to the President and the Congress. Any request for such authority must be substantiated by firm, objective evidence of need, particularly if favorable matching requirements are needed.
- ♦ Since the earliest days of the program, questions have been raised repeatedly concerning the need to clarify certain provisions of the law. We shall have an opportunity in the Report to identify these areas and provide interpretation.
- ♦ The law authorizes grants only for the planning and establishment of individual Regional Medical Programs. It has been suggested that the goals of the program might be achieved more readily by expanding this authority to allow grants for activities involving multiple regions that will support the work of individual Regional Medical Programs.
- ♦ A fourth major question has been how rigidly or freely one may interpret the emphasis on the disease categories of heart, cancer, and stroke. I invite your attention to two paragraphs from the Issue Paper concerned with the Report. "During the planning phase, the major activities undertaken by Regional Medical Programs have involved the establishment of a planning staff, the initiation of studies to obtain the basic data concerning pertinent health needs and resources, and the develop-

ment of cooperative relationships among major health resources in the region. These activities are generally generic by nature and consequently have not significantly involved problems of categorical definition. In most cases in order to plan effectively for heart disease, cancer, and stroke it has been found necessary to consider at times the entire spectrum of resources available for personal health services. However, the emergence of the operational phase of the program will put a more intensive focus on its categorical purposes. Only projects which can be shown to have direct significance for combating heart disease, cancer, stroke and related diseases can be assisted with Regional Medical Program grant funds," The implications of this issue requires careful consideration as you discuss the future of these programs.

It should be emphasized that this Report to the President and Congress will be the basic document on which recommendations for future legislation extending and modifying Public Law 89-239 will be based. In addition to your participation in the discussions at this meeting. I invite each of you personally to send me any written suggestions which you think will be helpful in the preparation of this important document. We anticipate the preparation of a draft of the Report shortly after this meeting. Thus, your comments can be most effective if they are forwarded to me promptly.

OPERATIONAL GRANTS. I come now to a very important section of this paper.

The planning phases of Regional Medical Programs are well on the way to covering the entire Nation. We are now in the process of reviewing the first applications for operational grants.

The initiation of operational activities is the most vital element of our mutual task ahead. It is the operational activities to be approved, funded and implemented under the current legislation that must constitute the central focus for recommendations for extension of the program. Based on experience to date which includes staff analysis, site visits, deliberations by the Review Committee and the National Advisory Council, and discussions with other Public Health Service programs, we have identified some of the important issues which must be considered in the review of applications for operational grants.

At the risk of generalizing from relatively few examples, I should like to review with you the characteristics of the operational proposals as we have seen them in the initial applications. Your actions in developing operational proposals, and the actions of our Review Committee and Advisory Council in approving these proposals, will express far more effectively the nature of Regional Medical Programs than general policy statements and will reveal most clearly the importance of these Programs to society.

The review of the first operational proposals has raised sharply the question of what methods should be used to evaluate such applications. Each is characterized by a number of specific activities within the overall proposal.

However, a Regional Medical Program must be more than a collection of projects. The review process, therefore, must focus on three general characteristics of the total proposal which separately and yet collectively determine its nature as a comprehensive and potentially effective Regional Medical Program.

♦ The first focus must be on those elements of the proposal which identify it as truly representing the concept of a Regional Medical Program, Our review groups have determined that it is not fruitful to consider specific aspects of the proposal unless this first essential determination concerning the core of the Program is positive. In making this determination the reviewers have asked such questions as: "Is there a unifying conceptual strategy which will be the basis for initial priorities of action, evaluation, and future decisionmaking?" "Is there an administrative and coordinating mechanism involving the health resources of the regions which can make effective decisions, relate those decisions to regional needs. and stimulate the essential cooperative effort among the major health interests?" "Will the key leadership of the overall Regional Medical Program provide the necessary guidance and coordination for the development of the program?" "What is the relationship of the planning already undertaken and the ongoing planning process to the initial operational proposal?"

♦ After having made a positive determination about this core activity, the next step widens the focus to include both the nature and the effectiveness

of the proposed cooperative arrangements. In evaluating the effectiveness of these arrangements attention is given to the degree of involvement and commitment of the major health resources, the role of the Regional Advisory Group, and the effectiveness of the proposed activities in strengthening cooperation. Only after the determination has been made that the proposal reflects a Regional Medical Program concept and that it will stimulate and strengthen cooperative efforts will a more detailed evaluation of the specific operational activities be made.

♦ If both of the two previous evaluations are favorable, the operational activities can then be reviewed, individually and collectively. Each activity will be judged for its own intrinsic merit, for its contribution to the cooperative arrangements, and for the degree to which it includes the core concept of the Regional Medical Programs. It should also fit as an integral part of the total operational activities, and contribute to the overall objectives of the Regional Medical Programs.

This is not a conventional review process. The total process for reviewing complex operational applications will often require up to six months or in some cases even more. The applications already in hand are providing us with a learning opportunity to develop the most appropriate review processes. Our experience indicates that the interplay of an initial site visit will be necessary to determine whether the essential criteria for a Regional Medical Program have been met. Neverthe-

less, the written proposal should include an exposition of the guiding philosophy and administrative processes which have gone into the development of the proposal and should explain how the specific activities proposed relate to these overall objectives. A justification of each separate project, however worthwhile, cannot provide a sufficient basis for making the essential determinations. Consideration of other characteristics of the initial operational proposals and their review also reveal the essential nature of a developing Regional Medical Program. They provide concrete examples of most of the issues to be discussed at this Conference. For instance, these proposals clearly lead from the strengths contained within the region. This is understandable and justifiable and may be the most effective way to implement the first phase of the regional medical program. Leading from strength may develop some activities which can serve as models for other regions or a resource which can be utilized by adjacent regions through effective interregional cooperation. Fortunately, there are examples in the initial applications which give evidence of interregional cooperation in capitalizing on the particular strengths within an adjacent region. I would like to add a cautionary note, however, that the full development of a regional medical program must show equal concern for strengthening the weaknesses of that region.

Our reviewers question repeatedly how weaker institutions, the minorities, the poor, will he helped by the proposal.

Not only are the reviewers concerned that the focus of the program is out towards the periphery, but that the applications themselves reflect this concern on the regional level.

Activities which have been chosen should seek to reinforce cooperation and mutual interaction between the academic community and the community practice of medicine. Such linkages will be among the most important contributions of the program. If the specific activities proposed in an application fail to strengthen cooperative arrangements or even interfere with such cooperation, the entire Regional Medical Program would be threatened. The maintenance and nurturing of the cooperation established in the planning phase of the program will surely pose a major challenge to all Regional Programs, especially those with more complex institutional relationships than are represented in the first applications. Thus, the review process must be concerned initially with the applicant's concept of a Regional Medical Program and his total proposal rather than with specific activities.

We also see evidence in these applications of the design of initial operational phases of the program that can serve through continued planning and evaluation as the basis for further evolution of Regional Medical Programs. We cannot emphasize too strongly the necessity of incorporating in the Regional Medical Programs the methods of evaluating and modifying the program so that it becomes to a considerable degree a self-monitoring system

which will supply those participants at all levels with the information and the motivation and the flexibility to direct future efforts towards those fulcrums of action that accomplish best the objectives of the program. For this reason it is important to avoid freezing the program towards permanent support of all initial activities undertaken. Some of the activities should be selflimiting with the transfer of effort to other priorities as the programs evolve. If these programs become just another source of funds to finance specific activities, we shall have lost the opportunity to develop a uniquely effective mechanism in bringing the advances of medical knowledge to bear on the health problems of the people of the regions. The development of the self-monitoring characteristic of the Regional Medical Programs is also a presumption of the review sequence described, for the future relationships between our review process and a regional medical program are to be based more on an evaluation of the effective results of the overall regional program and achieving its goals rather than on a detailed review of specific activities proposed.

As anticipated, categorical questions do arise. The initial proposals are directed toward the problems of heart disease, cancer, and stroke. Some broader activities do involve the more effective functioning of the total health-care system as essential requirements for improvements in the diagnosis and treatment of these diseases. The initial proposals show the unique opportunity provided by Re-

gional Medical Programs to consider both the specific and broader approaches for meeting identified health needs in the region. While the many types of activities proposed in the applications complicate the process of review, they show evidence of a serious effort to match resources with needs and to bridge the gaps among science, education, and service.

Regional Medical Programs represent a new relationship between the Federal review mechanism and the regional framework for decision-making. Neither grant support or formula grant support can be applied. We intend to work closely with you in developing the potential of this new relationship. Yet, there is a potential contradiction between the need to evaluate proposals at the national level and the intent that the Regional Medical Program represent a new framework for decision at the regional level. If specific approval actions in Washington were entirely on a project-by-project basis. this would tend to move the major decision-making responsibility for determining the nature of each Regional Medical Program to the national level. Under these circumstances regional decision-making would be confined largely to the choice of which activities to propose for national approval, and we will have failed to achieve a major objective of the Regional Medical Programs.

Our whole review process is concerned with strengthening responsible regional decision-making. In order to provide the Regional Medical Program with an explicit and concrete mechanism for playing a meaningful role in the continued development of the overall Regional Medical Program after the award of grant support, we are considering the possibility of including in the grant award for operational activities a proportion of the funds to be used for carrying out the purposes of the RMP at the discretion of the RMP with the approval of the Regional Advisory Group. This approach would lend substance to the intent that the Regional Medical Program be more than the sum of its parts.

SUMMARY. The purpose of this paper is the purpose of this Conference:

- ♦ To help set the stage for a fruitful discussion of the Report to the President and Congress; and
- by free exchange of information, to be able to implement the next stages of the program in the best ways possible.

I have focused first on certain issues, then on the Report to the President and Congress, and finally on the applications for operational grants and their review, as the basic tools for you to begin defining the Regional Medical Programs to serve patients in 1969-1974.

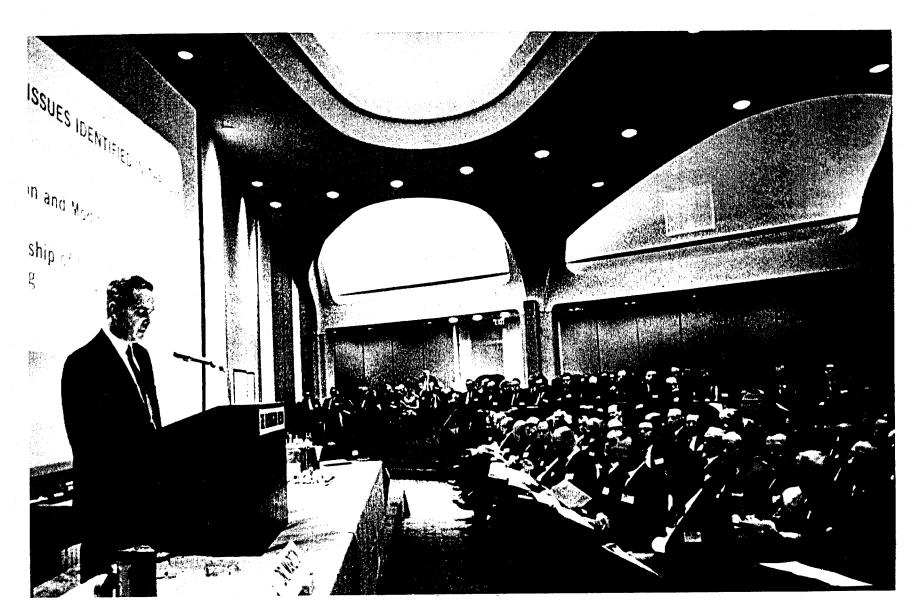
Talented and distinguished speakers and panelists will assist you. There are high hopes for this Conference and even higher expectations for Regional Medical Programs—so high indeed that we must face realistically the possibility that the many challenges may exceed our combined ability to meet all of

them as we would like. There has never been a greater opportunity to link science, education and service, but the difficulties are very great.

But "no ashes, no Phoenix" . . .

Mythology offers no tale more dramatic than that of Phoenix. With his flashing gold and scarlet plumage he descends to the altar of the sun and is consumed to ashes. With the rising of the sun he is reborn more glorious than before to signify for another 500 years eternal hope arising from disappointment.

Like the soaring Phoenix, Regional Medical Programs have arisen from previous hopes, expectations and disappointments. They offer new hopes and opportunities for new achievements in American medicine.



James A. Shannon, M.D.

Director, National Institutes of Health

There was an article in a recent issue of Science on "The Art of Talking about Science." The author—a distinguished British scientist—discussed the oral transmission of scientific information in a manner that is devastating to those, like myself, who have been called on to make general presentations. His penetrating comments on the foibles of lecturers are even more apt for those who would engage in a luncheon talk such as I am about to make.

In fact, I was embarrassed to read this article at the very time that I was preparing for today.

His first rule is that a 'talk'-as distinguished from a 'paper'-should never be read. He made the point that it is simpler to read than to listen and understand-implying, though not precisely saying, that to take the time of a captive audience to read a dissertation came perilously close to insulting their intelligence even though the thoughts expressed are suitably profound. He argued that to deliver a tightly argued thesis in well-rounded phrases conceived in the leisure of one's study does not give the audience time to think and is like asking a friend to go for a walk while you drive along beside him in a car.

His second point was that only a limited number of points should be made, and few of these should be supported in great detail. He suggested that the effectiveness of the discussion could best be judged by the extent to which the selected points presented could be recalled when talking to one's wife or

husband at breakfast the following day.

I suppose that the author has heard, as have you and I, many brilliant presentations of complex subjects in which a clever and intelligent speaker builds a complex structure in a manner that enables us

- $\diamond$  to follow the construction point by point,
- ♦ to understand the transition from one level of complexity to another, and
- ♦ to have the feeling, at its end, that we have participated in a satisfying intellectual tour de force,

only to find the next day that we really do not remember much about the presentation except the name of the lecturer, the title of his talk, and the brilliance of his performance. At best we may remember some of the major points made but not the logic of the setting in which they were contained nor the way in which the major threads of thought were woven into a significant and logical pattern. I suspect that, if we remember the pattern at all, it is because it may be inferred from the title.

The author recommends that a lecture be loosely constructed of few parts. It should

- start from a base of knowledge shared by the audience,
- ♦ build the basic structure of thought,
   ♦ provide for its elaboration within the time available, and
- ♦ most importantly, allow time to summarize the major thoughts or ideas one wishes the audience to retain.



author made many other pertinent its but one I remember very well. recalled the practice of the Royal itution, from whose directorship he just retired, of giving the speaker is 30 or 40 minutes of solitude in to his discussion—even to the ent of placing a guard at the door prevent any intrusion into the prity of the speaker's thoughts as he iposed himself for his presentation.

#### v I want to make three points.

The article is commended to you reading—it is serious but presentin a light, readable fashion;

the adoption of its principles would ke for less slumber during presentais such as this; and, finally,

my inability to match what he coners the minimal excellence of pernance can be rationalized, in part, my inability to have the 30 minutes so of solitude which he so strongly ommends.

hall, however, in a rather halting hion, attempt to abide by some of imperatives. Incidentally, he was opposed to the use of notes.

hall start from a common base of derstanding.

dical services at the community levhave a lesser degree of perfection in would be possible if all the availe information were at the disposal the physician treating the individual tient and if the physician were suprted by all the diagnostic and therautic resources that are needed to ply this body of old and recent inmation to the problems presented. A further point of general understanding is our common appreciation of the fact that in our advanced institutions, especially in our better university hospitals, there is little useful knowledge lying undisclosed in laboratory note-books or unread in journals and books in the library. Knowledge that can help to solve a patient's problems is, indeed, utilized in the day-to-day work of university-based physicians in such a medical center.

However, a comparable situation does not exist in many communities—though I do not say all—where the physician has been out of the mainstream of learning for a considerable period of time and where the diagnostic and therapeutic resources are less than optimal.

The next relevant fact is that through legislation-and particularly through Titles 18 and 19 of the Social Security Amendments of 1965—the Nation has asserted that each individual has a right to superior medical care and has begun to provide, through many Federal, State and private mechanisms, for payment systems by which this right may be secured. We are agreed, however, that such systems must not interfere with our general private base for the delivery of medical services. It is the national purpose to correct deficiencies in the delivery of medical services by using the present system as the core structure for social embellishment rather than by attempting to build a new system.

Finally-and still within our base of common understanding-vou are with us for a few days to examine the circumstances developing in relation to the Regional Medical Programs in order to determine how, within a broad segment of medicine, certain moves be made, in accordance with the intentions of the law, to facilitate the development of excellence in our handling of a series of so-called dread diseases -heart disease, cancer, stroke and related medical disabilities. You will be asked to comment, for the ultimate benefit of the President and the Congress, on the adequacies of the initial moves that are now being made or that are immediately in prospect. You will also be asked to anticipate some of the problems, assess the likelihood of success of current strategy, and on this basis, advise the Division of Regional Medical Programs on how they may best project their action into the immediate future.

More importantly, you will be asked to assess, on the basis of an informed professional judgment, the extent to which the Division should seek simple extension of present legislative authority or seek its modification in order to heighten the prospect of success for the program.

Now, you will not be asked at this time for specific recommendations but, in view of the complexity of the undertaking, to comment on the problems of applying the proposed strategy to your own regional situation whether this be rural or metropolitan and whether it be rich or poor in medical resources.

A sifting of your informed discussion will be a major input of information to the National Advisory Council which will advise and to the Division which must act.

You may well ask, at this point, "Of what concern is all this to the NIH?"
—an organization which, in recent years, has been largely concerned with the development of new knowledge rather than the delivery of services.

One can give either of two answers to such a question—either would appear to be correct and, indeed, each is in fact partially correct.

- ♦ The first answer would be that the creation of Regional Medical Programs permits a large social experiment to determine what is needed to facilitate the rapid use of available knowledge in the solution of serious disease problems in the setting in which these problems generally occur—that is, in a typical community. In this sense it is straightforward operational research.
- ♦ The second answer reflects the fact that in the best of our university medical centers we have a unique mix of professional talents. This consists of scientists engaged in fundamental research, physicians eagerly attempting to apply such fundamental information to the solution of disease problems, and physicians primarily concerned with the problems of medical care and the education of young physicians. This combination of skills and interests makes possible the delivery of medical services in a professional setting that approaches the ideal. It is in

such a setting that the best of medical services are delivered or can be delivered. The problem is to determine how such know-how and such excellence can be exported for use by the community at large. Or, to put it another way, how can the university-type hospital-and there are many of these that are not, in fact, part of or closely associated with a university or medical school-how can such an institution vield the isolation that protects and fosters scholarly activity and assume a larger social function without, at the same time, placing in jeopardy its present purposes.

As the one single institution most concerned with these present purposes—that is research and education—the NIH has been given the task of working with groups, such as you, in developing programs, suitable for regions of quite diverse character and medical resources, that will

- ♦ preserve the excellence of the present programs, and, indeed, foster and develop institutional excellence in science and education where it is now lacking,
- provide for the discharge of a largely new social responsibility in a manner that will strengthen, rather than weaken, the current institutional programs, and
- provide, under suitable auspices, for the linkage between these science based programs and the community apparatus within which medical services are delivered.

We believe that we can do the first of these three—given adequate funds.

We look to you to help us do the latter two.

Let me hasten to add that, in our view, the full elaboration of the new mechanisms we seek will not be achieved in a year or two.

We also expect that not all of your strivings will be successful. There will come a time in some—and, perhaps, many—of your programs when it will be more appropriate to take your losses and begin anew, profiting by your own experiences and those of others. If this were not the case, our problems and yours would be very simple. Unfortunately they are not.

The problem will be made both more difficult and more urgent by the rapid evolution of the medical scene. I believe that we are fast entering a period of really rapid pay-off from our large investment in the biomedical sciences. Advances have been substantial in the past two decades but they are only a harbinger of what is to come.

The biomedical science establishment, in its present magnitude and diversity, is something less than 5 years old. This is a fact that is frequently overlooked. However, scientists now capable of entering the field, at either the laboratory or clinical level, are better trained and generally more capable than was true heretofore. It is predictable that as the biomedical sciences move from the empiricism so characteristic of the past to the clarification and generalization of our understanding of biological phenomenon,

their impact on the day-to-day happenings in medicine will be profound.

This transition will result in an even higher rate of professional obsolescence for practicing physicians and will require a much more purposeful system of professional renewal in the future than in the past.

And this brings me to my final point. Each regional advisory group must concern itself as much with the maintenance of the professional capabilities of local physicians in a rapidly changing and increasingly complex situation as with arrangements for improving the support for and utilization of these capabilities.

Now, following my British mentor's advice, I shall remind you of the points I would have you remember.

- ♦ The delivery of services is less than optimal for many segments of our population.
- ♦ The financial barriers to good services are being rapidly removed as a consequence of State and national judgments that every individual has a right to excellence in the medical care he requires.
- ♦ In a privately-based system for the delivery of medical services, general excellence is now most frequently found in a situation where there is a mix of science, education and service.
- ♦ Although we must contend with many diverse geographic and social circumstances, NIH, in administering the Regional Medical Programs, will strive to preserve existing centers of excellence in science, education and service while, at the same time, work-

ing with State and local forces, evolve a system that will make available to the bulk of the population medical services that are excellent in quality and adequate in quantity—at least in a major segment of the diseases that plague us all.

NIH does not have the responsibility of achieving these desirable ends alone but in conjunction with a series of other programs with similar objectives. But I believe that the Regional Medical Programs, properly developed, is the keystone of a structure which will permit the delivery of the type of medical care services we all desire.

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ne dilemma of a dean from the day his appointment is to know when to beak out and when to remain silent. Deaking requires at least an acknowled topic and at best a brief, flavori and meaty content. In pursuing the mewhat evanescent title assigned r this topic—which evolved from Program," to "Program and Evaluan," to "Program Evaluation," I must onfess that the merit of silence omed ever more attractive.

nce detailed discussion of technical raluation procedures would not be oppopriate under our limits of time, tous compromise and discuss some ell known principles of program and, or the health field, some relatively nused principles of evaluation. We ill examine both in the light of oppornities presented by the Regional ledical Programs.

he challenge to Regional Medical Prorams, as I see it, is to demonstrate 1at this new endeavor, established rimarily in behalf of heart, stroke, ancer, and related diseases, is more nan a static assemblage of existing esources. This in itself is a basis for ery careful thought. Most of the priniples and programs which can be conidered in the field of health and ealth care have been studied by one r another of the existing Governnental, academic, professional or volntary groups. Thus, at the outset it eems apparent that the aim of the legional Medical Programs must be ne of synthesis, an effort to combine hese various factors into a whole thich will be greater than the sum of he parts.



We have already heard that the appearance of the Regional Medical Programs through Federal legislation was a direct result of growing public and professional unrest centered around the slow rate at which new knowledge was being put to use. This concern is not unique to the health field but it is new as a major emphasis among the concerns of the health care professions. The agricultural and engineering experiment stations, long an integral part of the land-grant colleges, represent one attempt to deal with this problem. The Engineers already have a term for it. They label this activity the "transfer of technology."

It would appear then that the special mission of Regional Medical Programs is primarily one of research in the "distribution of health care" with the focus placed firmly upon the patient's needs, rather than upon those of the institution or the health professions.

Until the early part of this century the healing arts possessed a dismally small amount of scientific information: consequently, the need was primarily for basic medical knowledge. With the momentum now established in basic research we can give increased emphasis to indirect factors, such as population size, number of related organizations and groups, increased capabilities in communication facilities, and an ever accelerating rate of obsolescence of knowledge. The magnitude of recent Congressional appropriations indicates the need for immediate action. Additional and similar legislation is under serious consideration. The comprehensive health planning act provides a logical outlet for knowledge developed under Regional Medical Programs. Thus, research being done in the more limited field of Regional Medical Programs can be of value throughout the total health care field.

Because of the large amount of time and money to be expended, realistic evaluation of the results is mandatory. Unfortunately, we are hampered by a lack of effective measurement tools. We must start by using available and simple techniques, while admitting their inadequacies. It is essential that collaborative research in system design for the distribution of health care be initiated in concert with those academic disciplines which have a long tradition in simulation, systems research, and communications research. thus providing a base for continuing analysis and measurement.

Existing resources for use in the design of such systems are impressive indeed. If one looks at the great array of governmental health agencies, academic institutions, voluntary and professional groups, as well as supportive organizations like welfare agencies, community action groups and others, it readily becomes apparent that the major problem is not that of creating resources which could appropriately handle the problem but rather a coordination of those resources into an effective unit. Although to some the comparison may be a bit unpalatable. I submit that this is a market and distribution process and should be handled as such. An approach of this kind does not deny the essential nature of

professional and academic contributions: it will require a formal and scientific search for an appropriate relationship between all academicians and professionals whose skills can be helpful. Concurrently, the integrity of the academic and research community must be preserved, both as an internal system and as a part of society at large. Thus, the analogy of marketing is in all probability much more than an analogy. It may prove to be an actual pattern which will provide us with illustrations and some basic principles for fruitful pursuit of the tasks ahead.

The Distribution Process. As a layman in this special field, may I offer the oversimplified explanation that the production and distribution process amounts to a coordination of many disciplines, assembled for the contribution which each can make to a single goal. While such grouping of resources, particularly in the research process, suggests the antithesis of the traditional academic departmental organization, the concept is not unfamiliar to academic institutions. It is exemplified frequently in institutes on university campuses, in land-grant experiment stations, and research centers. These patterns allow many disciplines to proceed in a systematic fashion in searching for new information and combining that information into an orderly whole.

Taking the marketing analogy one step further, the rational distribution process would be simulated and developed as follows: The first step is the establishment of need, either recognized or unrecognized. The next step, after the need is determined, is to define it and to create recognition of that specific need in both the consumer and producer. Here we have a direct parallel with the opportunities open to Regional Medical Programs.

Having identified a specific need or needs, it is necessary to undertake basic and applied research in materials, resources and their synthesis. The medical profession has expended proportionately small amounts of its own energies in the endeavor of synthesis and at the same time has frequently poorly utilized the contributions which could be made by other disciplines.

Having completed the "basic" research and formulated working models, the next step is the production and delivery of materials and services which may come from a variety of places. In the analogy the patient may move to the resources, or the resources may be brought to the patient, but finally the delivery process requires that the end product of health care be synthesized in a coordinated and personalized manner for the benefit of the consumer.

Market Identification. If we consider health care in the light of the patient's need, recognized or unrecognized, the first painful but necessary step will be a shift in emphasis. Much basic research has been sponsored upon the assumption that improvement of the professions and institutions will automatically benefit patients. However, it may be that the goals of the patient

and those of the profession are not always the same. To accomplish our task we must now direct extensive study toward the patient and his needs within the context of his normal pattern of living.

Professional action has classically been one of response, after the patient requests and is given access to the formal health care system. We must now accept responsibility for health care of the public as a dynamic, intimate part of daily performance.

Identification of needs for concentrated research endeavors will require the development of end points or goals against which the effect of change in qualitative performance can be measured. Unfortunately, at present, such end points are few and largely unproven.

Most of the measurement systems currently used in the health professions are quantitative rather than qualitative in nature. We can measure quite adequately deaths, morbidity, numbers of personnel, and similar items, but we have few means by which we can test the impact of health care upon the daily performance of a given individual. Thus, our first requirement is for a measurement system which can assess the ability of the individual to perform as a useful member of society and his own attitude toward that performance. Also required will be a measurement of the social or peer group's estimate of the value of the individual's contribution to the group and their attitude toward that contribution. No single one of these factors can be used as the

sole parameter, but when assembled as a pattern they should provide at least the first steps in a qualitative measurement of health care.

Since diagnosis is also a part of market definition and since diagnosis often opens communications between professional individuals, early detection of disease would appear to be a logical first research effort for improvement in the distribution of health care. Such research avoids the necessity of premature decisions having to do with delivery of health care and would allow a "tooling up" of the communications system under reduced emotional tension. Much diagnostic support can be provided to individual practitioners with a minimal change in their present practice patterns.

Status of the patient needs study. Interaction between individuals is heavily influenced by the status, stated and felt, of each person. We are proposing major changes in the status of the patient in the health care system. This calls for a "shorthand" method interwoven into the system itself to assess status, and change in status, particularly of the patient.

An interesting correlation exists between the way we use the time of others and our estimate of their importance. Consequently, accurate determination of our expenditure of the patient's time through the design of health services is accessible, measureable, and potentially valuable.

Another little used field of knowledge is that developed in advertising research. A significant portion of estab-

lished knowledge about health is not utilized even by those best acquainted with it. Advertising research has a rich body of basic knowledge and techniques dealing with facilitators, or why people choose one service or product as opposed to another. These tools and techniques used so successfully in advertising could be adapted and should be useful in broadening public education and personal responsibility in health care.

Turning to the third item in our analogy, namely research in materials and resources, we should comment first on basic research which has a long university tradition and is the foundation upon which applied research is conducted. Basic research in almost all academic disciplines will make important contributions to health care. High on the list should be research in synthesis of systems, including model building. In our past, testing through models has had little systematic and comprehensive attention. It could produce large savings in time, as well as funds, but will require the talents of a variety of existing disciplines—the engineers, for example, who until recently were seldom formally invited into the health research conversation.

An interesting facet of the dilemma related to manpower shows in the fact that although we are faced with a tremendous shortage of health personnel and a low level of national unemployment, we as a health care group have largely ignored one of our greatest potentials—the patient himself. He is usually the most involved, often the better educated, and certainly the

most highly motivated party in the interchange, yet we have assigned him the most passive role. Patients, I submit, may not be so helpless as some of our practices would seem to imply. Our friends in sociology should be able to help us here.

In the fourth and final phase of our analogy, we will face a variety of problems in the delivery of health care. These include implementation of research and development in distribution. All patients should have access to the best source of care regardless of geography, financial resources, or special interests of particular professional groups. New patterns are required.

The relationship between centers of excellence and the population which they would serve will need to be defined, Most organizations which support health care use politically determined boundaries, i.e., the city, county, or State. The probability of gaining coordinated support from all interested organizations for the assistance of a single and specific individual will be enhanced by a maximum overlap in geographical areas of designed responsibility. This is particularly important in evaluation procedures, which depend upon many groups for their information.

A second problem to be considered deals with control. Should such distribution systems be totally under the control of the health professions? If not, how much of the process should be conducted in cooperation with other interested groups? When should control be turned to them?

A third problem concerns the obsolescent mind, both as it relates to the medical profession itself and to the public at large. It is clear that planned, continuing education for the profession and the public is necessary. A searching look at potential integration of such education with the care process seems called for. Feedback mechanisms must be established for a progressive analysis of cause and effect, or, at least, correlation between continuing education and change.

A successful distribution system will itself require an integrated information service. Information should be derived from the home, from the avenue of access to the health care system, the local hospital, and the large medical center. It will require the development of common identification systems and vocabularies. Many of us hope that in the very near future the social security number will be issued at the time of birth, or entry into the country, and will provide such identification. The proposed information system should be designed to utilize, assist and refine present systems, not compete with them.

The decision for diagnosis and treatment of the patient will take into account his desires which, among other things, relate to the distance from health care and the patient's knowledge of and confidence in the recommended resource. Other considerations are the adequacy of the health care resources, the cost to the patient and the involved agencies, and the maximum benefit from the care process

which includes such by-products as education, research, and economic impact upon the community at large.

Finally, as we have already heard, no matter how one may describe a Medical Region, it must interact with other regions. Mechanisms must be developed which will minimize the mechanical problems of interregional relationships and permit us to focus upon the patient.

The Example. With no claims to assured success, the Missouri Regional Program has attempted to face these challenges in the planning process. Projects will arise from community groups and be funneled through a refinement process. This should encourage maximum motivation and participation at the grassroots level.

A general objective of the program is the development of models of early detection integrated with continuing education.

Primary emphasis will be placed on those endeavors which can be quantitatively evaluated, and the initial assumption is made that adequate information and communication will provide qualitative improvement. The long range plan provides for qualitative measurement of delivered health care.

Only a few projects are proposed for studies of delivery of care. It is our intent simply to be supportive to existing care patterns while setting up the necessary information-gathering mechanisms. Under this plan, a request for information by the physician will be

met by a specific answer to the question, along with additional synoptic background information or bibliographies which should be helpful in his continuing education. Such inquiries will also serve as a guide to the physician's needs. In this manner diagnostic and delivery patterns of health care can quickly be modified in detail when research indicates the desirability of doing so.

The data handling facility developed at the University of Missouri for the purpose of extending the competency of the physician will be integrated with cooperative data handling programs established by hospitals, physician's offices, and state agencies. This integrated system is expected to furnish feedback and monitoring which will make it possible to provide the desired information while studying and coordinating the total process in an objective and efficient manner.

A University multidiscipline research unit is developing new tools with which to measure achievement. Its staff members have joint appointments with other schools on campus, including Nursing, Education, Engineering, Journalism, Business and Public Administration, Liberal Arts, and Veterinary Medicine. Presently members of this unit are studying two different communities in which they will measure efforts toward community health goals, such as rehabilitation of the patient, family reactions and the like.

In conclusion, let us review, quite briefly, some goals worthy of consideration. These goals were picked be-

cause progress toward them can be measured. Their evaluation should give us some insight into whether or not we are moving in the direction that may be most effective in meeting the actual needs of patients.

♦ The primary goal is to deliver the highest percentage of quality patient care as close to the patient's home as possible. This is not only economical in the total picture but in keeping with the desires of most patients. Certainly the latter assumption merits study.

♦ Every patient should have equal access to any needed national resource. For very special services which are not available in the area, patients can be sent to centers of excellence elsewhere, thus eliminating the necessity for needless duplication of expensive equipment, staff and facilities.

♦ Maximum coordination will be sought between the inputs of those who provide health care directly, as well as those involved in supporting that care, such as welfare, community resources, environmental control groups, and others.

♦ The development of programs to assist in early and effective detection of disease will be an important goal. The information gained can be used to effect changes in delivery of health care, both through personnel and systems. Early detection is perhaps least threatening to the present health care professions and is among the easiest procedures to measure quantitatively. It also possesses the highest potential for successful qualitative measurements of health care.

♦ Postgraduate education should be

integrated with detection and health care systems.

♦ Lay health education will be a vital part of the regional program. Existing adult education and extension programs and activities of voluntary organizations will be utilized so that the potential recipient of care may be informed as to the role which his physician, the hospital, and the various supporting agencies will play and to the things which he, the patient, can expect. We need more scientifically designed studies of public attitudes toward health care.

♦ Finally, in my view, a crucial goal will be for each of the several regions to take a unique approach to the special needs for their particular areas. Through meetings such as this one, we can share ideas so that a minimum of waste will ensue as we seek to meet our respective responsibilities.

New paths are seldom explored by faint hearts. We need to be mindful in the development of new systems that one may at times work with less than perfect parts in order to set the system itself in operation. It is possible, even desirable, to have "proof runs", a practice long utilized by the printing industry. From less than perfect initial operations, changes and corrections can be made to improve the final product.

As participants in this national program, I believe we dare not do less than marshal the best available talents, from whatever quarters, to join in this quest for improved health care. The opportunities are attractive and challenging, to say the least.

# The Idea, the Intent and the Implementation

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The privilege of speaking at the First Conference on Regional Medical Programs is one for which I am deeply grateful. It is hard to believe that in a little more than a year since the historic signing by President Johnson of Public Law 89-239 on October 6. 1965, with less than a year of administrative operation, it has been possible to bring together representatives of the health professions from all over the country for a report on progress and a discussion of future plans, plans for 90% of the people of this country. This evidence of truly phenomenal progress must be heartwarming indeed to the President and the members of the Congress who have shown such deep interest in this program, and productive of new hope and courage to families throughout the land with loved ones suffering from the dread diseases with which we are here concerned. I see here today ample evidence for the statement made repeatedly during the past few months by veterans in the health professions that this program has done more to bring the many segments of the health activities of the Nation together than any other event in the history of the Nation.

What is the magic which has been responsible for the achievement of a creative concert among the many separate health interests that in the past have never worked together in this fashion? What is it that has bridged the gulf between town and gown and lured the medical school faculty from its ivory tower into community activities in a manner never before wit-

nessed, that has won the enthusiastic interest and cooperation of medical societies, sharpened the focus of many diverse agencies concerned with human problems of disease, and inspired medical schools and hospitals alike to look beyond their own institutional concerns to broad community needs? Many reasons might be mentioned and must play a role, but the one of overriding importance above all others I am certain is the motivation behind all activities of the health professions: the desire to give to all our people the very best in medical care, It is clear that the response of the Country to the remarkable opportunity opened by Public Law 89-239 stems from our devotion to those who are ill, and this transcends personal considerations or pre-occupation with the interests of one discipline or one institution. This, then, is the greatest attraction to all of us-the opportunity to develop a program which has as its goal the delivery of the best of medical services and diagnosis and treatment to every man, woman and child in the Country, without the intolerable delay between discovery and application caused or explained by the lack of the needed medical strength, mechanisms and facilities which will be provided in these Regional Medical Programs. The idea behind these programs is based on the simple desire to save lives-of those people who could be saved today with the knowledge available today, if they could have it; to save even more lives if we speed up and intensify clinical investigation to match the great strides in pre-clinical research; to eval-

uate much more quickly, safely and effectively, new methods of diagnosis and treatment; to achieve actual prevention of the complications and progress of these dread diseases; and to communicate with the aid of methods already available and perfected by



technology between and among regional programs for the rapid dissemination of knowledge to assist doctors everywhere in the care of their patients.

The development of the policy under which power and responsibility for whatever happens is placed at the regional level has answered the fear that the Federal Government and specifically the National Institutes of Health might dictate to any applicant or group what to do and how to do it. The only requirement that I can find that the Federal Government has imposed is that there must be assurances that there is understanding and commitment to the purposes of the program with true regional concert involving representation of the various health agencies and the public in any given region. As a close observer of this program and the way it has been administered. I have satisfied myself that this point of view on the part of the Government is genuine, and in line with the great traditions of the research and training programs of the National Institutes of Health. It was for this reason that a wise Surgeon General put the program under the administration of the N.I.H., under the leadership of Dr. James A. Shannon, who, with his Deputy, Dr. Stuart Sessoms, and a splendid staff, has presided over the greatest and strongest growth of medical research and training programs in history. You are all thoroughly familiar with the insistence on quality by the N.I.H. and the great tradition that major reliance for final decision must be placed on the expert

review by non-Federal groups or our peers, our own peers, to assure that quality is maintained and scientific and professional freedom is protected.

The caliber and dedication of the primary Review Group under Dr. George James and of the members of the National Advisory Council on Regional Medical Programs have been responsible for sound and important decisions so far. I have had the opportunity to attend a number of the meetings of this new Council, as a representative of the National Advisory Cancer Council, and can assure you that the stipulation of the Public Law concerning membership on the Council has resulted in the appointment of men and women in whose vision, fairness and wisdom you can have complete confidence. It is a great pleasure for me to add that in continuation of the highest standards of excellence which the N.I.H. has always maintained in its administration, the Division of Regional Medical Programs staff, headed by Dr. Robert Marston, is one of the most able, enthusiastic and helpful groups I have encountered in or out of Government.

The appropriation needs of the program will require solid justification and the strongest support from all of us, so that its full potential may be realized. I have a sad personal detail to share with you. Just a few days ago, actually two weeks ago last Thursday, before the tragic sudden death of Congressman John E. Fogarty, I had the privilege of a long discussion with him on one of his periodic visits. We dis-

cussed the many programs of the N.I.H., and he spoke of his deep interest in the several categorical institutes and in the Institute of General Medical Sciences in which he had great pride. He then turned to a consideration of the rapid progress in the Regional Medical Program activity and remarked that this was the goal for which everything else in the N.I.H. was dedicated. for, as he put it, "this is the payoff," It is here that the newly generated knowledge from medical research must be applied as rapidly as possible for the good of patients everywhere. I can still hear his words of deep concern about the availability of sufficient money properly to support the Regional Medical Programs in this time of budgetary pressures. I am confident that among the large number of devoted and informed members of the Congress there will be found a leader worthy of taking his place, for the Congress has shown its dedication to health and medical research and its understanding of the importance of the N.I.H. programs by their appropriation record these past 20 years. These years witnessed the construction of a remarkable foundation for the programs with which we are concerned in this Conference. Unless there is adequate volume and continuity of support, the great promise of this Program cannot be fulfilled and the high hopes which have been raised throughout the Nation will end in bitter disappointment.

The principle of diversification of support is built into the Law and the administrative regulations and has been under discussion as one of the issues at this Conference. The need for the provision by the Federal Government of enough support to insure a critical mass of medical strength, however, is a prerequisite to fulfillment of the Program. We should remind ourselves and the Government, too, that all experience in the support of biomedical research and in the support of construction of research and hospital facilities has shown that substantial Federal support attracts substantial support from other sources.

These words so far have been spoken in gratitude and recognition of the great progress that has been made in such a short period of time. There are some tough issues, however, that must be faced now and in the immediate future in connection with these program activities. I would like to discuss a few of the sensitive problems that must be solved, particularly in connection with the Report that must be made to the President and to the Congress on June 30. 1967.

The first question which was raised particularly before the Congress passed this Law was whether this program could make effective progress without interfering with the practice of medicine in a given area. It is my hope and expectation that there will be interference, of a very special kind, with the practice of medicine by these programs—interference that will bring good both to the practioner and to the patient. May I cite my own personal experience in this connection which gave me con-

fidence that these Regional Medical Programs would be a great success throughout the country. Just 20 years ago, January 1st, I organized a Children's Cancer Research Foundation, a private institution affiliated with a medical school and surrounding existing hospitals. This Institution was concerned with both fundamental and applied research and with the care and study of children with acute leukemia and all other forms of cancer found in children. From the very beginning we established a relationship with the doctors of the region of our country with these words: "We are here to assist you in the care of your patient." What we did was to accept any patient sent to us by any doctor, make all the diagnostic studies and then carry out all the expensive laboratory studies and specialized therapy. As soon as possible we put the patient back under the care of his own doctor, because the best place for any patient is at home as soon as that is possible. The doctor is backed by a partnership with a research institution, one kind of a regional center, which carries out all the expensive diagnostic and follow-up studies and provides the specialized treatment not available to the doctor in his own community.

I am happy to report to you that in these 20 years of close cooperation with doctors throughout New England, I have not heard a single complaint from any doctor that we had interfered with his relationship to the patient, or the family, or taken anything from him that properly belonged to him. What we have done for the doctor, however,

is to place behind him the knowledge and skills of experts who are not in the private practice of medicine, and to provide for him forms of therapy for his patient for whom he had nothing else to offer. The doctor makes his contribution to the generation of new knowledge by his reports to us which parallel our reports to him. By this method we enable the doctor to face both himself and the family secure in the knowledge that he was obtaining for his patient the results of research carried out anywhere, and diagnostic and therapeutic assistance of a caliber not otherwise available to him.

It is true that one cannot easily apply what has worked in one part of the country to another area, and this is good, but I am confident that the variations best suited for a given region can be worked out along the lines of the formula I have suggested. Above all, I plead for flexibility in this program from region to region in this Country, flexibility within any one region, as experience dictates what is best for the progress of this program.

I have spent the major portion of my life in the field of cancer research and care and must state that the time has long since passed, if it ever existed, when any one doctor, no matter what his specialty, can give proper care to any one patient with cancer. From the moment of suspicion or discovery of the tumor, the patient should have the benefit of discussion and consultation of a whole group of people, which will include the surgeon who must operate, if operation is the choice; the radiotherapist; the internist with special

knowledge of cancer and cancer chemotherapy: the pathologist; the hematologist, and any other specialist required in a given case. Such a patient's family, too, should be given the benefit of study by epidemiologists and trained fact finders who seek to learn more about the background or causation of cancer in a particular case. Rehabilitation, long-term care facilities, as well as home care programs, are all required if patients are to receive the best care possible. Specialized activities, therefore, require a framework of cooperative arrangements involving a wide variety of individuals, institutions, and agencies if they are to be effective. In view of the problems stated in the Issue Paper in this regard, I would like to review the manner in which the President's Commission on Heart Disease, Cancer, and Stroke dealt with this question.

Early in its deliberations the Commission faced up to the issue that was inherent in the categorical nature of its charter. On the basis of thorough discussions of the full Commission and the advice of expert consultants. the policy decision was made that it could not react adequately to the three categories of health that were its charge without becoming involved in the broader gamut of health problems. The Commission in its Report stated, "But heart disease, cancer and stroke cannot realistically be considered apart from the broad problems of American science and medicine."

It consequently gave consideration to some of the underlying problems, al-

though broader than the categorical areas with which we were concerned. Thus attention was given to the support of medical and continuing education, and of medical libraries, better methods of constant communication between and among centers and between centers and doctors, and the need for some mechanisms for achieving cooperative relationships among the major health resources that were considered essential to progress against the problems of heart, stroke and cancer. Mention should be made, too, of the broad scope of the recommendations in the DeBakey Report which were not included in this legislation at this time, but which can be supported in part today through other programs of the N.I.H. These include the creation of Centers of Excellence in the sciences basic to medicine and in the several disciplines in the clinical fields. It is my hope that these recommendations will not be neglected and that adequate support will be found too for the educational and research activities which are essential for the successful operation of these medical programs.

The question has been asked by many: "Is the present program weaker or better than that advocated in the De-Bakey Report?" The answer is clear. When all the planning carried out by the hundreds of experts in the many regions of the country is complete and all the new needs discovered or uncovered by such studies are supported, the program will, indeed must, be better than the original recommendations or Dr. DeBakey and the Commission will be sorely disappointed.

I believe that the categorical thrust is important to this program, particularly at the outset. Specialized activities must be related to the more generalized functions to be effective. I think this is why Congress made so clear in enacting the law that the program was to have a broad involvement of all of the health activities in the region. Clearly, the program should not serve to bring about further fragmentation in the health field. Its very nature is that of an instrument of synthesis among diverse elements, agencies and individuals. A representative of a medical society is quoted as having said "If this cooperation among all of these health resources in our state is good for heart disease, cancer and stroke, shouldn't it be good in helping to meet other health needs?" I think the answer is obvious. It should be of such benefit. I am sure we all agree that if the cooperative pattern of the regional medical programs for heart disease, cancer and stroke has byproduct values of importance to the total health problem of the region involved, we have reason for satisfaction, not dismay.

These programs are developing just as the medical schools are taking measure of the needs of the communities around them. These programs, I believe, are responsible for accelerating this trend. There are still those who oppose involvement in a meaningful way of the medical schools in these programs on the ground that a medical school is only an educational institution. I believe that a medical school is an educational institution—and

And finally, to fulfill its mission and make its full contribution to society, the medical school must make the greatest possible contribution to meeting the medical needs of the community in which it has been nurtured. This can be no token contribution, tossed from the ivory tower. If the medical schools do not meet this challenge, they will lose the greatest opportunity in the history of medical education—now so happily offered through these regional medical programs.

Cognizance should be taken of the fact that medical schools traditionally are discipline-oriented and have given little support to categorical developments of real strength. A critical mass of research and clinical strength is required to develop, accumulate and apply truly expert knowledge in a given field as. for example, in modern cardiology or in the field of cancer. The time has come for the medical schools to embrace the development of categorical strength and no longer to reject such developments as a cardiovascular institute or a cancer institute as foreign bodies ill-suited to the traditional tables of organization of a medical school. The challenge is here to work out in each region how categorical strength and greatness can be achieved within a university or medical school framework. Those who solve this will find rich rewards. I have worked out such a plan, which will preserve and increase greatness of the discipline structure of the medical schools and permit the development of maximal interdisciplinary cooperation with those whose deepest concern and dedication is to one category of the dread diseases. Other plans—and better ones—can be and will be fashioned.

There is another question deserving of frank discussion-one of greatest importance to the future of the health of our people. I refer to the charge made by some before this Bill was passed that the Regional Center plan would lead to socialized medicine, I shall not attempt to define this commonly employed and badly abused term, but will assume that what is meant is Federal control of the practice of medicine, or, in short "Government Medicine". As Dr. DeBakey has pointed out repeatedly and, with him, all the members of the President's Commission, this piece of legislation and the programs that will be created by virtue of it provide the best means of preventing "Government Medicine". We all realize the vast increase in demand for good medical care since the end of World War II alone. This is shown by several thousand community hospitals built with the aid of the Hill-Burton Act, fathered in the Senate by that great champion of medical research and health, Senator Lister Hill. The demands for health services which have increased so rapidly in the last year alone, for reasons

with which we are all familiar, cannot be met by the available manpower and facilities utilized and distributed in the manner presently employed. And now at this Conference we proclaim the right of every man, woman and child in the categories under discussion to the most expert in diagnosis and treatment available in the medical world today. These needs of our people, for the best in medicine-let us not call them demands-must be met either by voluntary methods with Government support through programs of the kind we are discussing here, best suited to each particular region of the country. or some system of Federal health services will be invoked. May I express a personal reaction to the frequently expressed fear of what is called the "threat of Government Medicine"? We are talking not about some alien land, but about our Government, in this democracy. I do not share such fear, nor will I as long as there is a forum where I have the right to speak, as long as there are men and women to harken to my words.

All of us have heard, I am sure, the background sounds of predictions that the way of voluntary cooperation is sure to fail, and that it will be necessary for the public sector to take over and bring order to the health field. This I do not believe. I am confident that the Regional Medical Programs have already demonstrated the potential to fulfill the promise and meet the challenge that was so clearly stated in the introduction to the DeBakey Report to the President's Commission, from which I now quote:

"We need to match potential with achievement, to fuse the worlds of science and practice. We need to develop and support a creative partnership among all health resources. This way, which is the way of a democratic republic—is the true path to conquest of heart disease, cancer and stroke".

We must never lose sight of the goals of all who work in the health fieldseradication or prevention of disease and, through the application of new knowledge from research, conversion of the incurable to curable. And while these goals are being achieved, let us furnish assistance through the Regional Programs, to every doctor in the care of his patient, and to those who have no private doctor too, thus making available for every patient in the country care of the kind all of us would like to have for all patients. This may be defined as the application of all knowledge of medicine, surgery and laboratory science for the prolongation of life, the relief of pain, and hopefully the cure of patients suffering from what the Congress calls the dread diseases. The only guideline of enduring value in the construction of these Regional Programs must be defined in terms of what is best for the patient. In the final analysis this is what the Regional Medical Programs are all about. The idea which gave birth to this program is clear. The intent of the programs should permit no misunderstanding. The implementation, within the guidelines of the law and the regulations, remains, as it should be, in the hands of those who plan in each of the many regions of the country.

## Section II-Panel Sessions

# Program Evaluation

The Report of the Surgeon General to the President and the Congress

Two panel sessions on the second and third days of the Conference provided representatives of the medical and health fields an opportunity to express their views on two of the major issues of the Conference.

### **Program Evaluation**

CHAIRMAN:
George James, M.D.
Dean
Mt. Sinai School of Medicine

#### PANEL:

Edward Kowalewski, M.D. Chairman, Board of Directors American Academy of General Practice Harvey L. Smith, Ph.D. Professor of Sociology and Director, Social Research Section University of North Carolina C. H. William Ruhe, M.D. Assistant Secretary Council on Medical Education American Medical Association Vernon E. Wilson, M.D. Dean School of Medicine University of Missouri and Program Coordinator Missouri Regional Medical Program

DR. JAMES: I shall introduce the members of the Panel and then ask each to speak in turn without further introduction.

Beginning on my right is Dr. Edward Kowalewski. He has been active in the Academy of General Practice with particular interest in continuing education but also in the delivery of medical care.

Next to him is Dr. Harvey Smith who is one of the friendly sociologists to whom Dr. Wilson referred. He is on the faculty of the University of North Carolina but he has also played a leading role in the North Carolina Regional Medical Program.

On my far left is Dr. Carl William Ruhe who is on the staff of the American Medical Association with particular interest in continuing education programs.

Dr. Kowalewski and Dr. Ruhe are members of the Review Committee that has been working diligently to review the many proposals which have been submitted for either planning or operational grants.

We shall begin with Dr. Kowalewski.

DR. KOWALEWSKI: We have two concerns. First, as members of the Review Committee we have been given responsibility to evaluate the program applications that come before us. Second, as physicians we try to interpret and bring into focus the practicing physician's responsibility in the area of evaluation. We attempt to integrate the latter concern with the continuing educational process in which we have great interest.

It is evident that to measure properly there must be a starting point. This program is in its infancy, but it is where we must begin our thinking in terms of evaluation of the programs our committee has reviewed. While many persons are vitally concerned and already have knowledge pertaining to evaluation, others submitting applications do not have this background of evaluation so it will have to be introduced.

In addition, we have the problem that regions differ; i.e., each particular area has its own scope. We can't apply one rule to all. The practicing physician is interested particularly in how one measures and evaluates the programs that serve the ambulatory patient.

There are some questions that have to be asked of Dr. Wilson, and we shall come to those as we go along, but the problem of evaluation, as shown by the applications that have come in, is certainly not solved. In many of them, an attempt has been made to answer the problem by the use of mechanical help. This perhaps will offer some answers but certainly not all. In the academic area there is a difference in degree of refinement and evaluation.

At this time, I will conclude by saying that I don't believe we can provide one rule that will apply to all projects because each project has a different origin and a different end point.

DR. SMITH: Dr. James, Dr. Wilson, fellow panelists, ladies and gentlemen: I shall try to keep my remarks within categorical limits but I suspect before I am finished I will be talking about evaluation in related diseases.

The Division of Regional Medical Programs, in asking us to evaluate a thing as complex as a regional program, has asked us to do the almost impossible. Yet I think the existence of the regional programs provides us with the necessity for trying to do this and provides us also with the opportunities and perhaps the beginnings of technical resources to try to do this almost impossible task.

I would like today, in responding to material presented to us both here and in other packets, to talk briefly on the perils and pitfalls of evaluation as I see them.

What I see is the future of evaluation in terms of the opportunities and challenges of the regional program and something of the necessary first steps. Lest any of you thinks I am here as the Olympian sociologist and listing somebody else's system, please be as sured I am deeply involved in these problems myself so it is my own limitations that I am speaking of here.

We are at the moment, I think, ven imperfectly equipped to undertake the major tasks involved. Let me start witi the one about which I know least. We have heard suggestions offered to us as to the kinds of things we need to evaluate, our involvements, for exam ple, in cost accounting. I myself knov (and have heard often from medica administrators and deans of medica schools) enough of the problems o cost accounting in the field of healtl care to know there are relatively fev things we can pick up and easily apply in this new and complex situation There is a great deal we shall need to learn and experiment with.

Other suggestions have involved focus on the patient, i.e., patient improvement or patient cure. Certainly this is hard enough to demonstrate in the difficult relationship of physician ampatient. It is hard enough to demonstrate improvement in many patient and even more difficult to demonstrate a relationship between that improvement and the ministrations of the physician. This is correspondingly muc more difficult to do in a large system.



George James, M.D. (Chairman)





Edward Kowalewski, M.D. Harvey L. Smith, Ph.D.





C. H. William Ruhe, M.D. Vernon E. Wilson, M.D.

I am reminded of what was enunciated by Robert Redfield, the anthropologist, who said the further away you were from the universe you were studying the more generalizations you could make. I think we tend to fall into this. The larger universe looks easier to generalize but all of us agree we need a tremendous amount of caution. Similarly, quality of medical care has been advocated as a focus of emphasis. This literature is filled with controversy. We have some things with which we can steer our way through but unless we keep it awfully simple we shall really be in peril.

The results of education are another factor we have been asked to evaluate. Well, this is something that has defeated educators over a long period of time—I include ourselves in this. What are the impacts we want to measure with our educational programs?—the number of people who come in?—the kinds of professions they represent?

This is one method of evaluation.

Then we have to evaluate whether the content of our programs is in line with our goals. This is another problem, then, to determine whether we have communicated it, whether it has been internalized, whether it changes behavior on the part of the practitioners and whether this has any impact on your clients when they return to home bases, or whether it has impact on their own institutions.

Some of these things we can monitor. I suspect as an inverse relationship here the things of lesser importance

are easier to monitor. The others become more complex.

We have heard a good deal of talk about systems analysis. My comments on this will of necessity be superficial because I am not deeply knowledgeable about systems analysis but I think some of them, in my experience, have perhaps been analogies rather than analyses. I think it interesting, for example, to point out some analogies between the line-up of customers in a cafeteria and the waiting rooms of our out-patient services, but I doubt that analogy at this level will help any of us to become either better customers or more successful patients.

It is extremely important that a much better bridge be erected between the work of many of the systems analysts and those who, like yourselves, are deeply knowledgeable about the health care systems. They, too, find it much easier to generalize about the health care systems the less they know about them! I think they require the corrective action of much deeper information.

We shall have to evaluate problems of coordination. This, in almost every aspect of complex human behavior, has been extremely baffling to us. There are some research projects underway now to see whether some criteria, and mechanisms at the program level among agencies, can be analyzed, isolated and communicated. Here again, we may have some leads for evaluation but it's only a beginning and the materials are somewhat fee-

ble. We are handicapped at all turns by the inadequacies of record keeping (or should ! say the irrelevancies of record keeping to the present task at hand?). The basic materials we require in epidemiology of illness and prevalence rates—i.e., getting effective base lines from existing records—are all but impossible to obtain.

Now, one of the things that the regional program is doing which initially may complicate the task of evaluation but would ultimately become its greatest contribution is that it is changing the functions of individual professions. For example, sociologists are emerging into the real world in connection with the regional program. (I don't say this may be its greatest achievement but it may be its most difficult in time.) They also are mixing and mingling with epidemiologists and biostatisticians in meaningful working relationships and this is really a kind of minor revolution. It may not solve all the health care problems but it may well develop some important resources.

Medicine and public health are now working far more closely together, (without stepping on each other's toes), in a very significant, rewarding fashion. What this means, I think, is that problems are being looked at in new ways by people viewing them afresh or learning to view them through the eyes of their colleagues. From this kind of mix will come elaborations of our frame of reference that will permit us to develop evaluative criteria and evaluative methods that we don't have now.

Similarly, hospital administrators and public health medical care personne are now living in each others pockets and elbowing at each other for a more effective role in the new program.

Medical schools are beginning to teach community medicine and beginning to search for practitioners and teachers who have this kind of orientation. They too are now standing side by side with public health people for the first time. The medical schools, in a very significant way, are beginning to relate medical teaching to the tasks and means of health care systems, rather than to some internal criteria intrinsic to the profession itself.

There are new emerging divisions of professional relationships and professional responsibilities. Medicine is not just content (as indeed it never was, but the order of magnitude has changed) to deal with the acute phases of illness but is now increasingly assuming responsibility for other stages of patient care. New emphasis is emerging on rehabilitation which will be better coordinated with other aspects of medical care and indeed medical rehabilitation itself is undergoing planning which will require synthesizing and evaluation in connection with the programs being discussed

Again, we have the problem of prevention as we plan to evaluate what we have done. This enormous opportunity and primary challenge addresses itself to all of us.

I think perhaps the time is also past when mavericks like myself can be

ressed into service to do planning and evaluation. I think we now need to agin to train planners and research valuators. The mix of professions and interests that I have indicated prodes us with an opportunity to pool ur resources in many directions to agin training for this field.

'e need also new record keeping sysms—health monitoring systems—
hat will endure over time and insure
hat we shall not have need to scramle again in the future, as we do now,
hind what our base lines are. We will
huild these base lines into the sysms.

ly comments have struck a somewhat egative note, emphasizing our probms. I don't think they are insurnountable. They will have to be surnounted and within the context of this
rogram. In the meantime there is
nuch that can be done.

re need to monitor the systems. We eed to study our aims and instituons, their caseloads, their needs. We eed to monitor our occupations and rofessions, their programs, their eeds, their functions and the key retionships in implementing those. We eed to do analyses of whatever illess and prevalence data we can muser and it is important to find where ur peaks of illness are, in which cateories of people, which kind of illesses, which areas.

ery important program guidelines will merge from this effort that can serve s precursors of a more extensive proram development. We have all had to take the first leap into program development without an effective data base. This base will have to be established and its impact brought to bear on the program. I think it will also permit gross monitoring of broad program impacts if we establish base lines in this way.

There is a clear and present need to begin to work closely with individual projects to develop, where feasible, evaluation designs so that we aren't constantly required to salvage even these at a later stage when we might have been more constructively involved earlier.

In short, the way of evaluation is a very difficult road. I think it is a feasible road, although some of what we attempt may turn out to be impossible. Now it may be necessary to plan for a future system that will enable us to do it. It certainly is absolutely necessary. Thank you very much.

DR. RUHE: Mr. Chairman, the panel has been kind to its members, if not to the audience, to give each member of the panel an opportunity to say similar things from a different set of biases and backgrounds.

I don't know that I have anything new to contribute but I guess I will say some of the same things in a little different way. I would like to plant at least a couple of thoughts in the minds of the audience and perhaps in the minds of the other panel members.

First of all, there is the thought that in a program such as this, as complex and as large as it is, there are many levels at which evaluation can and should take place and that when we use the term evaluation we may be referring to any one of these levels or to all of them.

Consider, for example, the responsibility of the Division of Regional Medical Programs to show what has happened. It has the responsibility as a Division to report to the President and to Congress and to the people, to show what has been done with the money, what has been done under this new program which has been started.

This can be done in a variety of ways and no doubt will be. Some of these have in them activity—a measure of success. Because this is a new program it is possible, for example, to show that activity exists where none existed before or at least measures of activity. It is possible to show that "X" number of projects are now in existence. It is possible to show that "X" number of the population is "covered" by the projects. All of these things will no doubt be done. People in the Division are conscious of evaluation of this kind-that is, just enumeration of what is going on-and also of an attempt to compare this with what the potential might be for the program so that even though one might be able to show gain, he is not necessarily showing the proportion of gain which could have or should have taken place in a given period of time compared with the ultimate possible gain.

The ways in which the gain is measured, of course, are multitudinous. When we get down to the details of

individual projects again, the way in which one looks at each individual project from the national level is in terms of the total overall gain. Now, I suspect that the people ultimately are a little concerned with these kinds of things. The expectation of the public as to what would come out of the Regional Medical Programs is pretty clear.

I think the legislation has been established on the basis that many people are not getting the ultimate or the best care in the areas of heart disease, cancer, and stroke, and that under the impetus of the program and through the provision of money to carry out the program, this care would be provided in a way which is better than it has been provided before.

As long as people continue to die from heart disease, cancer, and stroke, the ultimate goal, the ideal, has not been achieved. Obviously we will stop far short of that potential but the question is: How far can the program take us down that road?

In the final analysis, I think this is really the thing which the public is interested in. Evaluation can take place not only at this level from the total national concept but from the regional level or within an individual institution, and here again it is dependent upon what the objectives are and the bias of the person who is looking at the program.

I have talked with some people who represent individual institutions—generally educational institutions. I sensed their feeling that if the program ena-

I think this is a reasonable expectation. It is another method of measuring. Some of these kinds of measures are relevant and simple. Others are complicated.

While sitting listening to other speakers I was thinking about years ago when I was young and spent all my summers on a farm. We were about two miles away from the nearest village and we used to trek across the hills every Sunday morning-we called it Sabbath morning-to attend Sabbath School Church-and in this little village church there was a signboard on the wall to record attendance. It had the number up for the attendance last week and blank for the attendance this week. Because of the Scotch background of the church, immediately underneath these figures they had their collection for last week and a place for collection this week. Before the service was over for the morning they always put in the figures for the attendance this week and the collection this week.

Now this way the congregation got an immediate feedback on its own efforts and the minister got an immediate feedback on the success of his efforts at exhorting the congregation.

It was kind of interesting the attitude this would produce in you as you walked back home. If you had more people there this week than last week and a greater collection this than last week, even if you had nothing to do directly with the collection, it sort of made you feel good inside. You got a good feeling that things were going forward and progressing and everything was better than it had been the week before.

I think that this is a kind of measure we could make readily. We could take some comfort, for example, if there were approximately 175,000 physician registrations reported in all formal continuing education courses during the year '66 - '67 as compared to only 150,000 reported in the year '65 - '66. I don't know exactly what that means and I am not sure that it means there was better health care but it is a reassuring statistic and it is one of the kinds of measure which can be made relatively easily.

We can measure head count, dollar amount, number of regions and number of projects. We can measure the population cared for. We could count things like this.

I don't mean to deprecate these or to minimize them. I think it is valuable to do them. But I guess what I am trying to get around to is to urge that some-

thing more than this be done, that we do get into the more sophisticated attempts at evaluation, recognizing that there are pitfalls. As one reads through Paul Sanazaro's paper and listens to Vernon Wilson talk and to the other members of the panel, he must stand a little bit in awe at the complexity of the job; and of the attempt to establish a base line of health care, recognizing that the base line changes all the time you are working. that it would change any way; and of trying to say whether what you are doing in one project out of 25 in one region, and what is being done in one institution in that region, or in one region compared with the national effort, that any one of these things makes a difference.

This is the kind of thing which occasionally overwhelms us and I would urge simply that we make an effort. It is most important to have the attitude of self-monitoring, to make an attempt to look at these things critically, to set up measures which are reasonable and in the long run will lead to what we are trying to do.

The planning phase of all of this program is extremely important to the region. The planning projects, I think, are very wise for that reason. Most of you are in the planning project stage at this time. This is a time when you can most effectively set up the means by which critical evaluation may take place later on.

The longer you wait to do it, the more indistinct becomes the base line from which you start, the more difficult it

becomes really to ascribe the change to what has been carried on in the program.

DR. JAMES: Thank you, Dr. Ruhe.

I think it is fair to say that every program is evaluated. Many of them are evaluated by what I would like to call the "ice cream soda" test. The patients like it, the doctors like it, the administrators like it, everybody likes it.

What we are after of course is something deeper. The Academy of Medicine in New York which is composed of the more prestigious practitioners in the community and which is about 120 years old has had a public health committee for many years. The major ticket to admission to the public health committee has been that you know very little about and certainly have had absolutely no formal training in public health. Yet the amazing record these men have compiled for asking searching questions, of bringing out exceedingly intelligent and provocative reports on public health problems and programs is truly phenomenal.

Similarly about 20 years ago public health people began to evaluate the practice of medicine and during the last 10 years the sociologists have been evaluating both. To the best of my knowledge no one has yet started to evaluate the sociologist.

It is true that in order to carry out a program of this nature there must be evaluation. The men that appeared before you today have given you a few clues.

f you came here searching for cookbook answers, obviously no one has them for you. We have a few minutes remaining and I thought perhaps some of you, if you speak up loudly, would like to direct a question to one or all of the members of the panel along any of the lines that your minds have been proceeding during this period. Would any of you like to comment?—Oh, yes, Go ahead.

QUESTIONER: I will stick my neck out. We have about 9,000 fellows coming into the medical profession every year. We probably have 120,000 doctors practicing now that don't understand anything about what we are talking about.

Is anybody besides Dr. Smith from down in Carolina trying to do anything to orient these people to the problems they are going to run into so that when they do get into practice (where they will have a hell of a time trying to make a living) they won't act in the same stupid way many of us have done for the past 20 years. (Laughter)

DR. JAMES: I think you perhaps posed something which is a problem. I won't refer to your adjectives, but at any rate there is a need for continuing education all the way beyond medical school in relation to all of these different programs. The way that many of these regional programs are being planned is to reach out into the communities and to continue the instruction of physicians in ways they would like to be instructed and in ways in which they need it. Would any member

of the panel like to make additional comments?

DR. KOWALEWSKI: Mr. Chairman, I propose that one practical means of evaluation will have to be based around this statement: What is helping me as the provider of medical care, the physician, and what is helping my patient?

I would hope that the individuals who are able in this area would attempt to build in a system around these two factors. What is helping me provide the service? What is helping my patient? It must be built in because we must spend the majority of our time in treating patients. If we will have to spend the majority of our time in evaluating, then we are indeed not fulfilling our purpose. So this practical area of evaluation somehow must be built in to answer these two questions.

DR. WILSON: Everybody who tries to impart his own approaches finds it amazing how little he really was able to transmit. I would submit that if we can get all of these groups to work together to gather any kind of information, no matter how simple, related to progress, this in itself will have been a major move forward and there are some very simple things which can be used for such an information gathering system.

One of these is the action that patients take in response to prescribed therapy. Our social service people embarrassed a number of our physicians recently when they did a review of what patients really did with the prescriptions which had been given to

them by the physicians in the ivory towers.

The time required for diagnosis is very easily measured. The amount of activity or participation of the patient isn't hard to determine, and I would argue about the utilization of patient time as a measure of quality of care, because if any of you has done a study in out-patient clinics, a close one, in a large clinic, and have looked at the people who leave without receiving the attention which they came to get, you will find there is a larger number of these people than you think. Not only that, but if you have someone in your school of journalism or some other department do a study of patients and their reactions to this process, you will find there are a number of people who do not seek care when they should because of bad utilization of their time.

These are simple things. These are not hard to measure, and I suspect that if we would measure a few like this together as a whole region we would have made a significant move forward. I hope that when those of us, now at the ivory tower, set up measurement systems we don't forget the individual, as Dr. Kowalewski has just said, who has a lot of other things to do besides work with measurement systems. If we make this simple enough so we can all get started together on it, perhaps the system itself will give us ways to do this easily for everyone.

DR. JAMES: Thank you very much. One final word and then we shall proceed to our group discussions.

All of you, I believe, have been on one side or another of the National Institutes of Health grants award process; either you have applied for grants, have been on study sections and site teams, or have been on the staff that has been involved. All of you, therefore, know that evaluation is something which is mentioned in practically every grant. All of you have written evaluation criteria diligently. I won't embarrass any of you by asking how many times you have carried them out.

This process of review is perhaps a little bit different because there will be visits, probably by site teams, to grantees as this program continues through the years. It therefore becomes evident that if a section is written on evaluation in a grant request it is apt to come back to haunt one later on.

It therefore means that evaluation is a subject which will receive and perhaps should receive an enormous amount of attention and if our group here today have been somewhat lacking in answers at least you can see that this is in the process of developing and everyone looks to you people in the field who are working with grant projects, working with Regional Medical Programs, to begin coming up with the answers which will then be rapidly shared with everyone who is working in this area.

Thank you.

# The Report of the Surgeon General to the President and the Congress

#### CHAIRMAN:

Storm Whaley Vice President for Health Affairs University of Arkansas

#### PANEL:

Green Clinic

Ruston, Louisiana

Michael E. DeBakev, M.D. Professor and Chairman Department of Surgery College of Medicine Baylor University James T. Howell, M.D. **Executive Director** Henry Ford Hospital Paul N. Ylvisaker, Ph.D. Commissioner, New Jersey Department of Community Affairs Formerly, Director of Public Affairs Program, Ford Foundation Ray E. Trussell, M.D. Director Columbia University School of Public Health and Administrative Medicine Bruce W. Everist, M.D.

Mr. Whaley introduced each of the panelists and then asked Dr. DeBakey to begin the discussion.

Dr. DeBAKEY: I had hoped to take advantage of this opportunity to say some things to this group with respect to the purposes and implementation of the program. But Dr. Farber who has preceded me has said it so eloquently I feel now it would be anticlimactic for me to say anything further in this regard.

As one who participated in the development of this program and since then has witnessed its birth and now lusty growth, it is most gratifying to see the tremendous interest and concern at this conference in relation to this program's activities. And I must echo one of the thoughts anyway that was expressed so well by Dr. Farber. And that is that such interests, such exchange of information and really thoughtful consideration by so many people, can't help but make the program better.

We are at that stage in the program when, as required by Congress, we must give it scrutiny and appraisal and suggest, if there is need to suggest, modifications in the legislation.

I must say that when legislation was originally drawn, there were certain things that we fought for but which were, through the wisdom of Congress, omitted from the original law. And now time has passed allowing us to give, perhaps, more prudent thought to these items. I do not now feel there has been any great loss, but at one time I thought there might have been. In light of the development of the program, we really lost little or no ground in this regard. In fact, perhaps the program will be strengthened by the fact that we will have had greater time to think about how best to do these

The one factor that still gives me concern, and I think there is reason for this on the basis of our experience, is that if the program is going to move forward as rapidly in the future as it

has in the past, there will be need to authorize in some fashion the support of construction. This is the one area that I think deserves our most serious consideration at this time, because, if this is an essential ingredient to the undergirding of the program, then now is the time to put it in.

I personally believe it is an essential ingredient.

I believe there will be need to provide space—space to carry out a number of the various activities of the program that really are essential to the program. And I doubt that there is any other way to provide that space except by funds that will support that type of construction. I doubt seriously that there are enough local resources for funding this type of construction. In fact. I am sure that there are not. And therefore. I think we need to give this most serious consideration. So I should place my greatest emphasis and perhaps my own focus upon this aspect of the report and this aspect of any amendment to the legislation.

Now, the second, and perhaps equally important, aspect of the report should be concerned with whether or not the legislative authority has sufficient breadth and flexibility. And here, again, I think we owe a great deal of thanks to those who worked on the language in the original draft and in the subsequent modifications of it. For this purpose, I would specifically call attention to the tribute we owe Dr. Dempsey in this regard because of the many hours that he spent working on this, I believe that experience now

shows it was wise to make the law as flexible as possible. And I would hope that we would continue to hold to this flexibility.

Obviously there are certain standards and guidelines necessary to maintain quality and excellence. But flexibility is essential to meet the varying conditions and circumstances that exist throughout the breadth of our country where there are so many different ways of doing things; and these varying ways are not necessarily less effective or less successful. They should be adapted or at least be adaptable to local circumstances so as to take the best advantage of the local circumstances and to use them in the most effective way.

I would doubt that we would want in any way to change the legislative authority to provide for any lessening of that flexibility. I would urge that we maintain that as strongly as we can.

Those are the two main things that I would say are most important to our future in effecting this program as a successful and useful one in achieving the goals that we are all seeking for it.

Thank you, Mr. Whaley.

MR. WHALEY: Thank you, Dr. DeBakey. Another member of the committee who has been working on the report, also a member of the National Advisory Council of the Regional Medical Programs as is Dr. DeBakey, is Dr. James T. Howell, Executive Director of Henry Ford Hospital. He has brought to the Council his experience in hospital administration, particularly teaching hospital administration.



DR. HOWELL: My enthusiasm for this public law in its initial year of activity has stemmed primarily from the simple flexibility and the brevity of the law. It has provided lots of latitude in which we may work. At the same time, in its simplicity and in its brevity, it does lead to some interpretative questions for which we must provide the solutions.

One must look to the legislative history for some of the answers to the questions about interpretation which naturally arise.

The National Advisory Council in drawing up guidelines has had to look for proper solutions to these questions. In doing so, as Dr. DeBakey has said, we have attempted to keep this flexibility, this simplicity. This may bother some people, as is evident from discussions in the corridors at this meeting, in telephone calls that have come in, in questions to the staff, in visits that I have been asked to make to various places in the country with regard to some of these questions of interpretation.

Keeping the flexibility, permitting opportunity at local levels for the determination of local need as well as local desire, in mechanisms by which the various professional elements of our health resources may work is something which, like Dr. DeBakey, I feel must be preserved in the law. The penetration will be to the community. And the first challenge, in my estimation, will go to the physicians of the community.

The second challenge, I believe, will go to the arena of the community into which the law and its activities will penetrate. I believe that arena we must consider to be the hospital. It is here where modern instrumentation is most likely to be placed, where space provisions may be made for education, for research effort. It is here that most physicians by tradition congregate for various types of meetings. Accordingly, I would say that the second challenge must be issued to the hospital itself.

Like Dr. DeBakev, those of us who have been working at the National Advisory Council level on this law, believe in its simplicity and its flexibility and feel that relatively little needs to be changed in the law itself. The National Advisory Council and the staff of the Division of Regional Medical Programs have attempted to take each of the proposals brought to us from various regions and really have tried to find some mechanism by which a grant can be awarded once the proposal is determined to be within the intent of the law. This, I, personally, would like to see kept. If the lack of structure or the lack of precision in spelling things out, one, two, three, bothers some people, then I would hope that we could look beyond this toward a greater opportunity for participation at the local level.

One other thing thas has been brought to me as a problem has to do with evaluation procedures. I listened to it yesterday in a discussion group. And I have had many questions posed to me with respect to evaluation. Most of the problem, it would seem, centers about

the evaluation of physicians. And I believe we need to think of some other elements that must come into evaluation procedures, ones that perhaps in our initial efforts may take precedence over the others.

These deal with phenomena; these deal with processes; these deal with various types of measurements which we may place upon goals or objectives of the program, rather than evaluation of physicians themselves.

Accordingly, I would hasten to ask you to think of evaluation procedures in terms of phenomena or procedures or processes rather than an evaluation of human events.

Thank you.

MR. WHALEY: One of the members of the committee who brought us his experience and a refreshingly different point of view is Dr. Paul N. Ylvisaker of the Ford Foundation, Dr. Ylvisaker has been advisor to the United Nations, has served in many different roles for the Federal Government, and soon will begin his career in State government. His particular concern has been in the area of urban affairs. He has moved the committee (and sometimes jarred the committee) with the things he has had to say. And I hope you will jar us this morning, Dr. Ylvisaker.

DR. YLVISAKER: I have just returned from some eye surgery and yesterday had to face the New Jersey Senate Committee for a confirmation of a new appointment and they asked me the usual questions. How do you pro-

nounce your name? How old are you? I could answer the latter by saying: "I could go to the bar with any of you without embarrassment." And, finally, when this was all done, one of them observed, "Well Commissioner, I will give you one thing: you are the first Commissioner in New Jersey who ever came into office with a black eye."

I would like to complicate the lives of my friends here in this room and in the National Institutes of Health and the Public Health Service. Perhaps this is the wrong time to do it because the mood of the country right now is that "we have done enough for a while" and "let's retrench." And the mood of an administrator must always be, "in that case, I will retrench a little more than the public expects me to. I certainly am not going to rouse any sleeping dogs. And once I have got a good thing going, I don't want to risk it at this time."

But there are a few of us, I think, who foolishly or otherwise are willing to say a few things that have to be said in the United States today. And that is, "yes, we have gone a remarkably long distance in the last few years. And this legislation, and Medicare in your field, certainly are cases in point. But we have a fantastic distance to go."

We are facing an incomplete revolution in the United States which is working itself out with great rapidity. And this revolution is on top of an even greater revolution going on in the world around us. The revolution is simply the assertion of the individual for equal treatment at a time when re-





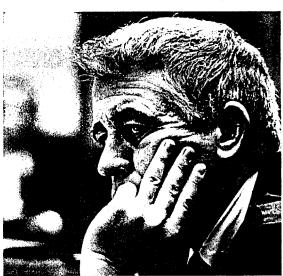




Storm Whaley (Chairman) Paul N. Ylvisaker, Ph.D.



Michael E. DeBakey, M.D. Ray E. Trussell, M.D.



James T. Howell, M.D. Bruce W. Everist, M.D.

sources are very scarce and they can scarcely go around to do the things we presently want.

But in this mood, I would like to complicate the discussion and the life of the United States and its administrators. The point I would like to make has to do partly with the phrasing used in this legislation.

This is a Regional Medical Program. Those of us who have worked with regional problems for a long time know what a Holy Grail this thing called a region is. And as a matter of fact, usually when you use the word, you are oversimplifying this issue. And you are doing what they said in the book African Genesis—"What a human being usually does is to add a territorial ambition to an otherwise complicated existence."

Now a region some wag once defined as that area which is safely larger or smaller than the last one whose problems we couldn't solve.

And when we begin to work for the perfect definition of a region either as principle of organizing medical services or principle of organizing any services, we soon realize the tremendous complexity of American life. It cries out, perhaps not so much for decentralization which becomes a centralization, as for instantaneous communication among people who are doing remarkably similar work in very different places, and the need sometimes is not so much to centralize or to concentrate even at the regional level, as to produce this kind of in-

stantaneous communication so that ultimately a patient in need of help knows exactly where to get it, how to get it, and those in the medical profession know where research is and how to avail themselves of it.

Now, the point I would like to drive home very hard is that you cannot retreat from the complexity which has become urban America, into either regional patterns exclusively or into professional patterns. And what I fear basically about the way this legislation has been drafted and carried out so far is that it has been given too narrow a base, which is the medical profession and largely the medical research academic community, to work out what is one of the great moving forces in the United States today.

And let me draw this perspective a bit for you. Ted Howell said that the problem is going to be that of the community. I could not agree more. The problem is going to be to relate the growth of medicine, both in its excellence and in its patterns of service, to the patterns of distribution of the American population and its mood and its aspirations.

Now, we have got to become, in all professions, in all the services, market and consumer oriented. If you don't, within two years, your medical schools will be picketed by a combination of the American Mayors Federation and CORE.

And I wonder if your medical faculties are ready for that experience.

The prelude to that experience is going

to come when this legislation comes up before some of the committees, and when some of the more consumer public oriented figures are going to begin to ask you questions. Unfortunately, they will tend to be of only one kind which are the more familiar ones you have heard, the most important ones of which relate to the patterns of medical care and to that consumer out there and how this will affect his life.

Let me add a few other considerations.

We are now, in the United States, going into a service economy based on large metropolitan areas. We have patterned those metropolitan areas on manufacturing and the mass production and consumption of material goods. The organizing principle of the metropolis in the days ahead will become the mass production and consumption of strategic services. And these services will be largely in the hands of certain guilds and certain public professions. For example, City Hall is going to be picketed because it doesn't give garbage services equally to Harlem and the rest of the community. And you will be picketed because you are not giving adequate medical service and equal access to many of these consumers.

Now, the planners of the future metropolis are going to have to get hold of the service economy and its growth and try to get some kind of pattern for it which provides equal access to the citizen consumer.

You people are now like the highway engineers, laying hold of one of the

great growth industries of the United States which is medicine, like education, like law, and like these other services. How are you organizing this? How even physically will you distribute the resources? Will it contribute to an orderly growth of the community or, like the highway program, will it become engineer-oriented—or in this case doctor-oriented—producing a wonderfully engineered system with cloverleaves and the rest, but very little relevance to the community of which it is a part?

Second, the growth sector of our economy is the service sector. It is here that the great market for employment will come. Is there in your planning for these regional centers, which is the planning for the profession and the science and the growth of medicine, thought for how you can distribute the employment all the way from the highest levels of skill down almost even to the leaf raking areas which we are going to be called upon to provide in the next years? That is, have you got nonprofessional employment worked into this? Are you extending this research and the work of the profession down to new occupations which are available to the poor? Which is one of the guestions that I think you have to answer before you are through.

And the final thought to throw at you is: Are you going to develop consumer complaint mechanisms in your business? If we become market oriented, if this is the day of the consumer and you are the growth industry, where is the consumer complaint mechanism?

Now, you have noticed that the police review board is a beginning. The Ombundsman is coming, and you better watch out for the Ombundsman in your profession. There is not a single local medical group you have ever talked to whose Young Turks have not said nervously, "We are not policing our profession; we are not market oriented."

The Ombundsman—will it come your way or will you anticipate it?

These are some of the questions, and I hope I haven't rocked you too much. Thank you.

MR. WHALEY: Dr. Ray Trussell is Director of Columbia University School of Public Health and Administrative Medicine. He has brought to our committee rich years of experience in the field of public health and education. Dr. Trussell.

DR. TRUSSELL: I want to congratulate Paul Ylvisaker on his carefully planned out career. He has gone from the international level to the Federal level, and now he is going to the State level. And I only want to invite him to New York City where we could use help.

The legislation which we are discussing today—yesterday and today—is the manifestation of a positive attitude on the part of the Congress toward health. This is an attitude which is not shared universally throughout the United States.

In New York State which has some of the most progressive health legislation in the country, the State Constitution has but one sentence in which the word "health" appears. And there are some people in the upcoming Constitutional Convention in April who would do away with any reference to health, holding that the police power in the State is enough to take all necessary measures.

There are others, and I share this view, who believe that a positive statement indicating the extent of the public concern should be included in the State Constitution so there would be no mistake about the will of the people with this respect to the kinds of problems that we are discussing here at the present time.

The Congress has enacted since 1956 about 65 major pieces of legislation in the health field. If this leaves any question in anybody's mind in this room that the public intent is that the best that the scientists and medicine have to offer shall reach the most people, they really should go and read the preambles to the various pieces of legislation for refreshing instruction on what the public wants and what the public hopes it is going to get.

The Congress has handed back to the scientific community the particular job of saying under what conditions the scientific community thinks it can deliver what it already knows and how it can deliver what it will know in the future as a consequence of research. This is an unusual function for the scientific community. It is not used to planning for anything that it doesn't want to do. It is used to planning very meticulously and very effectively for the things that it does want to do.

And yet the community and the scientific community must come together if we are to satisfy what is clearly the expressed intent of the public in the use of public funds. Yet, there is ambivalence in the minds of the Government about how these things are to be achieved.

We have the Regional Medical Program legislation underway. We have legislation, passed in the last week of the last Congress, which will put a similar but broader planning function in the hands of the State agencies and also parallel or competitive areawide planning agencies as soon as it is funded. Now, appropriately, this legislation has not been discussed here in this conference because, as was explained to us very clearly by Dr. Marston last night, there are discussions going on at the policy level. And nobody knows how much money there will be, but those of us who have had to do with the delivery of health services are urging that in the report to the Congress there be mentioned the need for coordination of these multiple planning efforts being engendered by Federal action in the longstanding Hill-Burton program, the Regional Medical Program, which is now getting off the ground, and the as yet inactive but upcoming State agency approach. If the scientists can't get together with the administrators at the local level, then the vacuum that will result will be a vacuum into which Government moves. I can tell you, from my own experience, that with the limited amount of tax money available in this country, Government tends to move only into

vacuums and only when they are convinced that they absolutely must move. Yet, the public expectation is such that the Government has clearly moved far beyond the thinking of the scientific community.

We have an enormous opportunity to maintain a working partnership in this country in contrast to the rapid or slow collapse into a total governmental system which has occurred in other countries. I look for an uneasy but happy marriage between the Government and the private sector as a consequence of Regional Medical Programs. And I feel if they do not fulfill the expectations that the marriage will get very lopsided and may, indeed, become no marriage at all.

It is coincidental that in this very building, in the next room, is a consumer group, the Teamsters, who contrary to their headlines are a very concerned group of union leaders, the largest union in the country and with a deep concern in you and your productivity and with your concern for the total needs of the public. We have worked with this kind of labor leader for many years and his management counterpart. They finance research, they finance demonstrations on a regional basis in the New York area. They support legislation. They supported legislation in New York which provides this looking-over-the-shoulder function that Paul talked about-namely, medical auditing by the State Department of Health.

But the State Department of Health in turn has turned to the State Medical

Society for a partnership arrangement so that Government and the professions with consumer support have an opportunity to discharge this function of keeping an eye on how well the public is served.

There is much going on around usso much that we must be careful not to be like a fish. The fish swims around in the water all day, and he never stops to think about the water in which he is swimming. And vet the water in which the scientific community today swims has changed tremendously as a consequence of public understanding and of Congressional and legislative action. And I think it is terribly important that we realize that the water in which we scientific fish are swimming has changed. And we'd better get used to it and adapt to it and try and meet the new temperature of our times.

I think I have said enough for the moment.

MR. WHALEY: A member of the National Advisory Council who is in private practice of medicine in Ruston, Louisiana, is Dr. Bruce Everist.

DR. EVERIST: I would like to ask the indulgence of this audience, and some empathy if you can imagine a country doctor having to follow one of the most honored physicians in the country, two directors, a vice president and a commissioner. It is obvious that I can only be dilutely paraphrastic.

Public Law 89-239 is a good law, new, innovative, imaginative, and even artistic. The language is so clear, concise,

and brief that it seems the law could only have been passed by accident.

The lack of obfuscation and the serendipitous nature of the law leave it devoid of the usual stringent measures for coercion and regulatory function. This is enough to unsettle the most sophisticated of Government staff.

This lack of regulatory function and of coercive power is also new to the private sector. And they have understandable misgivings when they see Government acting like a true Christian gentleman. Incidentally, the clarity of the law is not matched in this conference.

Mix as used in Washington means putting Dr. Hudson, Mr. Cohen and Dr. DeBakev on the same program, I am not a lexicographer, but I think the word should be not "mix", but "courage." Semantics aside, Public Law 89-239 has other virtues than clarity, brevity and conciseness. It places a new emphasis and a new direction on local responsibility for the health of all citizens. Doctors in the past have assumed this responsibility for the indigent as a good neighbor, for the affluent for a fee. This can no longer obtain for the poor for our current concept allows for equal medical attention for the poor as for the rich. But as a right, not as a gift.

I have no doubt but that this change can be made by local physicians in concert with Government, but with the lines of responsibility clearly drawn. American medicine is conservative enough to resist undue pressure and yet responsive enough to effect this And I will recognize anyone who change.

Public Law 89-239 cannot mean all things to all men, but it is probing for new and better ways of delivering health care without wholly disrupting the established tradition of medicine. For example, continuing education requires no dissembling on our part. We recognize our need for current knowledge. And most of us will admit that we don't always have it. Cooperative arrangements among all health agencies have already begun at this conference. And they have been relatively painless. Demonstration of patient care is not a restrictive or nebulous term, but rather a unique opportunity for broadening the educational process to include the patient.

It is a good law. It was a good law when it was written. And I think it is the good fortune of the people at this conference to make it a good law in practice, not by accident, but by design.

MR. WHALEY: I am sure you can understand now that it was truly restraint on my part when I refrained from mentioning that Dr. Everist is the poet laureate of our Council. His performance today is just as I have seen many times. (I have applied for the publication rights of the gems which he has dropped: so far I haven't gotten them.) Some of you might shudder to think he happened to be the reviewer of your application. He gets to the point. I am sure we have other comments from members of the panel.

wishes to be recognized in the panel. Dr. Howell.

DR. HOWELL: One of the very major concerns that I have had with the law itself has to do with the interregional program. What do we anticipate will happen one of these days when methodological approaches for evaluation or measurement determine that some plans have more effectiveness than perhaps others?

Another concern in the interregional area has to do with gaps of areas of the country that are not now covered. And what will we do here on the National Advisory Council to make certain that these areas have been covered?

I think there is a major problem for us to consider with respect to the sharing of information from one region to another.

And another of the problems is the one that Paul Ylvisaker has mentioned. the regions within a major urban area. How may they be put together? How may they share information? What is the communication across these regions?

Now, I propose this as a major issue about which we on the National Advisory Council are going to require a tremendous amount of feedback from you people. You will note that this provision is not in the law. How this cooperative arrangement is to be made is largely going to depend upon you, obviously upon us at the National Advisory Council level as well.

MR. WHALEY: Thank you, Dr. Howell.

Others? Do you have questions from the audience for just a few minutes? We have about 10 to 12 minutes. Yes.

QUESTIONER: I would like to ask Dr. Ylvisaker with whom I agree entirely in terms of being consumer oriented or market consumer oriented—Dr. Trussell referred to it as the environment in which the fish swim—whether his reference to the Ombundsman and consumer complaint bureau was a figure of speech which he used with something more explicit in mind. And if he had something more explicit in mind, would he be good enough to tell us what he had?

DR. YLVISAKER: Yes and no.

I have been interested to see how this Ombundsman concept has begun sweeping the country. Inside of ten years, it has gone from, you know, where did that come from, to almost a common figure of speech in the United States. It is being adopted in a number of jurisdictions, in Long Island, as I recall, in one of the New York suburban counties. And I think you will see probably many municipalities adopt it very shortly. It will be an experiential thing. It will grow.

There are several things about it to keep in mind.

One is that there is a public receptivity to the idea of a consumer complaint mechanism. Second, that they are not satisfied to start in one field. The fact that you overthrew the New York Police Review Board is a warning in point that no one group is probably going to accept this, but probably you will have an overview.

Whether this is adaptable in the medical field, I don't know. I would think that the medical profession, seeing the trend of the times, might begin inventing a variant of the Ombundsman and to begin experimenting with it before the public might foist it on to the various professional groups.

So, as I say, yes and no. I am talking about a wave, a concept, a demand, but I am feeling my way in the institution.

MR. WHALEY: Other questions?

QUESTIONER: What type of construction did Dr. DeBakey have in mind being built into this law?

DR. DeBAKEY: Well, actually, I think it might be best described as construction that is essential or needed to carrying out the program, wherever it may be—affiliated institutions, the center itself, and so on. It is related primarily to program activities such as those related to continuing education, those related to demonstration of care, those related to administration of the program, and so on.

I would say that this type of construction is pretty hard to come by from other sources—that is, from other financing. And speaking of that, if I might just take a few more moments, I would call your attention to the fact that there is written into the law certain interests that Congress had in re-

porting back to them about the activities. Among these are this particular request that we return to Congress a statement of the relationship between Federal financing for this program and financing from other sources of activities.

This, of course, points up the variety of sources of financing for the various medical activities that we are engaged in today. And they wanted a statement indicating what sources are being used. And I think it is important also to point out that there are non-Federal sources of financing that are being used in this program, the extent of which is sometimes difficult to determine, but it would be certainly highly desirable in your own thinking in your own regions to try and make some estimate of this. Because, for one thing, it is important to maintain it. And in a sense, it is part of the partnership that exists.

So I think Congress would take some interest in having information on these aspects of the financing.

MR. WHALEY: Our time has run out. I had written down a few comments on the remarks of each of our panelists, but in the words of Dr. Everist, I don't wish to be dilutely paraphrastic because it would ruin the very fine statements which we have had.

So, members of the panel, the deep appreciation from all of us for what you have done.

(Applause)

# TRIBUTE TO JOHN EDWARD FOGARTY

DR. OLSON: During the past week, we have all been shocked and grieved to learn of the death of Mr. Fogarty who has had such a deep interest in the health problems of this nation. We have asked Dr. Sidney Farber if he would come and pay tribute to Mr. Fogarty.

DR. FARBER: Dr. Olson and members of the Conference: Just one week ago today, we lost John Edward Fogarty, longtime chairman of the Committee of Appropriations concerned particularly with matters of health and education.

There are some in this room who knew him as a devoted friend. There are many more who had the privilege of appearing before him as a citizen witness and learned then of his great integrity, his deep devotion, his compassion and, above all, his great knowledge of the needs of the country for medical research, training and care.

I believe it can be said without exaggeration that no man in the history of the House of Representatives has made a contribution to the health of the country as great as that made by Mr. Fogarty. The enormity of his contributions will be felt all over this country and over the world for generations to come. It was felt proper that all of us who had benefited so much from his labors might stand for a moment in his memory.

(The group stood in silence.)

DR. OLSON: This concludes the final plenary session of the conference. The attendance has been a splendid one. We have had approximately 650 registrations. We have had outstanding representatives of the health field both on the platform and in the audience.

We are deeply grateful for your presence and for your contributions. We would ask that you make two further contributions.

The first you will make in the discussion sessions to which you will adjourn in just a moment.



The second we hope you will make after you have returned home and have had an opportunity to reflect on the matters you have had under discussion these past two days. I would hope you would write to Dr. Marston and give him your considered judgment about any aspect of the program you consider to be important and significant.

Dr. Farber made reference to the capable, dedicated and loyal staff that Dr. Marston has developed in the Division of Regional Medical Programs. I have come to know this staff and their capabilities in the past seven weeks that I have been associated with the preparation of this conference. I should like to take just a moment to recognize several people that have performed in an outstanding fashion.

These are Mrs. Judy Silsbee, Mr. Lyman Van Nostrand, Mr. Edward Friedlander, Miss Dale Carter, Mr. Charles Hilsenroth, Mr. Stillman Wright and Dr. John Hamilton.

In addition, as you know, the staff has served as recorders for the discussion sessions. The stenographers have worked, some until one o'clock, some all night, to get out the various things that were needed for the conference program and registration.

I should like to ask the staff that is here to stand so that we might recognize their very significant contribution. (Applause)

I would call your attention to the fact that you will be going into a different discussion group for this final session. I met Dr. Pellegrino in the corridor as I was coming into the hall this morning. He said, "Stan, is there anything special you want out of this discussion group?" And I commented that he ought to use his judgment; that the discussion group should feel free to pursue anything it wanted and in depth. I told him we had had plenty of breadth in the last couple of days, what we needed now was some depth.

So I would hope that participants and chairmen alike would address themselves to the issues that have been so ably presented here this morning and that you will come to your own conclusions about what is right with the law, what is wrong, what needs to be retained, what needs to be changed.

Dr. Marston, is there anything you want to add?

DR. MARSTON: No.

DR. OLSON: I would just like to say this has been a wonderful experience for me to work with Dr. Marston. And I hope that many of you have an equal opportunity to get to know him as I have.

Thank you.

# Section III—Issue Papers

Cooperative Arrangements Program Evaluation Continuing Education Surgeon General's Report Four Issue Papers were prepared to provide a focus for discussion. "These are not the *only* issues calling for attention, but, certainly, these are areas of common concern. . ." said Dr. Marston in his Conference speech.

Prepared by the staff of the Division of Regional Medical Programs as background to the first discussion session

In an editorial in the November 23. 1962 issue of Science. Dael Wolfle pointed out that honesty and objectivity, reliance on the evidence rather than upon bias, wish, authority, or personal advantage, is one of the greatest gifts that science has given to society. A goal of the groups applying for Regional Medical Programs is to work toward meaningful relations which will be based on objective data and real needs. There has been concern for some years because health resources and organizations with nonidentical but related and overlapping goals have often not been able to work together effectively or to seek joint solutions to new problems.

Many have defined the problem and have offered a logical solution. A fine example is given in the following statement by Dr. Charles L. Hudson at the 1962 Teaching Institute of the Association of American Medical Colleges:

"A restoration of harmony among the elements involved could be effected by a sincere collaboration among physicians as physicians, in teaching and research, in training of interns and residents, and in patient care in the hospital and in the office. This, an education and practice complex, could be formed if physicians were willing, if necessary, to surrender some prerogatives in the interest of creating an effective private medical care system that would be recognized by the public

for its superiority over systems established by government and welfare.

"Evaluations could be made of the needs of the public for medical care, of the kinds of services required, and of the numbers and kinds of physicians and institutions needed to provide these services. Based on these evaluations, educators could construct curricula to deliver graduates consistent with modern requirements. Community hospitals could continue to employ directors of medical education required to provide excellent training programs of perhaps a different character but of quality equal to those in the university centers. Differences between university hospitals and community hospitals would disappear in the collaborative efforts to train interns and residents through an interchange of teachers and trainees, the sites to be determined by the competence of the hospitals to satisfy the future service requirements of the trainees.

"The inevitable centralization of knowledge and techniques with stratification according to levels of knowledge and competence would continue, but equally important would be the areas manned by the physician with broad training. His primary contributions to the system would be in medicine, with occasional exceptional additions where circumstances required them.

"The key to success of an integrated medical practice would be the proper identification of the physician now sometimes referred to as the general practitioner, personal physician, family physician, first-contact physician, in-

ternist - pediatrician - psychiatrist, and other mixtures. If the profession fulfills its promises, there will be new and increased efforts to keep people well, an emphasis on health rather than disease, an augmentation and an enhancement of the field of preventive medicine.

"The greatest challenge of the present is inherent in the job description of this physician, who must feel the significance and importance of his practice and must believe in his unique ability as a true specialist to perform duties that others in the more narrow specialties might find impossible. Under no other circumstance will there be effective competition to careers in subspecialism. The divisive forces in the profession of medicine themselves point up the interdependence of its parts and the real need for cooperative effort. With such a sincere effort I would predict that our intraprofessional differences would disappear.

"Numerous unilateral attempts at adjustment of medical practice have failed, because any undertaking that seeks to alter the position of one element, without regard to the effect on the integrated system, causes unhappiness and strife in the whole professional complex and will increase its susceptibility to outside interference and even domination.

"As to the medical practice of tomorrow—if intelligence, good will, and technological advances exert their potent force—the changes should hopefully go in the direction of better care for the sick and greater fulfillment of the hopes and aspirations of physicians.

"As I finish this chapter after six months of struggle and interrupted effort, I am at my desk, having just returned from seeing a patient with disseminated lupus erythematosus who is alive and at the moment well because of the miracle of medical progress. In recalling her happiness and the look of fondness and gratitude she gave me, I cannot help reaching out in appreciation to those persons, some known to me and many unknown, whose efforts have permitted me this, the supreme reward of the physician.

"A moment's reflection will show us what we all must know: we are not self-sufficient; even as an individual one does not practice alone."

Congress and others involved in the development of Regional Medical Programs were convinced with Dr. Hudson that individuals and even institutions cannot cope with the complexities of modern medicine in isolation. Public Law 89-239, which authorizes grants for the planning and establishment of Regional Medical Programs, begins with the following two statements of purpose:

♦ To encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions and hospitals for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases.

♦ To afford to the medical profession and medical institutions of the Nation, through such cooperative arrange ments, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases.

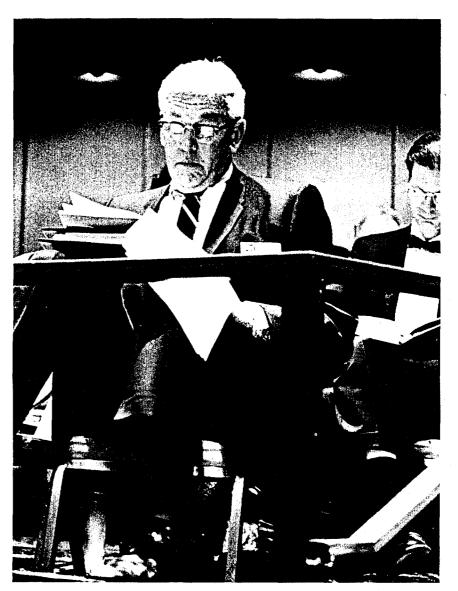
Other sections of the law and the legislative history that led to its enactment indicate that all organizations and groups concerned with realizing these purposes are to be included as an integral part of the cooperative arrangements. These include, in addition to those identified above, medical societies, health departments, voluntary agencies, other health professions and individuals concerned with health, Section 903 specifically provides that the Regional Advisory Groups must be "broadly representative" and must approve applications for operational grants.

The Program Guidelines emphasize the essential importance of regional cooperative arrangements among these groups throughout the planning and operational phases of the Regional Medical Programs. While it is recognized that the full development of such arrangements involves all medical institutions, organizations and individuals within a Region, and may take considerable time, the initiation of this effort is a critical aspect of the planning process for a Regional Medical Program.

"Cooperative arrangements" are intended to facilitate effective exchange of information and ideas and working relationships among centers of advanced capabilities, private practitioners, community hospitals, and other interested private and public agencies throughout a Region. Through such channels, information and assistance can be moved out to upgrade and maintain daily practice at the highest possible level. The same local groups can feed back information on needs as a basis for further research and training. In this way, science and service may be linked in systems of mutual support and benefit.

In the development of the program, emphasis has been continuously placed upon its cooperative and centrifugal features. It is believed that the extension of excellence in health care to all parts of a Region can be facilitated by bringing together all the major institutions and interests for planning and action. The product of the efforts of organizations working together can be much greater than the sum of the separate efforts. As the President's Commission on Heart Disease, Cancer, and Stroke pointed out: "A creative partnership among all our health resources . . . is the true path to the conquest of heart disease, cancer, and stroke."

During the first year of the program, a great deal of emphasis was placed on the term "cooperative arrangements" both by the applicants and by the reviewing groups. One applicant, who was also a consultant to the program, stated that in the strictest sense, justification of the program would rest on the ability to demonstrate the development of cooperative arrangements where they had not existed pre-



viously. All have agreed that the documentation of this aspect of the program is an appropriate accomplishment to report to the President and Congress.

The requirement for the development of regional cooperative arrangements was the major factor in determining the sizes and shapes of Regions as various parts of the country probed for what seemed to be the best workable conditions. A part of the planning process will be to reexamine the factors that lead to the conclusion that a given Region offers the best opportunities for effective utilization of resources. In some instances, political considerations may have deserved a relatively higher priority in the establishment of an application for a planning grant than will be the case with regard to operational grants. In others, deficiencies of resources may require the development of cooperative arrangements across great distances, at least for interim purposes. Almost surely, close relationships between adiacent Regions will prove beneficial. An editorial in the August 12, 1966, issue of The Journal of the American Medical Association comments that cooperative arrangements within Regions seem assured and that the next question is whether such cooperation can exist between Regions.

The development of cooperative arrangements requires organization and communication, sharing of resources, ability to reach joint decisions, and the development of the capability to evolve new and creative approaches to

complex problems which cannot be met by individual institutions or organizations. In the early stages, it is inevitable that most decisions will be



made on a basis of the wisdom and experience of the participants and the advisory groups. A primary goal should be, as Wolfle suggests, to begin by establishing mechanisms which will allow the substitution of objectivity for bias, and data for wish or authority.

Some insight into the problems to be anticipated in the future can be gained from a study of the issues which have arisen in the review of the early operational applications.

A primary goal of Public Law 89-239 is the establishment of decision-making mechanisms on the local level which assumes that different priorities exist in different parts of the country. On the other hand, neither the National Advisory Council nor the Public Health Service can delegate their basic responsibility and accountability that Federal funds will be expended wisely.

A number of Regional Medical Programs have submitted applications for operational grants which are currently being reviewed. These applicants, the Review Committee, the Council, and staff have identified issues in the process of working with these applications. The following list is not meant to be complete, for future grant requests will bring out additional issues, and one could speculate that still others will arise:

- I. Characteristics of early operational proposals
- A. Many projects contained in each complex proposal
- B. Sizable budget requests, including large hardware requests

- C. Commitment of effort by individuals, organizations and institutions
- II. Regional Medical Program vs. collection of projects
- A. Relevant characteristics of Regional Medical Program on which this judgment can be made
- 1. Overall leadership and guiding philosophy
- a. Is there a unifying conceptual strategy which will be the basis for initial priorities of action, evaluation, and future decision making? Are there sufficient feedback loops in the strategy?
- b. Is there an administrative mechanism which can:
- make decisions
- ♦ relate to regional needs
- ♦ stimulate cooperative effort among major health interests
- c. Are the key leadership persons identified? Do they work with the major health interests? Do they have experience and skills appropriate for providing leadership to a complex endeavor?
- d. Is there involvement and commitment of the major health interests such as:
- ♦ Medical schools
- ♦ Practicing physicians
- Hospitals
- Public health agencies
- e. Will the ongoing planning process interact with the first operational steps in the development of a program that meets the broader needs of the entire region?
- 2. Nature and interrelationship of specific proposed activities in regard to the goals of PL 89-239

# Evaluation of Medical Care Under Public Law 89-239

- B. Evidence that priorities have been set at the regional level
- III. Quality standards
- A. Regional vs. National standards
- B. Emphasis on grantees' own evaluation mechanisms as quality uplifting factor at regional level
- IV. Criteria for judging appropriateness of support
- A. Scope and limitations of Regional Medical Programs legislative authority, including categorical focus
- B. Availability of other sources of support
- C. Priority on innovative and leverage effects
- V. Criteria for judging level of support
- A. Geographic distribution Should consideration of availability of funds for later proposals be a part of decision on amount awarded to first applicants?
- B. Partial or phased support as mechanism for:
- Allowing fuller development of plans before proceeding to fuller implementation
- Permitting better decisions on distribution of funds
- 3. Early review of progress
- C. Need to support "critical mass" of activity which will have a sufficient impact to permit evaluation of results
- D. Support of costly activities as national or interregional resources when justified by the involvement of unique capabilities in a specific Regional Medical Program
- E. Extent of need for support of op-

erational activities as necessary for further development, extension, and solidification of regional cooperative arrangements

- VI. Length of commitment
- A. Degree of emphasis to be placed on self-limiting nature of projects
- B. Need for long range commitment for "core" activities which are essential investment for conduct of specific projects
- VII. Relationship of operational proposals to ongoing planning activities
- A. Need for documentation of relationship
- B. Extent of prior planning and its relationship to proposed operations and continued planning
- C. Extent to which needs of periphery of the region need to be documented as basis for undertaking operational activities
- VIII. Need to spell out relationship with adjacent regions and to justify the proposed region
- IX. Adequacy of administrative arrangements, including fiscal accountability of grantee

Examples such as these coming from early operational grant requests, and others yet to come, will continue to test the workability of developing cooperative arrangements over a wide range of activities. The first Conference discussion session is directed at reviewing experiences in the development of these regional cooperative arrangements and considering plans for extending and modifying these arrangements in the future.

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Prepared as background to the second discussion session

Evaluation in the field of medical care consists first in collecting information on the operations and end-results of a program, then making judgments regarding the effectiveness and efficiency of the programs or services under study with respect to both individual patients and communities. On a shortterm basis, evaluation identifies needed revisions and improvements in an operating program. Its long-term function is to provide a rational base for broad policy decisions governing the future directions of such programs or services. When conducted with a high order of technical competence, evaluation may also contribute substantive knowledge to the field of health services research and is then designated as evaluation research.

A distinction exists between evaluating a Regional Medical Program and evaluating medical care. Public Law 89-239 and the Guidelines emphasize the delivery of medical care, i.e. the personnel, facilities, services, and resources necessary to improve diagnosis and treatment. However, only in certain limited situations will increasing the capabilities for delivering medical care automatically assure an improvement

in the quality of care. For example, increasing the number of trained personnel or providing specialized facilities and services in areas where these are marginal or nonexistent constitutes, on the face of it, a distinct improvement in the quality of care. In this sense, evaluation of a Regional Medical Program can be directly comparable to evaluating the quality of care.

The term "medical care" has several unique meanings depending on whether it is defined as a process, as a system, or as an area of study. It is also analyzed in different ways depending on whether individual patients, a community, or the entire Nation are the recipients. The following components of medical care are particularly relevant to the evaluation of a Regional Program:

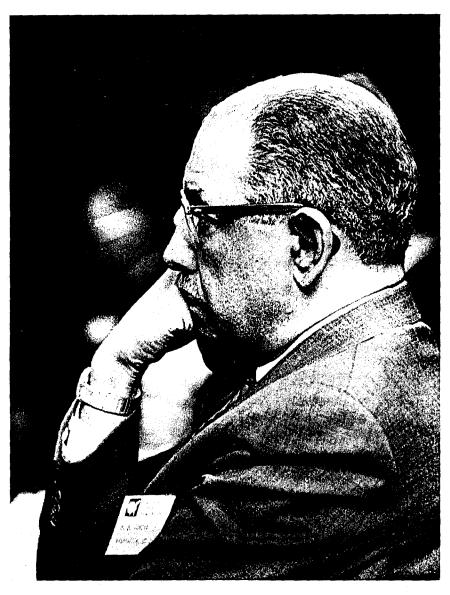
- ♦ Supply or availability of health care personnel, facilities, and services, including preventive measures.
- Utilization of personnel, facilities, and services, including preventive measures, by individual patients or population groups.
- Process of patient care: accuracy of diagnosis, adequacy of treatment, and appropriate utilization of consultative resources and specialized technical services.
- ♦ End results: the effectiveness of a treatment or program as determined by the consequences for the individual patient or population, including expressed views of patients and potential patients toward the availability and acceptability of medical care.
- ♦ Unmet needs: individual patients or population groups with identifiable dis-

eases not yet diagnosed, or diagnosed but not under treatment.

In a limited, technical sense the requirements for evaluating a Regional Medical Program in accord with the stated purposes of Public Law 89-239 can be met by limiting the evaluation of medical care to its first component, supply or availability. However, in order to evaluate the effectiveness of the increased supply of personnel, facilities, and services and their improved distribution, it is necessary to include the other components of medical care: utilization, the adequacy of diagnosis and treatment, end results, and unmet needs. The assumption seems warranted that the law was passed with the implicit belief that there would be demonstrable improvement in the care, and in the results of care, of patients with the specified diseases. It appears to be a legitimate responsibility of those conducting Regional Medical Programs to ascertain so far as is feasible the relationships between improved health manpower. facilities, and services and the other defined elements of medical care.

As stated, evaluation is a dual process of data collection followed by judgment. Depending upon the particular program or services, evaluation may be carried out at varying levels of precision and sophistication. These levels will be described separately.

1. Evaluation to determine whether the stated objectives of a particular program were met. If the stated objective of a program is to train ten rehabilitation aides, and this is accepted as



the only objective of the program, then the evaluation of this program rests entirely on the fact that ten rehabilitation aides were or were not trained. By analogy, this level of evaluation applies to the establishment of specialized patient care units, demonstration programs, diagnostic or treatment services, and so on. The fact of their establishment provides the necessary and sufficient information needed in judging whether or not the objectives were met.

2. Objective description and analysis. For this level, descriptions of education and training programs, facilities, services, and capabilities of personnel are compiled in accord with prevailing professional concepts and standards. For example, a program for training nurses to staff coronary care units should be described in terms of the functions nurses will be expected to perform as a result of their training. These functions will have been defined by appropriately informed and experienced experts. Evaluation of the training program will be directed at answering two questions: (1) Has the program been designed in accord with generally accepted principles of such training? and (2) Was the program carried out as planned? Descriptive data bearing on these questions must be collected before a judgment can be made. Similarly, with respect to the operation of coronary care units, the basis of judgment regarding their adequacy is simply an accurate description of the services which these units provide, together with a description of their overall operation and administration. These descriptions are then compared with prevailing professional and administrative judgments of what constitutes proper staffing, organization, resources, and administration for coronary care units.

3. Evaluating utilization by patients or populations. The question of whether or how the improved staffing, facilities, and services bring about improvement in medical care cannot be answered without information concerning the utilization of such personnel, facilities, and services by patients. Two approaches are possible. Prior to the institution of the program, baseline data can be obtained on the utilization rates of various personnel and services by all persons with the specified diseases in the population served by the Regional Program. If baseline data are not available, a comparison group of patients to whom the new resources are not available must be studied in order to determine that other changes totally unrelated to the Regional Medical Program have not brought about equivalent changes in utilization. Both approaches require the use of epidemiologic methods applied to probability samples of general populations, It is inappropriate both in terms of the overall objectives of Public Law 89-239 and correct methodology to base evaluation on changes in the numbers or characteristics of only patients who receive care. Similar approaches are necessary to determine whether changes in frequency of duration of hospitalization for equivalent disorders or their complications are brought about by the program. Judgment of the adequacy of utilization will rest on two comparisons: (1) between rates per 1,000 general population in control and experimental communities or before and after the introduction of a program in the same community, and (2) between utilization rates and known prevalence of the target diseases.

- 4. Evaluation of improvement in the patient, care process. Direct comparisons on a controlled basis are required to determine changes attributable to the program in accuracy and completeness of diagnoses, adequacy of treatment programs, and appropriate referral of patients for specialized services. This level of evaluation encompasses the techniques of the medical audit in office, clinic, and hospital settings.
- 5. Evaluation of end results. This level constitutes the definitive measure of effectiveness of personal health services. By use of matched populations, data can be compiled on decreases in interval between onset of symptoms and receipt of care: end results of care: prevention of complications; alleviation or reduction of disability; improvement in social functioning; increased longevity; and so on. Whereas techniques for the preceding four levels of evaluation are well worked out and can be applied in pre-tested form, the determination of end results is still under research and development.
- 6. Analysis of cost-effectiveness. This form of evaluation focuses on the efficiency of a program and questions whether the results of a given program

or program element are achieved economically in terms of dollars, manpower, time, space, and resources. Competence in operations research and economics is required. Two or more training programs for aides might be compared to discover whether comparable skills can be achieved more economically. Appropriate economic bases are needed to compare these programs with training programs which produce fully qualified professional personnel. Similarly, the costs of establishing and operating different types of coronary care units need to be compared in relation to demonstrable improvements in the outcomes of care given in these units. It is also appropriate to compare costs and staffing economies or the functional efficiency of such specialized units with an at-large monitoring system dispersed throughout the hospital. The critical element in such evaluations is an agreed-upon set of criteria of adequacy for services and end results. Only then can the relative costs be rationally analyzed.

7. Evaluation of the effectiveness of preventive measures. This is the most difficult level of evaluation since it attempts to determine the extent to which diseases are being reduced, controlled, or eradicated from the population by the application of preventive measures. The use of epidemiologic methods is also essential for this form of evaluation.

Evaluation is a sequential process, each step of which must be appropriately planned and carried out before

the next step can be taken. The sequence may be outlined as follows:

- I. Collection of information and data.
- ♦ Specification in detail of the objectives of the programs, services, and end results which are to be evaluated.
- ♦ Establishing the criteria on which judgments will be based.
- ♦ Designing the instruments or records for data collection.
- ♦ Applying the appropriate methods for collecting the relevant descriptive information with minimal bias.
- ♦ Statistical analysis and/or summary of descriptive information.
- ♦ Interpretation and comparison of results against agreed-upon criteria.
- II. Judgments regarding adequacy or inadequacy of program, program components, or results.

Ouality, effectiveness, and efficiency of medical care cannot be measured directly in standardized units. They can be inferred from one or more objectively specifiable indexes derived from established professional standards. These indexes can serve as the base information or data for judging the degree to which a program or its results meet or do not meet the criteria specified. Judgments of quality are based on consensus of physicians and other professional personnel. Effectiveness and efficiency of a program or procedure can be defined somewhat more objectively, because data can be collected on effectiveness, and the dollar and manpower investment can be objectively related to outcomes (cost-effectiveness analysis). However, even under the best of circumstances.

Section 908 of Public Law 89-239 states that the Report to the President and Congress will include "an appraisal of the activities assisted under this title in the light of their effectiveness in carrying out the purposes of this title." On page 65 in the first paragraph, the Guidelines stipulate that "special effort" is to be made to incorporate evaluation in the planning and operational phases, "Research into better means of accomplishing the purposes and objectives of the Regional Medical Program" qualifies for support in an operational grant. In order to analyze the role of evaluation in the Regional Medical Programs, it will first be necessary to identify the intent and provisions of Public Law 89-239 which have implications for the purpose, scope, level and limitations of evaluation.

Within Public Law 89-239 and the published Guidelines, the following major categories of objectives are defined:

♦ making available to patients the latest advances in prevention, diagnosis, treatment, and rehabilitation:

 developing more effective distribution and utilization of all types of medical resources;

♦ establishing cooperative arrangements among medical institutions and professions to overcome fragmentation and insularity and meet the diversity of needs, resources, and existing patterns of education and services;

o improving health manpower and fa-

cilities through education and training of health care personnel and demonstrations of patient care;

extending the productive interrelationships of extensive research, teaching, and patient care activities to community hospitals and practicing physicians;

♦ creating an effective environment for continuing adaptation, innovation and modification without interfering with the patterns or methods of financing patient care or professional practice, or with the administration of hospitals.

It is legitimate to question whether augmenting existing patterns for the organization and delivery of services will automatically bring about maximum possible improvements in the health of the population in proportion to available knowledge and techniques. The potential impact and the projected total investment in Regional Medical Programs are such that considerable effort should be devoted to the development of standardized data on incidence and prevalence of the target diseases in the general population (as described in paragraph 1, page 16 of the Guidelines). Furthermore, significant effort should be devoted to analyses of factors which determine the degree of success achieved in improving the delivery of medical care to all persons who could benefit from it.

It is only by using techniques of evaluation which link together personnel, facilities, services, utilization, end results, and cost-effectiveness analyses that an approach can begin to be

made to the evaluation of the impact of any program on the medical care system and on the quality of care. Study of one component of the medical care system will not provide sufficient information to make possible wise decisions concerning needed modifications in other components and links. The evaluation of medical care within Regional Medical Programs must be comprehensive in scope and long-range in perspective. The most productive attack on this problem will result from cooperative efforts by universities and private organizations utilizing the resources of a number of units within the Public Health Service.

Evaluation as Operational Research. The particular form of evaluation which is undertaken and the technical competence of those who design and conduct the study are essential considerations. In addition, failure to properly utilize or apply the results of evaluation will defeat the basic purposes of evaluation, namely, to improve programs and their effectiveness and efficiency.

Many circumstances may vitiate evaluation and prevent its effective contribution to the continual improvement of programs. The list of potential contaminating factors is long. It includes such factors as the introduction of undue bias and subjectivity by those administratively responsible for the program; resistance of professional personnel to evaluation; arbitrary restriction of the limits of evaluation; changes in the program while it is being evaluated; use of inappropriate

methods of data collection; failure to specify clearly the goals and end results to be evaluated; failure to establish criteria before attempting evaluation; confusion of availability of services with utilization or with actual patient benefit; inadequate access to or lack of availability of standardized rates for prevalence and incidence of diseases.

One approach of proven merit is the establishment of a health services research unit, a form of an operational and epidemiologic research unit, as an integral part of a health services program. By this means, an administrative mechanism is set up for feeding the results of evaluative studies to those who must make decisions governing the day-to-day operations of the program as well as future improvements. Given long-term responsibilities, such units are more likely to develop and maintain records which cumulatively become more valuable and informative because of the documentation of changes over time. This resource is not likely to be developed when ad hoc evaluative studies are carried out on a short-term basis by consultants who have no continuing responsibilities to the program.

Even under the most advantageous circumstances, continuing evaluation of health services based on operational and epidemiologic research encounters certain problems with predictable regularity. These will be listed briefly:

One of the most important potential contributions of evaluation is the analysis of alternate approaches to the

attainment of program objectives. Very often the decision at issue is not whether a particular program in operation is effective but whether an alternate program might be more effective. To base evaluation upon an all-or-nothing answer for an entire program is much less productive than providing alternate program components which can be independently evaluated with respect to their consequences and costs.

♦ It may be that the major contribution of evaluative research is to determine whether the traditional ways of carrying on professional practices and delivering medical services are, in fact, the most effective. If arbitrary assumptions and unwarranted limitations are placed upon the scope of evaluation, even though some limitations are always necessary, the hope that continuing experimentation and innovation will lead to dramatic improvements in medical care is less likely to be realized.

♦ There are several stages in the evolution of new health care programs, on a local, regional, or national level. Initially, decisions are made and implemented on the basis of best judgments of those responsible for the program. After a program has been established, a number of new, unrelated facts begin to influence decisions, but in the absence of an organized and definitive body of data, the administrators of the program require wide latitude in making decisions because factual guidelines are still imprecise. The third phase of such programs emerges

when cumulative evaluation, studies, reports, and research have both defined the system and its component parts and related their operations to objectively specifiable effects. In this period, the data base becomes more important in supporting operational decisions than empirical judgments of administrators.

Many Regional Medical Programs are in the first stage. It will be some time before the second stage is reached. The third stage can only be dimly glimpsed in the distant future, and will not be reached at all unless activities in acquiring appropriate data bases are promptly established.

Evaluation of demonstrations in which the purely medical aspects of the services rendered are assumed to be effective may be based on a false assumption. To the extent feasible, evaluation should concern itself with all the factors that actually or potentially influence effectiveness, as it has been defined for the purposes of evaluation. These factors include the reliability and validity of the medical measures of diagnosis and treatment. In settings where such access is feasible. such factors should be identified as the objects of evaluation. If this is not done, programs may be evaluated as highly effective in terms of their operation and costs, although they may not be advancing the actual care of patients.

♦ Finally, the question may properly arise whether a particular program is an appropriate one for the area or population to be served. Presumably

this decision was made when the particular program was instituted. Nonetheless, it is legitimate to subsume, under evaluation, questions concerning the appropriateness of the program in terms of the cultural attributes of the area or population and the likelihood that elements of the program might be applicable to other areas and populations. The methods used must take into careful account the possibility that the unique circumstances operating in a particular program may make it impossible to achieve comparable effectiveness and efficiency in other areas.

Sources and Resources for Evaluation. A sound program of evaluation in the field of medical care requires the direct and cooperative involvement of a number of disciplines and competences. Background or experience in medical care is not essential for all contributors in order for them to make substantive contributions; the principles of evaluation can in many instances be transferred from other fields. Many individuals will have to be recruited into the medical care field to make possible the level and scale of evaluation that is called for.

Potential sources of professional assistance or consultation include many departments in the university: Sociology, Social Psychology, Economics, Political Science, Business Administration, Administrative Science, Educational Psychology. Schools of Public Health generally possess highlevel competence in epidemiology and medical care organization. In several such Schools, as well as in several

Medical School Departments of Preventive Medicine and a few other university departments, medical care research units have developed well-qualified faculties in medical care and patient care research, health economics, medical sociology, operations research and systems analysis, epidemiology, demography, health services statistics, and medical care administration.

The national impact of Public Law 89-239 will best be evaluated through the cooperative efforts of the Public Health Service, other governmental agencies, the individual Regional Programs, and a number of other public and private resources. The National Institutes of Health, the Bureau of Health Services and the National Center for Health Statistics as well as other offices within the Public Health Service have unique sources for medical care research and evaluation. The task of evaluating the effectiveness and efficiency of Regional Medical Programs calls for the cooperative effort of staffs of universities, members of the health professions, and of units of governmental agencies, Only then can the requisite talent and competence be mobilized to provide the data essential to local and national policy determinations which must shape wisely the future of medical care for all our citizens.

# Continuing Education and Regional Medical Programs

Prepared by Staff of the Continuing Education Branch of the Division of Regional Medical Programs also as background to the second discussion session

Continuing education and training address themselves quite directly to the primary purpose of the Regional Medical Programs-to make more widely available to the patients of the Nation the latest advances in the diagnosis and treatment of heart disease, cancer, stroke and related diseases. Because the more successful continuing education and training programs are often dependent upon cooperative efforts of a number of individuals and organizations, the creation of regional cooperative arrangements by the Regional Medical Programs may provide significant new opportunities for the development of effective continuing education activities. The regional nature of the Programs can also provide other assets to continuing education and trainingan opportunity for close relation of teacher and learner in development of programs, convenience and accessibility of programs, and opportunity to build together links between education and health care. Indeed one of the real potentials of continuing education and training within Regional Medical Programs is the opportunity to integrate these activities into the larger sphere of health care which they subserve.

Relation of Educational Needs to Health Needs. Although Regional Medical Programs have stimulated additional attention to the problems of continuing education, this new interest is

only an additional increment in the extensive array of activities already underway along with widespread discussion of needs and solutions. Yet there is cause for thoughtful concern and a hard look at past accomplishments and future prospects, for there are a number of knowledgeable persons who have entertained serious reservations about the effectiveness of current activities in continuing education in improving patient care. The approach to developing truly effective training programs must be viewed in the broad context of health care.

Educational program design takes its origins in identification of the educational needs of the health professional. These educational needs in turn have their origins in the health needs of individual patients and in the patterns of medical care and the total health needs and resources of the particular region. The sequence of educational design commences then with the identification of the health needs of the population accompanied by an analysis of the existing resources to meet those needs. Out of these considerations, discrepancies between resources and needs become apparent. The challenge then becomes the design of methods to meet these discrepancies.

Some of these discrepancies can be met by programs in continuing education and training. Often, however, the human resources available within a region for continuing education are scarce. Conservation and appropriate utilization of these scarce resources requires close working relationships

between all individuals, groups and organizations involved in continuing education in the region. Difficult judgments will have to be made as to which educational programs will receive priority, for all educational needs cannot be met at once. Strong consideration to the health needs of the region should be given in setting these educational priorities.

Design of Education Programs. The design of educational programs to meet these needs requires considerable creative thought. Based on previous experiences, however, some of the important factors to be considered in effective educational design can be identified. Many educational experiences which have staying qualities are characterized by active participation of the learner in the learning experience. These experiences have also linked that participation to the ultimate focus of the educational process-care of the patient. The clinical clerkship, internship and residency programs in medicine have recognized the importance of participation. Judged on this basis, the standard two-day program of sequential lectures may not be the most effective mechanism for continuing education.

Although health care has become increasingly complex with resulting requirements for close collaboration among specialized personnel, our educational programs continue to be designed in a manner which suggests each health professional is functioning independently. Educational programs designed to meet patients' needs

should give consideration to these areas of interrelated function. It is meaningless, for example, to design educational programs for physicians in the functioning and appropriate use of intensive care units without considering the education of the other personnel essential for the unit's operation as well as the availability of the necessary facilities and equipment. It is also wasteful of scarce human and physical resources to carry out such programs where they will not be utilized optimally.

Continuing education by definition implies some continuity to the educational process, yet the continuing education of most individual health personnel today is characterized by the lack, rather than the presence, of continuity. The framework of the Regional Medical Programs provides an opportunity for program design which can achieve better continuity. The challenge is to structure programs which relate not only to current educational needs but which take into consideration the previous educational experiences of the participant.

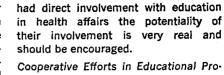
Consideration must be given to other factors which have inhibited effective educational activities in the past such as the problems of time, distance, commitment of available effort to the actual delivery of health care, financial loss, and established habit patterns. Modern technology offers potential for overcoming some of these problems. The use of television, computers, teaching machines, or other applications of modern techniques and hardware is being explored in some places

and many Regional Medical Programs are considering the effective utilization of these educational tools. The comments in this document about design and evaluation are, however, very relevant for educational programs utilizing these techniques. By providing an opportunity to integrate the use of these techniques into a total educational program related to the real educational program related to the real educational medical Programs can help to avoid the danger that these techniques may be developed in isolation from those needs.

Educational Evaluation. Even if the design of educational programs gives careful consideration to the factors discussed, one may anticipate that the resulting programs will not be totally successful in meeting the educational needs. The successes and the failures must be evaluated and analyzed to serve as the basis for appropriate decisions about the improvement and continued renewal of the educational activity. Since resources for continuing education and training are scarce, continued evaluation of educational effectiveness is necessary to assure the efficient use of these resources. As discussed above, the ultimate criterion of effectiveness of an educational activity in health resides in his swiffs ments of change in health care. There are many components, however, of the effectiveness, including the success in reaching the desired audience, effectiveness of information transfer, effectiveness in bringing about behavioral change, and the effectiveness of the behavioral change in improving patient care. These factors need to be assayed at each step in the process for one to understand fully the relative significance of their effect on the ultimate goal of improved health care.

The manpower resources of those who have competencies and experience in educational evaluation as it applies specifically to continuing education and training in the health professions

are limited. One potential resource for advice, counsel, and training is the modest cadre of individuals who have established units of research in medical education in recent years. A resource exists in the colleges and schools of education throughout the country where graduate activities in educational research are being carried out. Although few of these units have



Cooperative Efforts in Educational Programs. In addition to ongoing evaluation and modification of educational programs, consideration must also be given to the development of effective cooperation among the people, institutions, organizations and agencies already involved in the education of health personnel. The development of improved programs requires utilization of their strengths and should, in turn, provide a mechanism for those strengths to expand and grow. Cooperative activity in continuing education and training should become a symbiotic relationship. If possessiveness by any single group occurs, or if monolithic programs are attempted, the benefits of symbiosis will be lost to the detriment of better health care.

The necessity of cooperative efforts for effective continuing education is inherent in the nature of our medical system. It is determined both by the requirements of modern medicine and the patterns of our society. The Regional Medical Program provides a mechanism for cooperative relationships between the medical environmant animarily agriffication of new opment and dissemination of new knowledge and the environment primarily concerned with the delivery of health services. Only if both environments are involved and cooperating will the full impact of continuing education and training programs be made



# The Report of the Surgeon General to the President and the Congress

Prepared by staff of the Planning and Evaluation Branch of the Division of Regional Medical Programs as background to the third discussion session

#### **PREFACE**

The Report to the President and the Congress is set forth as a specific requirement in Section 908 of the Act authorizing support for Regional Medical Programs, as follows:

"On or before June 30, 1967, the Surgeon General, after consultation with the Council, shall submit to the Secretary for transmission to the President and then to the Congress, a report of the activities under this title together with (1) a statement of the relationship between Federal financing and financing from other sources of the activities undertaken pursuant to this title, (2) an appraisal of the activities assisted under this title in the light of their effectiveness in carrying out the purposes of this title, and (3) recommendations with respect to extension or modification of this title in the light thereof."

The purpose and importance of this provision was clearly stated in the following excerpt from the related Report of the Senate Committee on Labor and Public Welfare:

"The bill calls for reevaluation of the program and the submission of a report to the Congress by June 30, 1967. The Committee views this requirement for accomplishments and recommendations of further development as an important and integral part of this legislation. This program provides the op-

portunities for major innovations. It is impossible to say with any precision at this time what the nature, extent, and diversity of these medical complexes will be in the future. We do know that these developments will be closely watched by the Congress and by the American people. The Committee does expect that, as experience is gained, the various aspects of the program may alter to deal with new problems and opportunities and to extend the coverage of the complexes into new communities and situations. The impressive endorsements of the concept give a basis for launching the program as soon as possible, but the final form in all its particulars is not and cannot be clear at this time. Therefore, the need for careful and continuous reevaluation assumes a special importance for this program. The Committee urges that the program be administered at all times with a view toward the identification of productive modifications for submission to the Congress when the extension is considered in the future."

#### INITIAL APPROACH

The Report is a staff responsibility of the Division of Regional Medical Programs. A special Ad Hoc Committee of leaders in the fields of health, education and community affairs was established to furnish expert advice.

The Committee held three meetings between September and November of 1966 to help shape the approach to the Report and identify issues which require consideration. In addition, it was considered important to obtain

the experience and insight of a wide variety of people concerned with Regional Medical Programs through a national conference. One of the major objectives of the Conference is to provide a forum for this purpose and a common frame of reference out of which an additional input of ideas can be secured before drafting the report.

#### **IDENTIFIED ISSUES**

Divisional Staff and the Ad Hoc Committee have identified certain items and issues. These points are set forth on the following pages for discussion during the meeting on January 17. In addition, conference participants are encouraged to identify and discuss issues and topics not included in this paper.

#### 1. Background of the Report

There will be brief discussion of broad trends in science, medicine and education, and social and economic aspects leading to the enactment of Public Law 89-239. The legislative history will be summarized including the Administration's proposal (S. 590 and H.R. 3140), the Senate and House Hearings, and their respective Reports.

II. The Nature and Purpose of Public Law 89–239

#### A. Basic Objective and Purpose

Primary objective is to ensure that persons throughout the country have the benefits of medical scientific advances in heart, cancer, stroke and related diseases. Attainment of this objective is impeded by the gap that exists between scientific advance and day-to-day practice in parts of the Nation.

The fundamental purpose of the Act as formally stated in Section 900 (b) is: "...to afford to the medical professions and medical institutions of the nation ...the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases."

B. Prescribed Mechanism for Attainment of Objective

The prescribed methodology is regional cooperative arrangements among medical schools, research institutions, and hospitals, with broad based advisory committees to insure commitment to broad regional needs and guard against the domination of any individual institution or group.

### III. Progress Report

In accordance with the specifications in Section 908, this Section will report on ⋄ activities supported under the program, ⋄ the relationship between Federal financing and financing from other sources of the activities undertaken, and ⋄ an appraisal of activities assisted in the light of their effectiveness.

- A. Activities under the Program
- 1. Chronology of implementation
- ♦ Bill signed into Law October, 1965.
- ♦ First Council meeting December, 1965.
- ♦ Division of Regional Medical Programs established at NIH February,
- ♦ First applications for planning grants received - April. 1966.
- ♦ First awards for planning grants June. 1966.

- ♦ First applications for operational grants received October, 1966.
- ♦ First national conference on Regional Medical Programs January, 1967.
- 2. Basic data concerning applications received and approved; amount of awards; population served; participating organizations; staffing; nature and variety of cooperative arrangements; feasibility and other studies undertaken, etc.
- 3. Analysis of Major Planning Activities
- ♦ Organization and staffing of planning unit.
- ♦ Collection and analysis of data on resources, problems and needs.
- ♦ Strengthening of communications and relationships among health resources.
- ♦ Development of feasibility studies and proposals for priority operational projects.
- ♦ Arrangements for continued planning.
- 4. Analysis of Major Activities of Operational Programs
- 5. Interregional Developments
- ♦ Multi-State (New England, Mid-West, Rocky Mountain area)
- ♦ Intra-State (New York, California)
- B. Relationship of Federal and Non-Federal Financing
- 1. Resources made available from nonfederal sources for pre-planning prior to grant awards
- 2. Resources made available from nonfederal sources for planning and operations after grant awards



- 3. Estimates of type of non-federal resources likely to be made available in the future
- 4. Policies and procedures for assuring diversification of support
- C. Appraisal of Effectiveness
- 1. Methods of evaluation being developed and applied by Regional Medical Programs
- 2. Data on scope of cooperative arrangements
- 3. Approaches being developed to measure changes in resources and facilities that will extend "opportunities" for applying the latest advances
- 4. Approaches being developed to determine impact of programs on the diagnosis and treatment of heart disease, cancer and stroke
- 5. Examples of "critical incidents" in the development of Regional Medical Programs
- IV. Problems and Policy Issues Requiring Consideration

This section is most important since recommendations for extension and modification of the law will arise from the problems and policy issues which have been identified. Inclusion of an item for discussion in the report does not necessarily mean that a change in the law is indicated.

## A. Continuation of Program

There is considerable and compelling evidence of the effectiveness of the Act in bringing about cooperative regional efforts among the major health resources for the purposes specified in the Act. Attainment of the fundamental purpose of assisting all physicians and medical institutions to bring the

benefits of medical research advances to their patients appears realistic on the basis of early experience. While current legislative practice makes it unlikely that a new authorization will not include a time limit, the Regional Medical Program effort should be established as a continuing program. Such a long-term commitment is particularly important in order to enlist the participation of all institutions and to provide a sound basis for recruitment of high caliber manpower.

#### B. Construction of New Facilities

The original Administration proposals for authority to support Regional Medical Programs included provision for grant assistance to aid both new construction and renovation. This provision was amended in the Congress to limit the definition of "construction" so that only renovation and remodeling costs were eligible for support. The Report of the House Committee on Interstate Commerce stated that "the lack of this authority for new construction should create no serious problems during the 3 years authorized in this legislation and when a request is made for extension of this legislation in the future, the committee will review this question again. . . . "

Experience to date has identified a number of areas in which authority to assist new construction is essential to the development of Regional Medical Programs. Priority needs have been reported for space in community hospitals to conduct continuing education programs and to carry on demonstrations of patient care. Most community hospitals do not include adequate

space for educational programs; acute shortages of patient care and supporting facilities have required immediate attention. The same conditions generally make it impossible to meet the needs for space for continuing education programs through renovation and remodeling.

During the conduct of feasibility studies and pilot projects, Regional Medical Programs have been forced to rent space outside the hospital for the conduct of educational programs and the use of the educational staff. This approach is not only costly but it significantly reduces the impact of these efforts. It is more difficult for many medical practitioners and allied personnel to participate. It is impossible for certain desirable programs to be organized, particularly those involving demonstrations of patient care.

The issue of matching requirements for construction also needs further consideration. Reports indicate that many community hospitals have insurmountable difficulties in raising funds for the construction of facilities for continuing education. There is a danger that a rigid matching requirement in this respect will distort or impede progress toward the achievement of the program's purposes.

# C. Relationship of Federal and Non-Federal Funding

Regional Medical Programs provide, through cooperative arrangements, a broad systematic framework for planning and action. It is recognized that the Federal grant funds should not finance all the needs identified in this process and should not take over total support for the application of all medical scientific advances.

Congress has evinced interest in the amount of non-Federal resources made available to these programs as an index of local commitment and support and as a reflection of budgetary realities. It has been emphasized that diversification of fund support will enhance local initiative and control.

In reviewing grant requests, primary attention is given to the extent and nature of local support. Continuing consideration will be focused on the policies and procedures that are employed locally for ensuring diversification of resources for Regional Medical Programs. It has been felt that a policy placing responsibility at the local level for assuring balanced, diversified support is a more effective and appropriate approach than a rigid matching requirement, particularly in view of the cooperative and innovative nature of this new program.

#### D. Inter-Regional Support Activities

Public Law 89-239 authorizes grants only for the planning and operations of individual Regional Medical Programs. No consideration was given during the development of the legislation to other types of grant support.

Reports have indicated that certain resources and activities to facilitate and support the development of Regional Medical Programs may, in some instances, best be developed on an inter-regional basis, e.g., training of continuing education and other leadership staff, preparation of teaching ma-

terials, standardization of data collection, refinement of evaluation procedures. The available methods of financing of these needed services are often awkward and inadequate.

It has been suggested that modification of the Act to permit grants directly for these "support" activities may be desirable in order to facilitate the development of individual Regional Medical Programs. Proposals for such support would have to be directly related to the achievement of the basic purposes of Public Law 89-239 and would be made only after review and approval by the National Advisory Council on Regional Medical Programs.

#### E. Interpretation of Act

A keynote of Public Law 89-239, in both its legislative and administrative aspects, has been flexibility of approach. The primary purpose of this approach is to place maximum responsibility on local leadership to develop appropriate mechanisms, plans and programs. Administrative guidelines and policies have encouraged local initiative while, at the same time, ensuring the established statutory purposes are pursued. Instead of rigid national directives, heavy reliance has been placed upon the review and evaluation of local program proposals by non-Federal consultant groups, both at the regional level through the Regional Advisory Group and at the Federal level by an expert Review Committee and the National Advisory Council on Regional Medical Programs.

Specific examples of flexibility of approach are:

- 1) The fundamental recognition that attention must be given to developing and maintaining a sound foundation of clinical capability upon which more sophisticated programs can be built. For example, it is recognized that increased accessibility to the most recent advances in cancer treatment is ineffective if there are serious gaps in basic diagnostic and treatment capabilities. Similarly, it is recognized that "improved diagnostic and treatment capability" must necessarily include preventive and rehabilitation activities.
- 2) The establishment of new organizational mechanisms to reflect the cooperative relationships required in the program. One expression of this development is the organization of new non-profit agencies to serve as the coordinating agency for the Regional Program. These new arrangements can involve a spectrum of new administrative and fiscal problems that require innovation and inventiveness for their solution.

On the basis of experiences to date, it appears that flexibility of approach has facilitated progress toward accomplishment of the aims of the program. However, reports have indicated that, in some instances, unreasonably rigid or lax interpretations of the Act and the Guidelines have complicated understanding and action. The question at issue is whether portions of the Act or Guidelines need to be clarified or amplified to insure needed flexibility.

# F. Categorical Emphasis

The legislative history of Public Law 89-239 indicates that the original Ad-

ministration proposal requested authority to make grants to encourage programs of regional cooperation among the major health resources for heart disease, cancer, stroke, and other major diseases. The law as enacted provided for grants to encourage programs of regional cooperation among the major health resources for heart disease, cancer, stroke and related diseases.

The categorical emphasis of the program has been widely discussed. Some have felt that it is not prudent or practical to develop Regional Programs on a categorical basis. Others have argued that the efforts of the program should be exclusively focused on immediate measures to reduce losses from the three "killer diseases"; they have pointed out that the highly complex skills and facilities required to apply the recent scientific gains against these categorical diseases make it particularly desirable to organize such efforts on a regional basis. Others have suggested that the scope of the three diseases and related diseases is so broad that their control necessarily requires attention to fundamental questions of manpower and facilities. The initial period of program development has provided opportunities to test these viewpoints through a variety of experiences.

During the planning phase the major activities undertaken by Regional Medical Programs have involved the establishment of a planning staff, the initiation of studies to obtain the basic data concerning pertinent health needs and resources and the development of co-

operative relationships among the major health resources in the region. These activities are generally generic by nature and consequently have not significantly involved problems of categorical definition. In most cases, in order to plan effectively for heart disease, cancer, and stroke, it has been found necessary to consider at times the entire spectrum of resources available for personal health services.

However, the emergence of the operational phase of the program will put a more intensive focus on its categorical purposes. Only projects that can be shown to have direct significance for combating heart disease, cancer, stroke and related diseases can be assisted with Regional Medical Program grant funds.

The experiences of the Regional Medical Programs will be especially important in determining what modifications, if any, are necessary or desirable on this issue in the legislative authorization. The impact of the categorical limitations on the potential of the Regional Medical Programs to contribute most effectively to improved health of the people and the best use of available manpower and facilities needs to be determined. Similarly, the best ways of facilitating the diffusion of knowledge concerning the diagnosis and treatment of heart disease, cancer, stroke and related diseases needs to be identified. These discussions must take into account the fact that the legislative proposal for extension of Public Law 89-239 will probably request authorization for the program through 1973.





# Section IV-Group Discussions

REPORTS prepared by four group discussion leaders, each of whom represents a different health interest, and

SUMMARY report by Division staff on thoughts and attitudes expressed in the group discussions regarding key issues of the Conference The registrants participated in three discussion sessions held during the Conference. The sessions served as a forum in which participants could freely express their thoughts on the topics which had been underscored in the Issue Papers and in the presentations of the principal speakers.

### REPORT: No Prospects For "Instant" Regional Medical Programs

MONDAY MORNING AND AFTERNOON, JANUARY 16

The twenty-five discussion groups were structured so that the health professions, public and private agencies, practicing physicians, and citizen members of Regional Advisory Groups were represented. The groups averaged twenty persons.

A typical group included representatives from fifteen States, six Regional Medical Programs, and the Advisory Groups of three of these Programs as well as the Program Coordinators of two others. The same group included three medical school deans, a private practitioner, a hospital administrator, a member of the National Advisory Council on Regional Medical Programs, the public information officer from a State university medical center, a member of a State board of health, a staff member from an agency of the Department of Health, Education, and Welfare, and a representative from a voluntary health agency.

The participants brought to their group discussions attitudes reflecting their respective regions, professions, and institutions or agencies. In the sessions they spoke with candor about the issues of the Conference and in the ensuing exchange brought out other matters of concern.

TUESDAY MORNING, JANUARY 17
For the final session the structure of
the groups was altered so that participants of many groups shared the
same interests. In this way, for example, Program Coordinators had the opportunity to discuss problems of mu-

tual concern and to share ideas.

Deans of medical schools, practicing physicians, regional information officers, hospital administrators, and other categorical groups met for the same purpose.

The reports by four group discussion leaders attempt to encapsule the content and preserve the tenor of the sessions they chaired. A staff summary of the problems and policy issues brought up during the discussion sessions is also included.



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Of the several ingredients for a viable and productive group discussion, none is more indispensable than to have at least one participant who has had reallife, three-dimensional experience with the subject under examination. Group four was more than thrice blessed. This optimistic and enthusiastic group included a former USPHS surgeon general, highly sophisticated in health care planning; a former assistant to the secretary of the Department of Health, Education, and Welfare, who had been deeply involved in the development of the legislative program under discussion; and a participant who had been intimately involved, for years, in a successful, ongoing prototype regional medical program. His skillful and objective account of the operation of the Bingham Associates, a regional plan to relate small, rural Northern New England hospitals to a metropolitan medical center, produced an affirmative climate for the discussions. A real tone of optimism and excitement was injected into the proceedings by the fact that for more than two decades a voluntary arrangement had been in effect for physician post-graduate education, improvements in professional staffing, periodic exchanges of key personnel, upgrading of technical personnel and services, and effective mechanisms for patient

referrals, which were all accomplished with no more than relatively modest philanthropic support.

Discussion group productivity can be measured in terms of both the matters discussed and those that, although important, never managed to surface. This exercise covered rather well most of the principal subject areas upon which the conference concerns revolved.

On the issue most vital at this timewhether or not the regional medical program concept should survivethere was no dissent from the position that it was far too early to make definitive judgments which would support a phaseout of the effort. It was well recognized that an "action-oriented" Congress and a highly expectant public were geared to the "instant program" concept and that the energy input requirements to achieve true momentum were far too great to warrant comprehensive appraisal for at least three years. Some felt that 1975 would be an optimum target date for overall appraisal for purposes of continuing or phasing out the program.

How to Change Without Changing?

One reason for the requirement for an extended period of trial for the program needed discussion in depth, but was well repressed. This had to do with the very basic nature of a concept that aims at improved patient care and implies experimenting with different methods for the delivery of health services, but there seemed to be an almost instinctive desire to avoid con-



fronting this essential component of the program in the face of the language of the law, "to accomplish these ends without interfering with the patterns . . . of patient care or professional practice." A careful review of the intent of the Congress to upgrade the operational effectiveness of the health care establishment and, at the same time, declare a state of permanent immunity against any change for the present methods of delivering health services could have been a neat and lasting contribution to the conference. If experimentation with different means to organize and deliver health services is desirable, the program should indeed be continued and a guaranteed life expectancy of the law should be such that an appraisal of the results would be valid from the standpoint of time as well as content.

#### Construction

Experience over the past decade with a host of other programs would lead one to assume that attitudes of the participants would be almost uniformly in favor of generous federal funding for construction of new facilities. This assumption proved to be in error. Several good and valid reasons were advanced for postponing this issue for a couple of years. The one most strongly espoused was that as some of the strong suspicions of one or more of the involved groups are beginning to abate somewhat, it would be the height of folly to reintroduce this feature, which had raised serious doubts about the earlier versions of the bill. It was clear from the discussions that the nature of the program direction in

the operational phase was so indistinct that the addition of a facility construction component would further becloud the issues.

#### Federal and Non-Federal Funding

When the relationship of federal and non-federal funding was discussed the usual doubts were expressed about the slim chances for new outlays by state and municipal governmental units for any reason, even though this program might well prove itself to be most useful and productive. The group did not appear to be sensitive to the fact that patient care, as a process, is presently being funded from a variety of sources and with high dollar outlays. By realigning some of the funds into somewhat different patterns, the necessary local and regional resources to blend with federal funding might well become available without the need to develop new local funding sources.

#### Inter-Regional Relationships

One area where there was total unanimity was the need for the law to be either amended or reinterpreted with respect to the relationships and activities which are sure to develop between regions. Patient care services for population groups normally follow traditional trading area lines. Because so many of these are at complete variance with political subdivision boundaries, substantial efforts will be necessary to maintain productive and smooth working inter-regional arrangements. This aspect of the Regional Medical Program was regarded as sufficiently important to warrant an amendment to

the law with specific funding mechanisms for effective implementation.

The categorical emphasis of the Regional Medical Program seemed to be an area where attitudes of the discussants reflected with remarkable precision the nature of their professional backgrounds. The participants whose occupational orientation was toward program planning for health care felt that casting regional arrangements in a disease oriented manner would be virtually self-defeating. Their own planning in the program had virtually ignored the categories in favor of health care of patients as a comprehensive process. The participants whose background was primarily in the private practice sector were overtly apprehensive when total health care was suggested as the framework for regional medical program planning. It would probably be fair to say that some of them would have felt a bit more comfortable if a single category, such as cancer, had been made the central focus of the planning process. Speculation on the part of the majority of the group centered around the distinct possibility that when the real core issue was faced, i.e., the operational phase of the program, it would be virtually impossible to maintain any real semblance of a categorical approach.

#### Continuing Education

The nature of the discussion on continuing education has been purposely left until the last, because this subject was interlaced throughout the three sessions and seemed to be the one on which most of the participants claimed

at least a bit of expertise and concerning which there were some strong and fixed feelings. It is entirely understandable why groups, such as this one, should seize on such an area and tease away at it, if not continuously, at least repeatedly. Continuing education is a subject that is uppermost in the minds of both academicians and practitioners, for each is forever reminding the other that there should be more to it and it should be better. The chairman attempted to probe precisely what was meant by "continuing education," what its content should be, how content should be determined and tested for validity, by whom and how often reviewed. It was further asked, "What is the proper setting for this educational process? How will the results be appraised? What kinds of tools and techniques are needed? How can they best be utilized?" There was as wide a disparity in responses to these questions, in this setting, as there has been on the national scene where it may not be much of an overstatement to call present efforts something of an educational wasteland.

In spite of the generally expressed doubts as to both the goals and the techniques of contemporary continuing education programs, many of the participants were willing, even eager, to settle most of the efforts, funds and hopes for the regional medical program concept on this one area, which both the medical education establishment and practitioners readily agree is important and essentially nonthreatening to existing patterns of the delivery of health services.

#### Flexibility—the Real Challenge

Withal, the discussions pinpointed the flexibility which is intrinsic in the programs and served to assure participants from widely separated regions of the country that the potential for imaginative and innovative thinking at the local and regional level is the real challenge of the legislation. The conversations reflected further a sense of relief that no single area of the country had either a corner on planning competence or any magic potions that could produce a live, effective, "instant" regional medical program.

More than anything else, the conference brought together individuals with widely diversified backgrounds, objectives, attitudes and motivations for a day and a half of ventilation, idea exchange and speculative conversation. As the chairman said in summarizing the conference, "Regional medical programs have brought together strange bedfellows; however, they are still a bit reluctant to turn out the lights."

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The discussion in group 5 was conditioned somewhat by its composition. It consisted of the coordinators of all regional programs approved to date. The opinions expressed were based in some operating experience, however slight, and covered most areas of the country.

#### Construction Funds

The coordinators did not exhibit a consensus on the important matter of construction funds as part of any revision of P.L. 89-239. Most were agreed that the housing of central facilities and administrative staff was a functional necessity in regional programs. But, rather firm differences were expressed on the matter of how to finance such facilities and where to place them. There were clear indications that the relationships fostered thus far between medical schools and practitioners by RMP were still rather precarious. Construction of an RMP facility on a medical school campus would reinforce the fears of the practicing profession that the program will become medical center dominated.

Both practitioners and medical school representatives, however, felt that

there was a real need for construction of facilities at community hospitals to implement programs of continuing education. Whether this should come from Hill-Burton funds, the hospital itself, or a revised RMP law was not agreed upon and no firm recommendation was made. The impression was clear that if the concerns of the practicing profession could be allayed, construction funds would indeed satisfy an important functional need not presently met by rental, renovation or Hill-Burton funds.

Relationship of Regional Medical Programs and Comprehensive Health Planning Legislation

A matter of obvious concern for all the coordinators was the present and future relationship of P.L. 89-239 and P.L. 89-749. Very few were familiar with the details of Comprehensive Health Planning legislation. One urgent need seemed to be for each coordinator to have as much information as soon as it is available. The group apparently felt that much depends upon the agency selected to administer P.L. 89-749 in any state. In those regions involving cooperative arrangements which cross state lines, there was genuine concern that confusion and conflict would occur if Comprehensive Health Planning were assigned to state health departments.

The need to coordinate the efforts of these two pieces of legislation at the national level was seen by all. Further questions concerned better definitions of relationships of Regional Medical Programs to all Public Health Service

programs and to Hill-Burton programs.

Most coordinators seemed to feel that their present efforts under Regional Medical Programs would eventually evolve into comprehensive planning even though the present effort is categorical. As "related diseases" are gradually included in RMP planning and operation, they thought some means of interdigitating with CHP would become essential at local as well as national levels.

Some of the coordinators indicated that in their states RMP and CHP might be handled by the same body. Others suggested interlocking boards as providing a reasonable means of communication and coordination.

One view held that RMP should be limited to demonstration and that it should turn its programs over to CHP when they are fully operational. Another opinion stressed the importance of RMP even in the presence of a well developed CHP. Under these circumstances, many said, the categorical approach would be an advantage since it covers a more manageable and easily identified set of disorders.

The coordinators were unanimous on a number of points:

#### Increased Communication for Unified Cooperation Action

All expressed a need for continuing contact with each other under the auspices of the RMP staff. Regular meetings were recommended to provide each coordinator with the benefit of experiences in other parts of the country and afford a ready means of

ongoing evaluation of methods and procedure. In addition, such meetings would impart some sense of unity to the entire program and facilitate interregional cooperation.

The program coordinators expressed the need for an organ of communication with the RMP Washington staff. A newsletter informing all coordinators of matters of immediate concern—like developments in CHP, awarding of grants, etc.—was suggested and welcomed by all.

A meeting between representatives of the Comprehensive Health Planning group and the program coordinators was strongly urged and is recommended unanimously to the staff of RMP.



### Inter-Regional Coordination

Some form of inter-regional coordination was considered desirable by many of the coordinators. Some have already engaged in such meetings with programs in contiguous areas. Support for other inter-regional activities besides meetings was acknowledged by some. Such support might be used to encourage inter-regional evaluation efforts to enable the sharing of scarce personnel and to foster compatability of computer programs and information networks.

#### Categorical Emphasis

The present categorical emphasis of RMP apparently has not produced any serious problems to this point. Most coordinators felt that at this time there is sufficient flexibility to permit rather broad planning.

No strong impressions were recorded on the functions and responsibilities of Regional Advisory Groups. Apparently the coordinators are feeling their way and trying to meet the requirements of the legislation in a variety of ways suited to local requirements.

There was general satisfaction with the law as now drafted and a general consensus that the program was too new to sustain drastic changes. The general nature of the present law permits the high degree of flexibility which each coordinator apparently feels is essential in evolving a program which meets the specific needs of a particular region.

### **REPORT: Practicing Physicians**

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Discussion group 13 was made up, in general, of doctors in the private practice of medicine with strong representation by the presidents of organizations representing men in practice. Most of the discussants had come to Washington to criticize the program, not to praise it. Initially, there was the usual ritual of damning all federal programs but in this group it was carried on with more ceremony than meaning. Most of the group had a clear idea of what the program is about. A minority had a distorted view.

Pervading the meeting was the overall feeling that though those present were certainly critical of the program they were also cognizant of a need for change and were willing to consider any reasonable proposal. The contributions to the discussion were concerned with the major problems of the program and scant attention was paid to petty issues and personal idiosyncrasies.

#### Continuing Education

Continuing education was discussed at length by the group and though nearly all felt that it was needed, no one seemed to have a clear idea of methodology. Motivation of the private

practitioner for continuing education seemed to be the key issue as seen by this group. They felt that this was a more serious problem for physicians than for paramedical personnel where motivation can more easily be supplied. The group felt funds for training paramedical personnel were a necessity.

#### Cooperative Arrangements

Cooperative arrangements were mentioned by several, noting that this law has given impetus to many cooperative arrangements not previously made. Several had noted the frequency of meetings among health officials, hospital administrators, practicing physicians and lay health organizations. The demonstrations of patient care section of the law was applauded. The men in practice felt this was still the best known method of continuing education.

#### Evaluation

A surprising aspect of the discussion was the sophistication and concern relative to evaluation of the program. Most felt that an unexamined program would be worthless and that meticulous care should go into new ways and means of evaluation, and that the results of each region's experiences should be shared by all. The majority felt that the program must be proved valid before long term extension can be advised. On the other hand, it was agreed that several years should elapse after operational programs are under way before a pertinent analysis can be made. No one in the group seemed particularly concerned or anxious about the ways and means of evaluation. No one mentioned the possible invasion of the privacy of practice and it seemed the paramount issue was improvement in patient care.

A less surprising, but unexpected, turn of the discussion was toward the dollar value of the program. The group dealt with the problem unemotionally and reiterated the need to show the economic advantages of this program over others. Several felt that the designation of regions allowed for better administration of the program and that the federal government should vouch-safe quality control.

#### Categorical Emphasis

The categorical emphasis of the program seemed agreeable to most of the discussants. The views expressed were those relating to a need for limited and workable programs in the disease categories cited in the law.

#### Construction

The majority of the group was not in favor of requesting construction funds at this time. The reasons were several, i.e., too expensive, adequacy of present construction authority, the fear of a change in the emphasis of the program, and the quality of patient care should have priority over buildings.

#### Other Items

Some general philosophic questions arose. The question of timing was discussed. Some felt that this program

might be 10 years ahead of its time. Others felt that we should wait until the medical manpower situation had improved before continuing the program.

The question of non-federal financing was brought up briefly. It was felt by several that local initiative and sharing of cost was a superior arrangement to 100% grants.

There was a near consensus on the inadvisability of changing the law in any important area at this time. The group felt that it was too early to give a valid judgment and that they would like to see the law continued long enough to make a proper evaluation. In general, they felt that the law as it is parallels other federal programs that are directed in large part toward directly affecting patient care, rather than indirectly affecting it through research.

In summary, the group was in favor of extending the law virtually unchanged. They were not in favor of a request for construction funds. They were concerned about program evaluation, the cost dollar, and new ways to motivate private practitioners toward continuing education.

# REPORT: Interpretation and Administration of the Act

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The flexibility that is evident in the enabling legislation and the initial administration of the Regional Medical Program for Heart Disease, Cancer and Stroke apparently is conducive to individual initiative and hopefully, innovative solutions in the several regional programs. The participants expressed satisfaction, even enthusiasm, for the permissive features of the program. If there was any manifest anxiety about the present approach it came from some allied health professions and voluntary health agencies who would advocate the use of guidelines or regulations to assure inclusion of their particular group.

At this admittedly early stage in the life of the program, group 6 demonstrated few if any tangible evidences of the possible benefits of the permissive approach in the form of truly creative regional planning. None of the programs represented defined specific integrating methodology or concepts that held promise of delivering on the original vision of regional arrangements.

### Creativity

This estimate must be strongly tem-



pered by knowledge that few programs had full-time staff, acknowledged leaders, or time to develop agreement on real or tentative plans. Even with the passage of time and with the emergence of structure and leadership it must be assumed that highly successful new regional arrangements for the diseases under attack will be rare events. It would therefore seem wise to construct a superb educational and intelligence system to spot these valuable rare events as they emerge and to rapidly permit others to hitchhike on the originators' successes. If permissiveness is next to godliness, so is plagiarism next to originality.

Categorical Emphasis: "We can live with it if you don't enforce it."

The Regional Programs' avowed purpose of breaking down old inhibitions to the rapid diffusion and application of discovery to everyday medical care coupled with the programs' retention of hardened categorical disease emphasis may seem inconsistent. It would indeed be inconsistent were it not for enlightened administration of the Regional Programs thus far. Our group did not dispute the political, social, or perhaps even the biological wisdom of focusing this effort on cancer, heart disease and stroke. They didn't wholeheartedly support it either -they accepted it. They accepted it on the premise that this is a realistic way to achieve a difficult objective.

It is important to recognize the context in which this endorsement was given. It was given passively, without consideration of the question: Should

the categories be hardened rather than softened? It might be speculated that there was unspoken and perhaps naive belief that greater categorization just couldn't happen.

Money, Sharing, and Continuity

Payment mechanisms outside Regional Medical Programs do not exist for starting or sustaining a program of this scope. Money as an incentive to begin and to continue will be necessary.

There was general support for the ideal of a partnership between the private and public sectors in financing the Regional Medical Programs. Some expressed skepticism that private support would be more than token amounts until ideas proved themselves and took their place along with other functional elements of the health care system.

The medical school deans in particular were outspokenly reluctant to start a program without some assurance of continuing but not necessarily spiraling financial support.

Random but Important Thoughts

Information systems are critical to the program. The contents of the Blue Cross information system are available to the program.

There is not such a great disparity between the physician and new methods as there is between the needs of people and the demand for medical care.

### **Staff Summary**

#### Group Discussions:

**Problems and Policy Issues** 

- ♦ Continuation of the Program
- ♦ Construction of New Facilities
- ♦ Relationship of Federal and Non-Federal Funding
- ♦ Inter-Regional Support Activities
- ♦ Interpretation of the Act
- ♦ Categorical Emphasis

#### Continuation of the Program

Discussion of this issue focused on the progress made in the development of cooperative arrangements, and on the potential for future progress. The consensus seemed to be that although the ultimate effectiveness of the program cannot be accurately determined at this early stage, progress to date appears promising and that the program has great potential. The discussions concerning current needs and desirable programs indicated there should be a continuation of the program.

It was generally felt that the present 3-year authorization will not provide enough time to put adequate regional programs into operation. It was pointed out several times that with only two years of the present program remaining, it is difficult to recruit personnel of the quality needed to insure the success of regional programs. Several statements were made to the effect that it will be 5 to 7 years before Regional Medical Programs will affect patient care widely.

Some practicing physicians felt that the gap between medical knowledge and practice had been exaggerated, and that the contemplated level of funding for Regional Medical Programs seemed high. Some misunderstanding of the program was also evident, as fears were expressed concerning the development of regional medical "centers" to which patients would be directed.

At one session there was extensive discussion of the need for continuing planning activities as part of the operational phase of regional programs. There was uncertainty about long-term support for planning activities in contrast to "action" programs. It was stated that rushing into the operational phase of a program without careful planning could prove detrimental in the long run.

On the assumption that Congress will extend the life of Regional Medical Programs, several factors were discussed as being important to its success:

- ♦ Advisory Committees must be deeply interested and actively involved.
- ♦ Regional programs must not be regarded as merely a means of setting up medical complexes.
- ♦ Active participation of practicing physicians is essential.
- ♦ Proprietary hospitals should be included in the program.
- ♦ Adequate support must be acquired from State and private sources.

In one group it was emphatically stated that local advisory groups cannot effectively establish priorities or make decisions without some indication of the dollar amount available to the region. It was recommended that minimum operational funds be allocated to

the regions. The group felt that such allocation is necessary in order for each region to receive a fair share of available Federal funds.

Nearly every group discussing the topic related continuation of the program to (1) the need to resolve the relationship betwen Comprehensive Health Planning (P.L. 89-749) and Regional Medical Programs; and (2) whether the scope of Regional Medical Programs should be categorical or comprehensive.

#### Construction of New Facilities

Comments on the need for construction authority covered a wide spectrum. No clear-cut majority "for" or "against" construction emerged. This issue clearly posed a dilemma for many. Some of those who saw a clear need for and philosophically favored construction, argued against it on pragmatic grounds. They felt that planning was not far enough along across the country to build a good case for such authority. Some felt that a clear idea of the types of facilities which will be needed when programs are established has not been developed. Others had reservations in connection with how this would affect the funding of other construction programs such as Hill-Burton and how Regional Medical Programs would coordinate with them.

References were made by those not favoring separate RMP construction authority at this time to the fears "construction" would arouse on the part of practitioners and community hospitals. It could revive the "centers" concept,

which has not yet been laid to rest, and accentuate the town-gown split. Others felt that construction needs could be adequately met under present programs, through changes in existing authorities, or through more extensive use of the construction possibilities under the present RMP authority.

Among those who favored construction authority, either now or in the future, the need was recognized for specific facilities which fell into four broad categories:

- ♦ For continuing education and training purposes. The needs of community hospitals in this regard were particularly stressed and included the upgrading and expansion of laboratory facilities to be used in training paramedical personnel. However, needs of medical schools for postgraduate facilities were also mentioned since no money is available for these under existing programs.
- ♦ For specialized facilities for demonstration purposes necessary for both continuing education and up-grading of care.
- ♦ For central or core facilities such as computer and tele-communication centers.
- ♦ For housing administrative staff.

Most of the alternatives to RMP construction were viewed as providing only partial answers. For example:

♦ Renovation is frequently not possible. Many hospitals, especially smaller ones, do not have any "excess" space. The same is true, though to a lesser extent, for certain medical schools—new ones and the "have not's."



Rental might in large measure meet the needs for office space, but not for specialized facilities.

♦ Hill-Burton is not really a viable alternative—the funds are insufficient and matching would be a very serious obstacle.

In sum, the reactions of the discussion groups were mixed. Many Conference participants recognized that new facilities would be necessary to accomplish the objectives of Regional Medical Programs. But the question of "when" and "by what mechanism" such construction should be supported turned out to be the real issue.

## Relationship of Federal and Non-Federal Funding

The question of Federal and non-Federal funding was discussed by most of the groups, with few strong feelings as to how the problem should be solved. Most of the groups agreed to the principle that the private sector must supplement and complement the funds provided by the Federal sector; that sharing of costs increases local initiative and forces a greater commitment to the program. In this connection, the large investment of time and money by interested individuals and organizations in developing applications was cited as evidence of such a commitment.

Several discussants recognized RMP funds as "seed money" but each discussant came to a slightly different conclusion about it. One individual insisted that it be clearly understood that pilot programs must ultimately

become self-supporting. This would not only bring in local funds, but would phase demonstration projects into the overall system of local health services. Concern was expressed, however, that support might be withdrawn prematurely and projects abandoned. In this same connection the apprehension was expressed that Regional Medical Programs might prime the pump and then leave regional resources to support the cost. It was noted that local money would be obtained more easily if the operational projects were of obvious benefit to the public.

The problem of providing a mechanism for coordinating multiple financing was discussed by some participants. One group recommended that the regional core receive full Federal support, while the operational projects would be funded on a variable matching basis, depending on the local resources available. Others suggested that there was merit to partial local funding of the core unit.

Some discussants related funding to the view of Regional Medical Programs as an interlocking, collaborative effort. This view holds that in order to coordinate funding, RMP must define the principles governing the distribution of funds, possibly by defining more clearly the role of the various interested groups involved. Some voluntary health agencies were participating, for example, but were concerned about losing their identity in the program.

Specific matching requirements were generally opposed, with the feeling that developing cooperative arrangements might be destroyed if these were required. The concept of a flexible, balanced support mechanism seemed more desirable. If construction authority was approved for the program, then more specific requirements relating to construction might be developed.

#### Inter-Regional Support Activities

The need for interregional cooperation was recognized by virtually all of the discussion groups. Some felt this need should be met by informal relationships among the regions, while others felt new mechanisms to support interregional activities should be developed.

Interest in this area is indicated by the number of interregional conferences already held, including a regular series in the Northern New England-New York area, meetings of Ohio Valley regions, and others for the Western States. In the Northern New England region, a formal interregional relationship has been developed for data gathering and communication.

It was generally agreed that regional boundaries are not yet firmly delineated, and that they should remain flexible in order to respond to future developments. In addition, since regional boundaries do not lend themselves to cope with all the health problems of an area (e.g., regional distribution for patient care is not necessarily the same as for education programs), flexible regional boundaries and strong interregional cooperation are useful and necessary.

The discussion of grant support for certain interregional activities brought forth a number of advantages which might be derived:

- ♦ Interregional communication and the sharing of regional capabilities and strengths would be encouraged.
- ♦ Scarce, skilled manpower and other specialized resources would be more effectively utilized.
- ♦ Comprehensive evaluation on an interregional basis could be developed.
- ♦ Communication and computer networks could be made compatible.
- ♦ National leadership and coordination might be developed.
- ♦ Such efforts would contribute to maintaining the flexibility of regional programs.

The most frequently mentioned activities recommended for interregional support were:

- ♦ Education, including programming, via TV, radio and telephone.
- Development of compatible hardware, including computers and communications networks.
- ♦ Data collection, including the establishment of compatible techniques related to disease patterns and medical care administration.
- ♦ Development of interregional systems of evaluation to effectively identify national as well as regional trends.
- Research programs, including operations research, studies of manpower and facility utilization, and studies of health needs of minority groups.
- ♦ Development of interregional facilities and resources.
- ♦ Information exchange systems among regions.

#### Interpretation of the Act

There were a number of issues brought up which reflected either: (a) confusion about and misinterpretation of the Act; and (b) suggestions for clarification or improvement of the legislation or guidelines.

The phrase, "the opportunity of making available to their patients the latest advances," caused some confusion. Among various interpretations, it was taken to mean that Regional Medical Programs would support basic research, diagnosis and treatment to the exclusion of prevention and rehabilitation, and research in the delivery of health services or actual improvement in such delivery.

Questions were raised about the requirement that the program not interfere with patterns of financing, patient care, or professional practice. It was pointed out that changes in patterns of patient care are obviously going to occur as the program is implemented and that the whole purpose was to bring about a change. It was stressed, however, that the program would not change the physician-patient relationships per se.

In connection with Regional Advisory Groups, it was suggested that a clearer delineation of responsibility be defined for these groups. The word "advisory" seems a misnomer, since the Guidelines state that the group is empowered to approve or disapprove projects. Some commented that the program has not placed enough emphasis on public or consumer representation. Whether Regional Advisory

Group members may represent more than one of the required categories was also raised as a question.

It was felt that the program needs health manpower training provisions with emphasis on paramedical personnel training. There is uncertainty about what can be funded by RMP in this regard.

The role of the practicing physician in the program was stressed, noting that it is through him that individual patient care is improved. For this reason many believed the practicing physician should be closely involved in the development of the program. It was recognized special provisions may be necessary to reach those physicians with no hospital affiliation.

There was some confusion as to whether local programs were intended to become self-sustaining after the planning phase, or whether they could expect continued Federal support. Would funding be limited to experimental programs, or would wide-scale demonstration projects be supported?

It was felt that RMP should build evaluation into the program. There was some suggestion that RMP offers many avenues for setting the criteria for improved patient care, possibly by providing guidelines listing indices and their applications for evaluating programs.

## Categorical Emphasis

Discussion on whether the categorical emphasis of Regional Medical Programs should be retained or eliminat-

ed covered the entire spectrum of possibilities. The consensus, however, seemed to be in favor of retaining the categorical limitations, at least for the present.



Reasons for retaining the categorical limitations ranged from questions of proper timing to outright opposition to broadening of the legislation. A number of participants felt it might be premature to modify the law: heart disease, cancer and stroke are major problems and they will provide further experience as to how the program can be expanded: let RMP take hold as a concept and an approach; don't confuse progress by introducing questions about disease categories now. In relation to this, it was felt that there was plenty for RMP to do within its present categorical limits. Some offered the opinion that RMP would be overburdened if it had other major diseases to deal with.

Some felt there was no need to end the categorical limitations now, although they assumed that the scope of the program would inevitably be broadened; if the concept of cooperative arrangements proved to be a valid one for heart disease, cancer and stroke, it would be a valid concept for other diseases.

It was stated that the cooperation of the practicing physician is essential to the success of the program, and that categorical limits on the scope of the program were and may still be very important to a large segment of the practicing physicians. There was also some discussion of whether "related diseases" should be defined. It was recognized that some medical groups wanted definition of these "related diseases," but most of the groups

seemed to prefer leaving this undefined and up to local judgment.

Those who favored broadening the legislation felt that the emphasis of Regional Medical Programs should be upon effectively coordinating diverse efforts to improve the Nation's health and upon raising the quality of medical care delivered to the patient wherever he resides. It was stated that these goals necessarily transcend categorical limitations. This group felt that the program should expand to include the entire spectrum of health care in the framework of regional cooperative arrangements: at the least, the law should be changed to read "and other major diseases."

Fear was expressed that if the program were limited to heart disease, cancer and stroke, this would only lead to further fragmentation in the health field. The fundamental need for everyone to have comprehensive health services was expressed, with the view that categorical limitations are a step backward. Planning of Regional Medical Programs should be approached in terms of patient needs.

Although one group did not consider the categorical limitation a hindrance to good regional planning, they did see it as a problem in developing practical and completely "economical" operational programs. Certain of these programs, such as continuing education, are sure to extend beyond the categorical limitations imposed by the present legislation. It did not seem prudent, therefore, to limit use of RMP operational grants on a narrowly categorical basis.



# **Section V**—Excerpts From Post-Conference Letters

All participants were urged to express their opinions not only during the Conference itself but afterward by letter. Many did, and in doing so helped the Staff obtain a clearer picture of how Regional Medical Programs are viewed at the "grass roots" level.

#### ... REGIONAL ADVISORY GROUPS

Much concern regarding the structure, the representation, the veto power, and the tenure of the Regional Advisory Committees was expressed. . . . Several regions jumped the gun, appointed advisory committees which took charge of the whole situation with almost complete disregard of important segments of interested groups within their areas.

There was much concern expressed of the tenure of these Regional Advisory Committees for many reasons. There is no law or regulation limiting the tenure of these committees and they can and probably will be self-perpetuating. There was a strong feeling that these committees be subject to rotation and limited tenure such as in the case of our Advisory Councils at NIH.

Cornelius H. Traeger, M.D.
Practicing Physician
New York City and
Member, National Advisory Council on
Regional Medical Programs

It is necessary to include more laymen in all stages of the program, particularly as members of the Advisory Committees.

Many feel that private practitioners have been excluded by either the medical schools or the State health departments. The private practitioner should be represented on the planning council in every region. Particularly should this representation be from the State, county, or city medical association

when the grant is not made specifically to that organization.

Darrell C. Crain, M.D. Delegate, D.C. Medical Society Washington, D.C.

The present advisory groups associated with Regional Medical Programs should be strengthened by more extensive lay representation. In my opinion the legislation should encourage active participation by business and consumer groups not excluding the insurance industry which serves as trustee for some hundred million consumers.

James F. Oates, Jr.
Chairman of the Board
The Equitable Life Assurance
Society of the United States

The medical schools of the country may have too important a role in this program.

P. M. Huggin, M.D. Medical Director East Tennessee Tuberculosis Hospital

Missouri RMP has found that community cooperative arrangements are facilitated by requiring each project proposal to provide for a community coordinating committee composed of representative health profession and lay leaders and vested with decision-making responsibility.

There appears to be evidence that the contributions of regional advisory

groups to a certain extent parallel their responsibility for decisions.

George E. Wakerlin, M.D., Ph.D. Program Director Missouri Regional Medical Program

The possibility of giving authority and responsibility to Regional Advisory Councils to establish priorities in grants, before grant applications go to Washington, was discussed. I believe that Regional Advisory Councils already possess this authority. Some guidelines from Washington indicating that they were expected to do this sort of thing would make their discussions and decisions much more meaningful. I believe that ours would be willing to accept this responsibility.

Russell C. Mills, Ph.D. Program Coordinator Kansas Regional Medical Program and Associate Dean, University of Kansas Medical Center

I want to take this occasion to congratulate you on the Conference on Regional Medical Programs held in Washington on January 15-17. It was an impressive assemblage of talent, the Conference addressed itself to an important problem, and I felt all of us learned much from the proceedings. As a member of your Review Committee, I have had a chance to think quite intensively about the program. I thus thought I might try to spell out some of my thoughts about the role of the Regional Advisory Groups in planning

and implementing operational grants for particular regions using some of what I have learned in our sessions. I am writing this letter, however, as an individual physician in the program.

it seems to me that one of the significant strengths of the current legislation is the clear fixing of responsibilities for health care planning and programming in the hands of Regional Advisory groups who are individuals identified with and committed to the region they serve. It is this facet of the program which makes it distinctly different from systems tried in other countries where responsibilities for the decisions about the delivery of health care have been progressively centralized. In watching dynamics in different regions to date. I am encouraged by the fact that various health groups are beginning to really talk to one another for the first time, to explore the actual needs in their area in a thoughtful and responsible fashion, and to design research programs to determine what kind of health care is required and how it can be delivered. These groups are beginning to take real pride and pleasure in mutual cooperative efforts designed to create better medical care.

I realize, however, that unless the Review Committee is terribly clear about its function, it runs the risk of making centralized value judgments about what is "important" in this or that program within a region. As planning and operational grants are reviewed, the Review Committee will become progressively more sophisticated. This

may cause it to develop unwittingly some rigidity about what is needed in regional programs. I thus hope that this group will try to keep the initiative in the hands of the region and carefully avoid making specific judgments regarding operational priorities or specific items within the context of individual proposals. To do so would create the hazard of making each regional program resemble every other—precisely the thing which the legislation is designed to avoid.

I thus believe that all involved must keep in mind that the only centralized responsibility to judge is whether a region does or does not understand the concept of a regional program, whether its advisory group has real commitments to it, and whether they are moving to obtain the kind of personnel who will plan broadly and imaginatively for the regions that they serve. Decisions regarding priorities for specific projects, what particular programs would be most profitable for an area, what data will be required to mount an effective program, etc., should and must be decided by the region. Clearly, the Regional Planning and Regional Advisory groups must feel true responsibilities for both the design and the ways of implementing their particular program.

I felt your conference went far to clarify this important, indeed, central thesis, upon which regional programs should rest. It is an exciting new concept and will make important and, I believe, profitable changes in the ways

in which we serve the health needs of I note the lack of any official reprethe American people. sentation from any voluntary health

David E. Rogers, M.D.
Professor and Chairman of the
Department of Medicine,
School of Medicine,
Vanderbilt University and
Member, Regional Medical
Programs Review Committee

#### ... THE REVIEW COMMITTEE AND THE NATIONAL ADVISORY COUNCIL

Voluntary health agencies are not specifically represented on any of the committees which comprise the review process for Regional Medical Programs. Insofar as the American Heart Association is concerned, I realize that on most committees there are individuals who for one reason or another are strongly oriented towards Heart. Even so, I hope that in the future when vacancies occur on these review committees that representation of the appropriate voluntary health agencies will be considered.

Lewis E. January, M.D. President American Heart Association

I was distressed by the lack of any emphasis or consideration of the role of voluntary health agencies as full partners in the development of "cooperative arrangements." I note the lack of any official representation from any voluntary health agency in the Regional Medical Program National Advisory Council, the RMP Review Committee, or the Consultants representing National Advisory Councils with related interests.

While it is true that advisory committees to planning groups have representation from the American Heart Association and the American Cancer Society, these are inevitably isolated and fragmented and not capable of bringing to bear the full organizational strength and capabilities of the voluntary health agencies.

How important it would be to utilize fully this wealth of dedicated individuals in a systematic organized manner to bring into reality more quickly and completely the goals of Regional Medical Programs.

W. A. Krehl, M.D., Ph.D. Director, Clinical Research Center University Hospitals University of Iowa

. . . IMPROVED COMMUNICATION ABOUT THE REGIONAL MEDICAL PROGRAMS FROM NATIONAL SOURCES

My general impression from the conference is that one of the biggest problems is the dissemination of information both by regional planning groups and at the national level on what is being done, particularly to

those who are not participating either locally or nationally; this would do much to alleviate the effect of rumors and false notions regarding the program.

Edwin P. Jordan, M.D. Executive Director American Association of Medical Clinics

A newsletter should be developed by your Division which could keep all of us informed as to the progress of the program. This newsletter could also point out some of the obstacles that may have been encountered and how these problems were solved.

Information meetings held periodically perhaps on a regional level might be very helpful as the program develops.

Guy F. Robbins, M.D. Director of Planning Memorial Sloan-Kettering Cancer Center

I would like to emphasize the importance of Dr. Vernon E. Wilson's suggestion concerning the dissemination of information with regard to the manner in which individual regions are proceeding with their work. The "Newsletter" that Dr. Wilson suggested would be extremely helpful.

J. S. Denslow, D.O. Kirksville College of Osteopathy and Surgery Kirksville, Missouri

# ... EVALUATION OF OPERATIONAL ACTIVITIES

Some regard evaluation as one of the chief strengths of the program—

The evaluation effort holds the greatest responsibility and challenge for the future. RMP staff should draw together those interested in evaluation from the several regions, so that they might be in contact. This could also encourage a uniformity in data collection that would make one program comparable to the other in the future.

James E. C. Walker, M.D.
Professor of Medicine and Society
School of Medicine
University of Connecticut

Research in the area of patient needs and how best to meet these needs, modes of practice, use of allied health professionals, specific and new educational processes, is greatly needed and should be specifically stated.

By title, the Act is disease-oriented. You have noted that it should be patient oriented. Here I think greater precision in the definition of goals would be valuable, both as a guide for the future and as a healthy exercise for the administrators and educators working them out.

E. S. Bowerfind, Jr., M.D. Assistant Professor of Medicine University Hospitals of Cleveland

# Others are dismayed by the complexity of the process of evaluation—

My opinion after a lengthy discussion was that we might have to forego the Regional Medical Programs for lack of adequate methods of evaluating our progress. I do feel that an obviously good program should not die for lack of ultra-sophisticated methods of measuring progress even though one of the most encouraging aspects of the Regional Medical Programs is this obsession with quality production.

Guy D. Campbell, M.D. Program Coordinator Mississippi Regional Medical Program

It is impractical for each region to develop its own methods for evaluating care and for documenting the effect on delivery of care of Regional Program activities. Methods of evaluation could more reasonably be developed as research programs in a few regions and then be made generally available.

The voice of practicing physicians at the Conference seemed rather faintly heard.... Future legislation should be acceptable to physicians and to the AMA, for without their active support and enthusiasm, a great barrier will exist between the Regional Program and its goal of improving patient care.

Charles P. Summerall, III, M.D. Secretary South Carolina Regional Advisory Group and Acting Regional Program Coordinator

#### ... NEW CONSTRUCTION FOR REGIONAL MEDICAL PROGRAM PROJECTS

Planning is not far enough along-

I do not think any major changes are needed in P.L. 89-239 this year. It is simple, permissive and allows wide latitude of support for planning and operating activity.

I do not think an attempt should be made . . . to provide money for new construction. From what I heard in Washington, planning is not far enough along across the country to build a good case for such money and a poor case would tend to cast doubt on the value of the total program.

Henry T. Clark, Jr., M.D. Planning Director Connecticut Regional Medical Program

To me, this program has tremendous potential to upgrade the caliber of medicine in our country. However, I don't want to consider changes in category, financing or construction until experience with the present program clearly shows the need.

W. J. Hagood, Jr., M.D. Little Retreat Clinic Clover, Virginia

Brick and mortar authorization will open the door for construction of regional "centers"—

Following the plenary session at which Dr. DeBakey spoke of construction,

several members in attendance were a bit unhappy. Apparently they felt much as did Dr. Hudson about the construction of large centers to which patients would be referred. They felt that the only function of the doctor in the field would be to beat the bushes to find people who needed referral.

William H. Raymond, M.D. Member, Albany Regional Advisory Group

The proposal for developing actual brick and mortar facilities for health care is beyond the scope that this program should now be considering.

Hector W. Benoit, Jr., M.D. Member, Missouri Regional Advisory Groups

I was quite concerned about the possibility that attempts might be made to modify P.L. 89-239 in this session of the Congress. In my opinion, this would be a strategic error since many of us have just now been able to reassure the uneasy private practitioner segment and other groups that the Regional Medical Program was not a Federal enterprise, the nature of which was going to be dictated from Washington.

Basically, I would oppose at this time an inclusion in the law of funds for construction of general facilities relating to the Regional Medical Program because most of us do not yet have a clear idea of the types of facilities which will be most suitable when our programs have been fully developed.

... On the other hand, there are some impoverished areas of the country where serious problems exist and where able people are struggling to cope with them.

Marc J. Musser, M.D. Program Coordinator North Carolina Regional Medical Program

Space is needed for continuing education and for administrative activities—

We wish to particularly encourage your support of legislation which will allow new construction. There is a need within the Medical Center and Community Hospitals for office space and for facilities devoted to education and training.

The Medical College hopes cost sharing will not be required, for if construction funds are awarded contingent upon matching funds being available, it might be impossible in many cases for the construction to take place.

Frank M. Woolsey, Jr., M.D. Program Coordinator Albany Regional Medical Program

If additional construction authority and funding seems necessary in the health care field, it should be thought of in terms of multipurpose facilities (general health care, professional education needs).

James F. Oates, Jr. Chairman of the Board The Equitable Life Assurance Society of the United States The legislation should be changed to allow for construction.

Merrill O. Hines, M.D. Medical Director Ochsner Clinic New Orleans, Louisiana

Possibly the time has come to add construction components to the legislation. The great diversity of programs may cause problems in defining construction needs. I hope that when construction features are built into the program, they will be coordinated with Hill-Burton, health research facilities, and health educational facilities legislation in such a way that insofar as university medical centers are concerned, structural needs can support educational concepts.

John Parks, M.D.

Dean, School of Medicine
George Washington University

I am writing both as an individual, and as the President of the national organization (Association of Hospital Directors of Medical Education) which represents over 70% of the nation's non-university teaching hospitals. While the universities and their medical centers may be the nervous system of the Regional Medical Programs, there cannot be much doubt that the non-university teaching hospitals and the community hospitals will be the muscle of these programs. It seems that the people, in the form of Congress, have spoken in a loud and clear

voice—the basic purpose of Regional Medical Programs is education. The basic form of this education is continuing education, with the explicit purpose of making productive in patient care the billions of dollars which have gone into basic research in the last three decades.

At this time the educational muscle of the non-university hospital is so weak that it is difficult for it to do its presently assigned task. If it is to become the cornerstone of the Regional Medical Programs and their educational muscle, then the non-university teaching hospital needs a great deal of help.

I am writing to ask in the strongest possible voice that your report to Congress in June make clear request for funding in two very important areas:

♦ Funds to provide educational facilities and equipment in non-university hospitals. These should include, most importantly, auditorium and conference room space and their accouterments, library facilities and materials, audio-visual materials, audio-visual departments, and areas designed specifically for educational demonstrations in patient care. These are brick and mortar and equipment funds which most hospitals simply cannot supply from monies available in their local communities or through their patient care efforts. They are the very basic equipment most of these hospitals must have to adequately perform their task in the future.

While the funds noted above should be of first priority, there should be monies available to assure proper and complete utilization of these educational facilities. One of the greatest problems for those of us with practical experience in continuing education concerns curriculum design and motivation. These are inextricably interwoven with a need to know patterns of medical care and physician function. The greatest single area of information lack and misinformation is in the field of the function of physicians in care and their needs and motivations in relation to continuing education. To make the primary building funds noted above really effective, we sorely need support within non-university hospital settings for the measurement and evaluation of continuing education, and for the measurement and evaluation of physician performance, drive and motivation. We should be able to really find out what it is that we have to teach, and what changes in behavior we are trying to bring about with our continuing education. It is of great importance that within each region, depending upon factors peculiar to that region, there be one or more nonuniversity hospitals with funds available to construct and staff divisions of measurement and evaluation in continuing education. These would be staffed with physicians, educationists, educational psychologists and sociologists. Each region is sufficiently different to have different needs and to require different approaches and measurements. Thus one center or

one university center would not suffice.

Robert L. Evans, M.D.

President

Association of Hospital

Directors of Medical Education

## ... THE CATEGORICAL EMPHASIS GIVEN BY CONGRESS TO REGIONAL MEDICAL PROGRAMS

We have found that we can work quite effectively within the present authorizations for heart, cancer, stroke, and related diseases. It would perhaps be somewhat easier to do what we think the program is designed to do if authorization were expanded to areas covered by all of the other National Institutes of Health, but this is not a critical problem with us at this time.

Russell C. Mills, Ph.D.
Program Coordinator
Kansas Regional Medical Program and
Associate Dean, University of Kansas
Medical Center

In the Missouri region categorical emphasis has not significantly interfered with program planning and development. Not unexpectedly, several physician leaders in fields of medicine other than heart, cancer, stroke and related diseases, have expressed regret that their fields are not involved. Ultimately, expansion of the RMP concept to include all fields of medicine would appear desirable.

George E. Wakerlin, M.D., Ph.D. Program Director Missouri Regional Medical Program The program goals of RMP should be emphasized, and the categorical nature de-emphasized. I would like to add the weight of my views to those who feel that "cooperative arrangements" and distribution of services are primary, and "Heart Disease, Cancer, and Stroke" are just means to that end.

The overlap between 89-239 and 89-749 will be confusing and hazardous to the future. I would hope that these two programs are made identical at least where state and regional areas overlap.

James E. C. Walker, M.D. Professor of Medicine and Society School of Medicine University of Connecticut

# ... THE RATE OF DEVELOPMENT OF REGIONAL MEDICAL PROGRAMS

We may, by moving too rapidly, restrict planning and, as a result, develop operational programs which will give very little direct help to weaker institutions. This, in turn, will tend to increase dependence on existing centers and fail to stimulate growth and development of presently weak but potentially strong centers.

I believe that the planning phase should be well developed before we suggest changes in the legislation. Once the need is documented, through careful planning, necessary changes can be recommended.

Frank L. McPhail, M.D. Montana State Director Mountain States Regional Medical Program Though I do not know the merits of the requests before you for operating funds, I have major misgivings about making awards in this field at the present time. Such awards would put huge pressures on program coordinators around the country to develop requests for operating funds before adequate planning has been done. This type of "hurry-up, half-baked" approach would, in my judgment, put the whole Regional Medical Programs development in jeopardy—just when a lot of first class people are becoming aware of its bright promise.

Henry T. Clark, Jr., M.D. Planning Director Connecticut Regional Medical Program

# PARTICIPANTS SPOKE TO THE IMPORTANCE OF . . .

... CONTINUING EDUCATION

I feel that the focus in this program, in its operational phase, will and should be aimed toward continuing medical education, both for medical and paramedical personnel. There is the problem of motivating physicians, as probably the people who need such education most would tend to use it least. Some sort of obligatory educational program, or re-examination for recertification at set intervals, seem to be the only sure method of keeping the medical populace current.

There seems to be overlap in areas of responsibility, and indeed of financing, of the various medical programs directed toward health. That some form of governmental and legislative house-

cleaning is necessary seems obvious. The major benefit from this law at the present time, and for some little while into the future, will lie in its effect in bringing together diverse groups within and without the medical community, with community health as a common goal.

Walter Hume, M.D. Louisville, Kentucky Member, Ohio Valley Regional Advisory Group

## ... HEALTH MANPOWER

The most critical immediate problem in organizing successful regional programs throughout the country will be the shortage of manpower. However, once this is solved the success of the regional programs will be determined ultimately by two factors: (1) the interest and enthusiasm that can be engendered and maintained in the two groups around which the program will tend to polarize, namely the clinical faculties of medical schools, and practitioners in community hospitals and (2) the extent to which motivation can be stimulated.

Samuel Proger, M.D.

President

Bingham Associates Fund

## ... PATIENT CARE

I was impressed by the necessity for emphasizing our efforts at improving patient care rather than any other consideration. This should be emphasized in the Report.
Kinloch Nelson, M.D.
Dean
Medical College of Virginia and
Program Coordinator
Virginia Regional Medical Program

#### ... DENTISTRY

In relation to Section 903 (b) (4) of the law, perhaps future regulations or administrative guidelines might be written to spell out the intent that the specific mention of "practicing physicians" should not be construed to exclude "practicing dentists" and that representatives of "medical societies" should not be construed to exclude "dental societies".

The last sentence of Section 901 (c) provides that "no patient shall be furnished hospital or medical care at any facility unless he has been referred to such a facility by a practicing physician." The term "practicing physician" should be expanded to include "or dentist" or a term such as "health practitioner" or "practitioner of the healing arts" should be substituted. This would allow referrals by dentists for such problems as oral cancer.

Maynard K. Hine, D.D.S. Immediate Past President American Dental Association

# ... AND PREVENTION AND REHABILITATION

I have been somewhat disturbed about the language in the Act which defines the objectives as "improved capability for diagnosis and treatment." I am sure that those of us who have a broad point of view understand this means diagnosis obviously has to include preventive medicine. . . . and detection programs. . . .

In fact, if, when the new legislation comes into being, I personally would like to see two words added. These would be "prevention" and "rehabilitation." I believe it would clarify what obviously was the intent of the Commission and the Congress as well as the directive from the President.

I would like to make a plea for continuing aid to the supporting services—facilities and medical education, both undergraduate and continuing education.

Howard A. Rusk, M.D. Director Institute of Rehabilitation Medicine New York University Medical Center

## **APPENDICES**

- ♦ Conference Program
- ♦ Registered Conference Participants
- ♦ National Advisory Council Review Committee Ad Hoc Committee for the Report
- ♦ Division Staff
- ♦ Directory of Programs
- ♦ Guidelines
- ♦ Public Law 89-239
- ♦ Regulations

#### Appendix 1—Conference Program

Conference on Regional Medical Programs SUNDAY, JANUARY 15

Registration-Concourse, 3-6 p.m.

Opening of Conference

Reception-Terrace, 6:30 p.m.

Dirner Meeting-International Ballroom-West, 7:30 p.m.

Chairman:

Robert Q. Marston, M.D.

Remarks:

Charles L. Hudson, M.D. President American Medical Association

Leo J. Gehrig, M.D. Deputy Surgeon General U.S. Public Health Service

Introduction of Speaker:

Philip R. Lee, M.D. Assistant Secretary for Health and Scientific Affairs U.S. Department of Health, Education, and Welfare

Address:

Wilbur J. Cohen Under Secretary of U.S. Department of Health, Education, and Welfare

MONDAY, JANUARY 16 General Session-International Ballroom-West, 9-10 a.m.

Chairman:

Stanley W. Olson, M.D. Conference Chairman

Speaker:

Robert O. Marston, M.D. Associate Director National Institutes of Health Director Division of Regional Medical Programs "Philosophy and Goals of the Regional Medical Programs for Heart Disease, Cancer, Stroke and Related Diseases"

Discussion Sessions: 10 a.m.-12 noon "Development of Cooperative Arrangements" Luncheon Meeting-International Ballroom-East, 12:30 p.m..

Chairman:

Stanley W. Olson, M.D.

Speaker:

James A. Shannon, M.D. Director National Institutes of Health "Science and Service"

General Session-International Ballroom-West, 2 p.m.

Panel Session: Program Evaluation

Chairman:

George James, M.D. Dean Mt. Sinai School of Medicine

Speaker:

Vernon E. Wilson, M.D. Dean University of Missouri School of Medicine

Panel:

Edward Kowalewski, M.D. Chairman, Board of Directors American Academy of General Practice C. H. William Ruhe, M.D. Assistant Secretary Council on Medical Education American Medical Association Harvey L. Smith, Ph.D. Professor of Sociology and Director, Social Research Section University of North Carolina

Discussion Sessions: 3:30-5:30 p. m. "Continuing Education, Research and Patient

TUESDAY, JANUARY 17

General Session-International Ballroom-West, 9 a.m.

Chairman:

Stanley W. Olson, M.D.

Introduction of Speaker:

Edward W. Dempsey, Ph.D. Professor of Anatomy Columbia University College of Physicians and Surgeons

Speaker:

Sidney Farber, M.D. Director of Research Children's Cancer Research Foundation Professor of Pathology Harvard Medical School

"The Idea, the Intent and the Implementation"

Panel Session: "The Report of the Surgeon General to the President and the Congress"

Chairman:

Storm Whaley Vice President for Health Affairs University of Arkansas

Panel:

Michael E. DeBakey, M.D. Professor and Chairman Department of Surgery College of Medicine Baylor University

Bruce W. Everist, M.D. Green Clinic Ruston, Louisiana

James T. Howell, M.D. **Executive Director** Henry Ford Hospital

Ray E. Trussell, M.D. Director Columbia University School of Public Health and Administrative Medicine

Paul N. Ylvisaker, Ph.D. Ford Foundation

Discussion Sessions: 11 a.m.-I p.m.

"Surgeon General's Report on the Regional Medical Programs to be presented to the President and the Congress"

Adjournment-1. p.m.

ACHTER, Mrs. Renee Chief Occupational Therapist, American Occupational Therapy Association: Director, Occupational Therapy, D.C. General Hospital ACOYA, Clarence Executive Director, New Mexico Commission on Indian Affairs: University of New Mexico School of Medicine

\*ADAMS, Wright, M.D. Associate Dean, University of Chicago School of Medicine

ALPERT, Louis K., M.D. American Diabetes Association: Professor of Medicine, George Washington University

\*AMES, Verner J., D.O. Professor of Practice, Kansas City College of Osteopathy and Surgery

ANDERSON, Gavlord W., M.D. Director, School of Public Health, University of Minnesota

ANDERSON, Otis L., M.D. Manager, Washington, D.C. Office, American Medical Association

ANDERSON, Robert S., M.D. Professor of Medicine, Meharry Medical College

ANDRESEN, Donald C., M.D. Chief, Cardiology, Darthmouth Medical

ANDREWS, Edward C., Jr., M.D. Dean, College of Medicine, University of Vermont

ANDREWS, Neil C., M.D. Assistant Dean, College of Medicine, Ohio State University

\*ANNIS. Jere W., M.D. President, American Association of Medical Clinics

\*APPEL, James Z., M.D. Immediate Past President, American Medical Association

ARBONA, Guillermo, M.D. Professor of Preventive Medicine and Public Health, School of Medicine, University of Puerto Rico

 Physician indicated in Conference Registry that activities also include regular practice

ARONOFF, Billie Louis, M.D. Associate Professor of Surgery, University of Texas S.W.; Member, Texas Regional Advisory Council

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\*BACASTOW, Merle S., M.D.
Director, Medical Education, Maine Medical
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Agency, Maine Regional Medical Program

BARNES, David A. Medical Administration, Mayo Clinic

BARNES, James T. Executive Director, Medical Society of North Carolina

BARR, Robert N., M.D. Secretary and Executive Officer, Minnesota State Board of Health

BARROW, J. Gordon, M.D. Director, Medical Education, and Clinical Professor of Medicine, Emory University School of Medicine; Member, Steering Committee, Georgia Regional Medical Program

BARTLETT, John C., LL.B. Assistant Program Coordinator, Iowa Regional Medical Program; Administrative Assistant for Plans and Operations, University of Iowa College of Medicine

BATSON, Randolph, M.D. Dean, School of Medicine, Vanderbilt University

BATTISTELLA, Roger M., Ph.D. Assistant Professor, Hospital and Medical Care Administration, Sloan Institute of Hospital Administration, Cornell University

BAUER, Franz K., M.D. Associate Dean, University of Southern California School of Medicine, Los Angeles; Los Angeles County General Hospital

BAUMAN, G. Duncan Business Manager, St. Louis Globe-Democrat; Chairman, Bi-State Regional Advisory Group BELL, Louise N. Research Assistant, Department of Preventive Medicine, University of Pittsburgh School of Medicine

BENNETT, Granville A., M.D. Dean, College of Medicine, University of Illinois

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BENSON, W. W. Member, Mountain States Regional Advisory Council; State Registrar of Vital Statistics, Idaho Department of Public Health

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BIHLMEYER, Earl F. Administrative Assistant to the Dean, University of South Dakota School of Medicine

BISTOWISH, Joseph M., M.D. Director of Public Health, Metropolitan Nashville Health Department

BLAIR, Lucy
Executive Director, American Physical
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BOETTNER, Charles H., M.D. Executive Director, Health Advisory Committee, Appalachian Regional Commission; Medical Director, Public Health Service BOREL, Richard A. President, WBNS-TV Inc.; Member, Ohio Regional Advisory Group

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BOUGHN, Pete Director of Public Information, University of Nebraska College of Medicine

BOWEN, Ted Member, Texas Regional Advisory Group; Hospital Administrator, Methodist Hospital, Houston

BOWERFIND, Edgar S., Jr., M.D. Secretary, Citizens Commission on Graduate Medical Education; Assistant Professor of Medicine, Western Reserve University

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BOYLE, Richard E., M.D. Assistant Professor of Medicine, University of Colorado Medical Center; Representative of Program Coordinator, Colorado-Wyoming Regional Medical Program

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BROWN, Ray E.
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Bi-State Regional Medical Program;
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ELLWOOD, Paul M., M.D. Executive Director, American Rehabilitation Foundation; Faculty, University of Minnesota

ELMORE, Marjorie J., Ed.D. Member, Mountain States Regional Advisory Council; Dean, School of Nursing, University of Nevada

ENGLE, H. Martin, M.D. Chief Medical Director, Department of Medicine and Surgery, Veterans Administration

ENNES, Howard Assistant Vice President, Community Services and Health Education, Equitable Life Assurance Society

ENSIGN, James M. Vice President, Blue Cross Association

EVANS, Robert L., M.D.

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FORNEY, Vernon J., D.D.S. Regional Health Director, Public Health Service (Region V)

\*FRANKLIN, Max S., M.D. President, St. Louis Medical Society; Member, Bi-State Regional Advisory Group

FRANTZ, Ivan D., Jr., M.D.
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FRECHETTE, Alfred L., M.D. Commissioner, Massachusetts Department of Public Health; Trustee of Tri-State Organization, Tri-State Regional Medical Program

FREYMANN, J. G., M.D. Association of Hospital Directors of Medical Education; Medical Director, Boston Hospital for Women

FRIEDRICH, Rudolph, D.D.S. Director, Division of Oral Surgery, Columbia University

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GALLAGHER, Joseph A., M.D. Deputy Director, Bureau of Health Manpower, Public Health Service

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GARCIA-PALMIERI, Mario R., M.D. Secretary of Health, Puerto Rico Department of Health

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GEIGER, Frank L., M.D. Chief, Cancer, Heart Disease and TB Services, South Carolina State Board of Health

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GILES, Julian W., M.D. Member, Alabama Regional Advisory Committee; Hospital Director, Tuskegee Veterans Administration Hospital

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GOLDSTEIN, Gloria Assistant to the Dean, Medical College of Alabama

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GROSSE, Robert N.
Office of Assistant Secretary for Program
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GROVER, M. Roberts, Jr., M.D. Director, Continuing Medical Education, University of Oregon Medical School; Program Coordinator, Oregon Regional Medical Program

GRULEE, Clifford G., M.D. Dean, University of Cincinnati College of Medicine

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- \*TOMITA, Theodore, M.D. President, Hawaii Medical Association

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# Appendix 3—National Advisory Council Review Committee Ad Hoc Committee for the Report

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YEAGER, J. Franklin, M.D. Silver Spring, Maryland

YERBY, Alonzo S., M.D.
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YLVISAKER, Paul N., Ph.D. Commissioner, New Jersey Department of Community Affairs; Member, Ad Hoc Committee for the Report to the President and the Congress

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<sup>\*\*</sup>Deceased, April 1967

#### Appendix 4—Division Staff

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PRINCIPAL STAFF OF THE DIVISION OF REGIONAL MEDICAL PROGRAMS The Office of the Director provides program leadership and direction. Director . . . . . . . Robert O. Marston, M.D. Assistant Director Associate Director for Continuing Education ........William D. Mayer, M.D. Executive Officer ...... Charles Hilsenroth Assistant to Director for Systems and Assistant to Director for Communications and Public Information . . . Edward M. Friedlander Public Information Officer . . . . . Harold Wolfe The Continuing Education and Training Branch provides assistance for the quality development of such activities in Regional Medical Programs. Chief ...., William D. Mayer, M.D. Assistant to Chief ........Cecilia Conrath Head, Evaluation Research Group ... Frank L. Husted, Ph.D. The Development and Assistance Branch, serves as the focus for two-way communication between the Division and the individual Regional Medical Programs. Head, Liaison Section . . . . lan Mitchell, M.D. Head, Clinical Programs Section ........Philip A. Klieger

The Grants Management Branch interprets grants management policies and reviews budget requests and expenditure reports. Chief ......James A. Beattie The Grants Review Branch handles the professional and scientific review of applications and progress reports. Head, Operations Section . . . Lorraine Kyttle The Planning and Evaluation Branch appraises and reports on overall program goals, progress and trends and provided staff work for the Surgeon General's Report to Congress required under Section 908 of Public Law 89-239. Chief ..... Stephen J. Ackerman Head, Planning Section . . Roland L. Peterson

# Appendix 5—Directory of Regional Medical Programs

#### INDEX

The Directory lists Regional Medical Programs for which planning or operational grants have been awarded or which are in earlier stages of development.

Regions were defined for planning purposes in the planning applications. State designations do not necessarily indicate that the regions are coterminous with State boundaries. The original definitions of the regions may be modified on the basis of experience.

August 1, 1967

Region	Page	MASSACHUSETTS, see Tri-State	OREGON 100
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ALASKA, see Washington-Alaska		METROPOLITAN WASHINGTON, D.C 102	
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CALIFORNIA	. 98	Memphis) 103	3 SOUTH DAKOTA, see Nebraska-
CENTRAL NEW YORK	. 98	MONTANA, see Intermountain; Mountain States	South Dakota
CLEVELAND	. 98	MOUNTAIN STATES 103	SUSQUEHANNA VALLEY
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CONNECTICUT	. 99	NEBRASKA-SOUTH DAKOTA 10-	TEXAS 108
DELAWARE VALLEY, see Greater		NEVADA, see Intermountain	
Delaware Valley		NEW HAMPSHIRE, see Tri-State	TRI-STATE 108
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GEORGIA	99	Delaware Valley) 10	VERMONT, See Northern Hen Charles
GREATER DELAWARE VALLEY	. 100	NEW MEXICO 10	4 VIRGINIA 108
HAWAII	100	NEW YORK, see Albany; Central New York; New York Metropolitan Area;	WASHINGTON-ALASKA 109
IDAHO, see Intermountain; Mountain States		Rochester; Western New York	WASHINGTON, D.C., see Metropolitan
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		NORTH CAROLINA 10	WEST VIRGINIA (see also Ohio Valley) 109
INDIANA (see also Ohio Valley)			
INTERMOUNTAIN		NORTH DAKOTA	FOR HIGHER EDUCATION (WICHE),
IOWA	101	NORTHERN NEW ENGLAND 10	5 see Mountain States
KANSAS	101	NORTHLANDS 10	5 WESTERN NEW YORK
KENTUCKY, see Memphis; Ohio Valley; Tennessee Mid-South		OHIO STATE (see also Cleveland; Ohio Valley)	WESTERN PENNSYLVANIA 109
LOUISIANA	101		WISCONSIN 110
MAINE	102	OHIO VALLEY	WYOMING, see Colorado-Wyoming;
MARYLAND	102	OKLAHOMA 10	

Name of Region	Alabama	Albany	Arizona	Arkansas
Preliminary Planning Area	Alabama	Northeastern New York and portions of Southern Vermont and Western Massachusetts	Arizona	Arkansas
Estimated Population	3,500,000	1,900,000	1,635,000	1,960,000
Coordinating Headquarters	University of Alabama Medical Center	Albany Medical College of Union University	University of Arizona College of Medicine	University of Arkansas Medical Center
Program Coordinator	Benjamin B. Wells, M.D. University of Alabama Medical Center 1919 Seventh Avenue South Birmingham, Alabama 35233 (tele: 205-325-4784)	Frank M. Woolsey, Jr., M.D. Associate Dean and Professor Chairman, Department of Postgraduate Medicine Albany Medical College of Union University 47 New Scotland Avenue Albany, New York 12208 (tele: 518-462-7521)	Merlin K. DuYal, M.D. Dean, College of Medicine University of Arizona Tucson, Arizona 85721 (tele: 602-884-1505)	Winston K. Shorey, M.D. Dean, School of Medicine University of Arkansas 4301 West Markham Street Little Rock, Arkansas 72201 (tele: 501-M04-5000)

Grantee	University of Alabama Medical Center	Albany Medical College of Union University	University of Arizona College of Medicine	University of Arkansas Medical Center
Effective Starting Date of Planning Grant	January 1, 1967	July 1, 1966	April 1, 1967	April 1, 1967
Program Period for nitial Planning	Two years, six months	Three years	Two years, three months	Two years, three months
Effective Starting Date of Operational Grant		April 1, 1967		

Name of Region	Bi-State	California	Central New York	Cleveland
Preliminary Planning Area	Eastern Missouri and Southern Illinois	California	Syracuse, New York and 15 surrounding counties	Northeastern Ohio
Estimated Population	4,700,000	18,600,000	1,800,000	
Coordinating Headquarters	Washington University School of Medicine	California Committee on Regional Medical Programs	Upstate Medical Center, State University of New York at Syracuse	
Program Coordinator	William H. Danforth, M.D. Vice Chancellor for Medical Affairs Washington University 660 South Euclid Avenue St. Louis, Missouri 63110 (tele: 314-361-6400, ext. 3013)	Paul D. Ward Executive Director California Committee on Regional Medical Programs Room 304 665 Sutter Street San Francisco, California 94102 (tele: 415-771-5432)	Richard H. Lyons, M.D. Director, Regional Medical Program of Central New York 750 East Adams Street Room 1500 State University Hospital Syracuse, New York 13210 (tele: 315-473-5600)	

Grantes	Washington University School of Medicine	California Medical Education and Research Foundation	Research Foundation of State University of New York	Application under development
Effective Starting Date of Planning Grant	April 1, 1967	November 1, 1966	January 1, 1967	
Program Period for Initial Planning	Two years, three months	Two years, eight months	Two years	
Effective Starting Date of Operational Grant				

Name of Region	Colorado-Wyoming	Connecticut	Florida	Georgia
Preliminary Planning Area	Colorado and Wyoming	Connecticut	Florida	Georgia
Estimated Population	2,300,000	2,800,000	5,910,000	4,400,000
Coordinating Headquarters	University of Colorado Medical Center	Yale University School of Medicine and University of Connecticut School of Medicine	Florida Advisory Council on Heart Disease, Cancer and Stroke, Inc.	Medical Association of Georgia
Program Coordinator	C. Wesley Eisele, M.D. Associate Dean for Post-Graduate Medical Education University of Colorado Medical Center 4200 East Ninth Avenue Denver, Colorado 80220 (tele: 303-394-7376 or 8406)	Henry T. Clark, Jr., M.D. Program Coordinator Connecticut Regional Medical Program 272 George Street New Haven, Connecticut 06510 (tele: 203-776-6872)	Samuel P. Martin, M.D. Provost, J. Hillis Miller Medical Center University of Florida Gainesville, Florida 32601	1. W. Chambers. M.D. Coordinator for Georgia Regional Medical Program Medical Association of Georgia 938 Peachtree Street, N.E. Atlanta, Georgia 30309 (tele: 404-876-7535)
Program Director	Paul R. Hildebrand, M.D. University of Colorado Medical Center 4200 East Ninth Avenue Denver, Colorado 80220			J. Gordon Barrow, M.D. Director for Georgia Regional Medical Program Medical Association of Georgia 938 Peachtree Street, N.E. Atlanta, Georgia 30309 (tele: 404-875-0701)
Grantee	University of Colorado Medical Center	Yale University School of Medicine		Medical Association of Georgia
Effective Starting Date of Planning Grant	January 1, 1967	July 1, 1966	Application under development	January 1, 1967
Program Period for Initial Planning	Two years, six months	Two years		Two years, six months
Effective Starting Date of Operational Grant				

Name of Region	Greater Delaware Valley	Hawaii	11finois	Indiana
Preliminary Planning Area	Eastern Pennsylvania and portions of New Jersey and Delaware	Hawaii	Illinois	Indiana
Estimated Population	8,830,000	800,000	10,700,000	4,900,000
Coordinating Headquarters	University City Science Center	University of Hawaii College of Health Sciences	Coordinating Committee of Medical Schools and Teaching Hospitals of Illinois	Indiana University School of Medicine
Program Coordinator	William C. Spring, Jr., M.O. Program Coordinator Greater Delaware Valley Regional Medical Program 301 City Line Avenue Bala-Cynwyd, Pennsylvania 19004 (tele: 215-M07-1790, 91, 92)	Windsor C. Cutting, M.D. Dean, School of Medicine University of Hawaii 2538 The Mall Honolulu, Hawaii 95822	Wright Adams, M.D. Professor of Medicine and Associate Dean Division of Biological Sciences University of Chicago Chicago, Illinois 60637 (tele: 312-MU4-6100)	George T. Lukemeyer, M.D. Associate Dean, Indiana University School of Medicine Indiana University Medical Center 1100 West Michigan Street Indianapolis, Indiana 46207 (tele: 317-639-8877)
	(1010-121-110-110-110-110-110-110-110-110			
Program Director		William D. Graham, M.D. Deputy Director Hawaii Regional Medical Program Leahi Hospital 3675 Kilauea Avenue Honolulu, Hawaii 96816		
		(tele: 808-78660 or 722)		
Grantee	University City Science Center	University of Hawaii College of Health Sciences	University of Chicago	Indiana University Foundation
Effective Starting Date of Planning Grant	April 1, 1967	July 1, 1966	July 1, 1967	January 1, 1967
Program Period for Initial Planning	One year	Two years	Two years	Two years, six months
Effective Starting Date of Operational Grant				

ne of Region	Intermountain	lowa	Kansas	Louisiana
liminary Planning Area	Utah and portions of Wyoming, Montana, Idaho, and Nevada	lowa	Kansas	Louisiana
imated Population	2,200,000	2,760,000	2,200,000	3,500,000
rdinating Headquarters	University of Utah College of Medicine	University of Iowa College of Medicine	University of Kansas Medical Center	Louisiana State Department of Hospitals
gram Coordinater	C. Hilmon Castle, M.D. Associate Dean and Chairman Department of Postgraduate Education University of Utah College of Medicine 50 North Medical Drive Salt Lake City, Utah 84112	Willard A. Krehl, M.D., Ph.D. Department of Internal Medicine University of Iowa Iowa City, Iowa 52240 (tele: 319-353-4843)	Charles E. Lewis, M.D. Chairman, Department of Preventive Medicine and Community Health University of Kansas Medical Center 39th and Rainbow Boulevard Kansas City, Kansas 66103	Joseph A. Sabatier, Jr., M.D. Program Coordinator Louisiana Regional Medical Program Claiborne Towers Roof 119 South Claiborne Avenue New Orleans, Louisiana 70112
	(tele: 801-322-7901)		(tele: 919-AD6-5252, ext. 422)	(tele: 504-522-5678)

gram Director

intee	University of Utah	University of Iowa College of Medicine	University of Kansas Medical Center	Louisiana State Department of Hospitals
ective Starting Date Planning Grant	July 1, 1966	December 1, 1966	July 1, 1966	January 1, 1967
igram Period for tial Planning	Two years	Two years	Two years	Two years
ective Starting Date Operational Grant	April 1, 1967		June 1, 1967	

Name of Region	Maine	Maryland	Memphis Medical Region	Metropolitan Washington, D.C.
Preliminary Planning Area	Maine	Maryland	Western Tennessee, Northern Mississippi, and portions of Arkansas, Kentucky, and Missouri	District of Columbia and contiguous counties in Maryland (2) and Virginia (2)
Estimated Population	985,000	3,520,000	2,400,000	2,050,000
Coordinating Headquarters	Medical Care Development, Inc.	Steering Committee of the Regional Medical Program for Maryland	Mid-South Medical Council for Comprehensive Health Planning, Inc.	District of Columbia Medical Society
Program Coordinator	Manu Chatterjee, M.D. Program Coordinator Maine Regional Medical Program 295 Water Street Augusta, Maine 04322	Thomas B. Turner, M.D. Dean, School of Medicine The Johns Hopkins University 725 Wolfe Street Baltimore, Maryland 21205	James W. Culbertson, M.D. Professor and Cardiologist Department of Internal Medicine College of Medicine University of Tennessee 858 Madison Avenue	Thomas W. Mattingly, M.D. Program Coordinator Metropolitan Washington, D.C. Regional Medical Program District of Columbia Medical Society 2007 Eye Street, N.W.
	(tele: 203-622-7566)	(tele: 301-955-3181)	Memphis, Tennessee 38103 (tele: 901-JA6-8892, ext. 437)	Washington, D.C. 20006 (tele: 202-223-2230)

Grantee	Medical Care Development, Inc.	The Johns Hopkins University	University of Tennessee College of Medicine	District of Columbia Medical Society
Effective Starting Date of Planning Grant	May 1, 1967	January 1, 1967	April 1, 1967	January 1, 1967
Program Period for Initial Planning	Two years	Two years	Two years, three months	Two years, six months
Effective Starting Date of Operational Grant				

Name of Region	Michigan	Mississippi	Missouri	Mountain States
Preliminary Planning Area	Michigan	Mississippi	Missouri	ldaho, Montana, Nevada, and Wyoming
	8,220,000	2,320,000	4,500,000	2,200,000
Estimated Population  Coordinating Headquarters	Michigan Association for Regional Medical Programs, Inc.	University of Mississippi Medical Center	University of Missouri School of Medicine	Western Interstate Commission for Higher Education
Program Coordinator	D. Eugene Sibery Executive Director Greater Detroit Area Hospital Council 966 Penobscot Building Detroit, Michigan 48226 (tele: 313-963-4990)	Guy D. Campbell, M.D. Regional Coordinator Mississippi Regional Medical Program University of Mississippi Medical Center 2500 North State Street Jackson, Mississippi 39216 (tele: 601-362-4411)	Vernon E. Wilson, M.D. Executive Director for Health Affairs University of Missouri Columbia, Missouri 65201 (tele: 314-449-2711)	Kevin P. Bunnell, Ed.D. Associate Director Western Interstate Commission for Higher Education University East Campus 30th Street Boulder, Colorado 80302 (tele: 303-443-2111, ext. 6342)
Program Director			George E. Wakerlin, M.D. Director, Missouri Regional Medical Program Lewis Hall 406 Turner Avenue Columbia, Missouri 65201 (tele: 314-449-2711)	Alfred M. Popma, M.D. Program Director Mountain States Regional Medical Program 525 West Jefferson Street Boise, Idaho 83702 (tele: 208-342-4666)
Grantee	Michigan Association for Regional Medical Programs, Inc.	University of Mississippi Medical Center	University of Missouri School of Medicine	Western Interstate Commission for Higher Education
Effective Starting Date of Planning Grant	June 1, 1967	July 1, 1967	July 1, 1966	November 1, 1966
Program Period for Initial Planning	One year	Two years	Three years	Two years
Effective Starting Date of Operational Grant			April 1, 1967	

Name of Region	Nebraska-South Dakota	New Jersey	New Mexico	New York Metropolitan Area
Preliminary Planning Area	Nebraska and South Dakota	New Jersey	New Mexico	New York City and Westchester, Nassau, and Suffolk Counties
Estimated Population	2,200,000	6,800,000	1,000,000	11,400,000
Coordinating Headquarters	Nebraska State Medical Association	New Jersey Joint Committee for Implementation of P.L. 89-239	University of New Mexico School of Medicine	Associated Medical Schools of Greater New York
Program Coordinator	Harold Morgan, M.D. Program Coordinator Nebraska-South Dakota Regional Medical Program 1408 Sharp Building Lincoln, Nebraska 68508	Alvin A. Florin, M.D. New Jersey Regional Medical Program 88 Ross Street East Orange, New Jersey 07018 (tele: 201-675-1100)	Reginald H. Fitz, M.D. Dean, School of Medicine University of New Mexico 900 Stanford Drive, N.E. Albuquerque, New Mexico 87106	Vincent de Paul Larkin, M.D. New York Academy of Medicine 2 East 103d Street New York, New York 10029 (tele: 212-TRG-8200)
	(tele: 402-432-5427)	(rete: 201-0/0-1100)	(tele: 505-277-2321)	

Grantee	Nebraska State Medical Association	Foundation for the Advancement of Medical Education and Research in New Jersey	University of New Mexico	Associated Medical Schools of Greater New York
Effective Starting Date of Planning Grant	January 1, 1967	July 1, 1967	October 1, 1966	June 1, 1967
Program Period for Initial Planning	Two years	Two years	Two years, nine months	Two years
Effective Starting Date of Operational Grant				

Name of Region	North Carolina	North Dakota	Northern New England	Northlands
Preliminary Planning Area	North Carolina	North Dakota	Vermont and three counties in Northeastern New York	Minnesota
Estimated Population	4,900,000	650,000	550,000	3,600,000
Coordinating Headquarters	Association for the North Carolina Regional Medical Program	University of North Dakota	University of Vermont College of Medicine	Minnesota State Medical Association Foundation
Program Coordinator	Marc J. Musser, M.D. Executive Director North Carolina Regional Medical Program Teer House 4019 North Roxboro Road Durham, North Carolina 27704 (tele: 919-477-8685)	Theodore H. Harwood, M.D. Dean, School of Medicine University of North Dakota Grand Forks, North Dakota 58202 (tele: 701-777-2514)	John E. Wennberg, M.D. Program Coordinator Northern New England Regional Medical Program University of Vermont College of Medicine 25 Colchester Avenue Burlington, Vermont 05401 (tele: 802-864-4511, ext. 244)	J. Minott Stickney, M.D. Northlands Regional Medical Program 200 First Street S.W. Rochester, Minnesota 55901 (tele: 612-224-5738)

Grantee	Duke University	North Dakota Medical Research Foundation	University of Vermont College of Medicine	Minnesota State Medical Association Foundation
Effective Starting Date of Planning Grant	July 1, 1966	July 1, 1967	July 1, 1966	January 1, 1967
Program Period for Initial Planning	Two years	Two years	Three years	Two years, six months
Effective Starting Date of Operational Grant				

Name of Region	Ohio State	Ohio Valley	Oklahoma	Oregon
Preliminary Planning Area	Central and southern two-thirds of Ohio (61 counties, excluding Metropolitan Cincinnati area)	Greater part of Kentucky and contiguous parts of Ohio, Indiana, and West Virginia	Oklahoma	Oregon
Estimated Population	4,480,000	5,900,000	2,500,000	1,900,000
Coordinating Headquarters	Ohio State University College of Medicine	Ohio Valley Regional Medical Program	University of Oklahoma Medical Center	University of Oregon Medical School
Program Coordinator	Richard L. Meiling, M.D. Dean, College of Medicine Ohio State University 410 West Tenth Avenue Columbus, Ohio 43210 (tele: 614-293-5344)	William H. McBeath, M.D. Director, Ohio Valley Regional Medical Program 1718 Alexandria Drive P.O. Box 4025 Lexington, Kentucky 40504 (tele: 606-278-6071)	Kelly West, M.D. Professor and Head, Department of Continuing Education University of Oklahoma Medical Center 800 Northeast Thirteenth Street Oklahoma City, Oklahoma 73104 (tele: 405-CE5-9421, ext. 395)	M. Roberts Grover, M.D. Director, Continuing Medical Education University of Oregon Medical School 3181 Southwest Sam Jackson Park Road Portland, Oregon 97201 (tele: 503-228-9181, ext. 519)

Grantee	Ohio State University College of Medicine	The University of Kentucky Research Foundation	University of Oklahoma Medical Center	University of Oregon Medical School
Effective Starting Date of Planning Grant	April 1, 1967	January 1, 1967	September 1, 1966	April 1, 1967
Program Period for Initial Planning	One year	Two years	Two years	Two years, three months
Effective Starting Date of Operational Grant				

Name of Region	Puerto Rico	Rochester	South Carolina	Susquehanna Valley
Preliminary Planning Area	Puerto Rico	Rochester, New York and surrounding counties	South Carolina	24 counties in Central Pennsylvania
Estimated Population	2,630,000	1,200,000	2,500,000	2,130,000
Coordinating Headquarters		University of Rochester School of Medicine and Dentistry	Medical College of South Carolina	Pennsylvania Medical Society
Program Coordinator		Ralph C. Parker, Jr., M.D. Clinical Associate Professor of Medicine School of Medicine and Dentistry University of Rochester 260 Crittenden Boulevard Rochester, New York 14620 (tele: 716-473-4400, ext. 3112)	Charles P. Summerall, III, M.D. Associate in Medicine (Cardiology) Medical College of South Carolina Department of Medicine Medical College Hospital 55 Doughty Street Charleston, South Carolina 29403 (tele: 803-723-9411)	Richard B. McKenzie Executive Assistant Council on Scientific Advancement Pennsylvania Medical Society Taylor Bypass and Erford Road Lemoyne, Pennsylvania 17043 (tele: 717-238-1635)

Grantee		University of Rochester School of Medicine and Dentistry	Medical College of South Carolina	Pennsylvania Medical Society	
Effective Starting Date of Planning Grant	Application under development	October 1, 1966	January 1, 1967	June 1, 1967	
Program Period for Initial Planning		Two years, nine months	One year	Two years	
Effective Starting Date of Operational Grant				•	

Name of Region	Tennessee Mid-South	Texas	Tri-State	Virginia
Preliminary Planning Area	Eastern and Central Tennessee and contiguous parts of Southern Kentucky and Northern Alabama	Texas	Massachusetts, New Hampshire, and Rhode Island	Virginia
Estimated Population	2,600,000	10,500,000	6,925,000	4,500,000
Coordinating Headquarters	Vanderbilt University School of Medicine and Meharry Medical College	University of Texas		Medical College of Virginia and University of Virginia School of Medicine
Program Coordinator	Stanley W. Olson, M.D. Professor of Medicine Vanderbilt University Clinical Professor of Medicine Meharry Medical College 110 Baker Building 110 21st Street South Nashville, Tennessee 37203 (tele: 615-255-0692)	Charles A. LeMaistre, M.D. Vice-Chancellor for Health Affairs University of Texas Main Building Austin, Texas 78712 (tele: 512-GR1-1434)	Norman Stearns, M.D. Medical Care and Educational Foundation 22 The Fenway Boston, Massachusetts 02115 (tele: 617-734-3300)	Kinloch Nelson, M.D. Dean, Medical College of Virginia 1200 East Broad Street Richmond, Virginia 23219 (tele: 703-M14-9851)

Grantee	Vanderbilt University	University of Texas		University of Virginia School of Medicine
Effective Starting Date of Planning Grant	July 1, 1966	July 1, 1966	Application under review	January 1, 1967
Program Period for Initial Planning	Two years	Three years		Two years
Effective Starting Date of Operational Grant				

Name of Region	Washington-Alaska	West Virginia	Western New York	Western Pennsylvania
Preliminary Planning Area	Washington and Alaska	West Virginia	Buffalo, New York and 7 surrounding counties	Pittsburgh, Pennsylvania and 28 surrounding counties
Estimated Population	3,200,000	1,800,000	1,920,000	4,200,000
Coordinating Headquarters	University of Washington School of Medicine	West Virginia University Medical Center	School of Medicine, State University of New York at Buffalo, in cooperation with the Health Organization of Western New York	University Health Center of Pittsburgh
Program Coordinator	Donal R. Sparkman, M.D. Associate Professor of Medicine School of Medicine University of Washington AA 312 University Hospital Seattle, Washington 98105 (tele: 206-543-3498)	Charles L. Wilbar, Jr., M.D. West Virginia Regional Medical Program West Virginia University Medical Center Morgantown, West Virginia 26506 (tele: 304-293-4511)	John R. F. Ingall, M.D. Director, Regional Medical Program for Western New York 2211 Main Street Buffalo, New York 14214 (tele: 716-833-2726, ext. 32, 50)	Francis S. Cheever, M.D. Dean, School of Medicine University of Pittsburgh Flannery Building 3530 Forbes Avenue Pittsburgh, Pennsylvania 15213 (tele: 412-683-1620, ext. 320, 321)

Grantee	University of Washington School of Medicine	West Virginia University Medical Center	Research Foundation of the State University of New York	University Health Center of Pittsburgh
Effective Starting Date of Planning Grant	September 1, 1966	January 1, 1967	December 1, 1966	January 1, 1967
rogram Period for nitial Planning	Two years, ten months	Two years, six months	Two years	Two years, six months

Name of Region	Wisconsin	
Preliminary Planning Area	Wisconsin	
Estimated Population	4,100,000	
Coordinating Headquarters	Wisconsin Regional Medical Program, Inc.	
Program Coordinator	John S. Hirschboeck, M.D. Wisconsin Regional Medical Program, Inc. 110 East Wisconsin Avenue Milwaukee, Wisconsin 53202	-
	(tele: 414-272-3636)	

Grantee	Wisconsin Regional Medical Program, Inc.		
Effective Starting Date of Planning Grant	September 1, 1966		
Program Period for Initial Planning	Two years		
Effective Starting Date of Operational Grant			

# Appendix 6—Guidelines for Regional Medical Programs

Division of Regional Medical Programs
National Institutes of Health
Bethesda, Maryland 20014
U.S. DEPARTMENT OF HEALTH, EDUCATION,
AND WELFARE
Public Health Service

July 1966

# TABLE OF CONTENTS AND USE OF THIS GUIDE

- History and Purposes of Regional
   Medical Programs
- II. Composition of a Regional Medical Program
- III. Policies and Definitions
- IV. General Grant Information
- V. Preparation and Review of Application

This Guide is for use in applying for support under Title IX of the Public Health Service Act (Public Law 89-239), which authorizes grants to assist in planning, establishing, and operating Regional Medical Programs to combat Heart Disease, Cancer, Stroke, and related diseases. It is therefore intended to be used for both planning and operational grant applications.

The contents of this Guide include the history and purposes, composition, policies and definitions and general information regarding the preparation and review of applications for a Regional Medical Program. The provisions of this Guide are intended to carry out the purposes and objectives of the authorizing legislation, consistent with overall policies of the Department of Health, Education, and Welfare and sound fiscal procedures. These provisions must be interpreted in light of the basic objectives of the program, and the clear intent of the Congress to stimulate initiative and innovation at the regional level in planning and implementing regional programs that are fitted to the needs and resources of the region.

If the applicant believes there is a conflict between the provisions of the Guide and the effective implementation of the proposed program in his region, he is encouraged to consult with the staff of the Division of Regional Medical Programs. This is a new program in an exploratory phase. It is expected that policies and procedures will evolve with time as both the applicant and the Division learn from actual planning and operational experience. As with all statements of policy and procedure, the Guide attempts to strike a balance among desirable and necessary procedures. The Division encourages diversity and innovation in the development of the Regional Medical Program. But this flexibility of approach must take place within the boundaries of the legislative authority, applicable general policies, and the necessary accountability for public funds.

# I. HISTORY AND PURPOSES OF REGIONAL MEDICAL PROGRAMS

The impetus for the Regional Medical Programs was contained in the President's 1964 Special Health Message to Congress when he proposed to establish a Commission on Heart Disease, Cancer, and Stroke "to recommend steps to reduce the incidence of these diseases through new knowledge and more complete utilization of the medical knowledge we already have." In March 1964, a Commission of distinguished physicians, scientists, and informed citizens was appointed to accomplish this task. The Commission collected information from agencies, groups, and institutions concerned with these diseases through letters, staff visits, surveys, etc., held hearings at which expert witnesses from the widest possible range of interests, both public and private, presented their views, and submitted a report which included the following points:

"Our Nation's resources for health are relatively untapped. The rising tide of biomedical research has already doubled our store of knowledge about heart disease, cancer and stroke. . . ."

"Yet for every breakthrough, there must be follow-through. Many of our scientific triumphs have been hollow victories for most of the people who could benefit from them." The Commission presented 35 recommendations aimed at reducing the toll of these diseases through the development of more effective means of making the latest medical advances available to a greater portion of the population and through the provision of additional opportunities for research. The major recommendations of the Commission are the basis for the proposed regional medical programs authorized by Public Law 89-239 (hereafter referred to in this text as "The Act." See Exhibit).

The Act is intended to assist our medical institutions and professions in capitalizing on the rapid advances of scientific medicine in the prevention, diagnosis, treatment, and rehabilitation of patients afflicted with heart disease, cancer, stroke or related diseases. To paraphrase the statement of purposes in the Act, these grants are to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutes, hospitals and other medical institutions and agencies for the purpose of affording the medical profession and the medical institutions the opportunity of making available to their natients the latest advances in the diagnosis and treatment of these diseases. Grant funds will support through these cooperative arrangements research, training (including continuing medical education) and related demonstrations of the highest standard of patient care. Through these means the program is also intended to improve generally the health manpower and facilities of the Nation. The Act states that these purposes should be accomplished without interfering with the patterns of professional practice or hospital administration.

The intent of the Act is built upon the following basic premises and assumptions:

- ♦ The program will utilize and build upon existing institutions and manpower resources.
  ♦ The active participation of practicing physicians is essential to the success of a regional medical program.
- ♦ The purposes can best be achieved through initiative, planning, and implementation at the regional level under conditions which encourage innovative approaches and programs specifically designed to deal with

the diversity of needs, resources and existing patterns of education and service.

- Scoperation among all essential elements of the health resources in a region is an essential means of coping with the complexities, specialization, high cost, manpower needs, and educational and training needs which are the by-products of the dynamic advances of medical science. The objectives of the Act will not be achieved by a program which serves the interests of a single category, institution, or organization. A basic aim of the program is to overcome fragmentation and insularity.
- ♦ In order to insure an effective linkage between research advances and improved patient care, it is desirable to establish a continuing relationship among the research and teaching environment of the medical center, the patient care activities involving the community hospital, and practicing physicians. The impact of research advances on the development of high quality patient care has typically been most direct in the university medical centers or other medical centers which combine extensive research teaching and patient care activities. The primary benefits of this interrelationship. however, have often been confined to the medical center itself and affiliated hospitals. A basic premise of the Act is the desirability of extending this productive interrelationship to additional hospitals and to practicing physicians through the establishment of regional cooperative arrangements.
- ♦ The financing of patient care is not the objective of the regional medical programs. The payment of patient care costs is limited to those costs incident to research, training and demonstration activities supported by these grants.
- ♦ It is assumed that the development of the full capabilities of a regional medical program will take a number of years. The purpose of the first three years of legislative authorization is to encourage and assist in the planning and implementation of the first steps toward the establishment of a regional medical program. It is assumed that the development of a plan and the implementation of the initial elements thereof will constitute a learning experience which can be utilized in taking additional steps in

the cooperative effort against heart disease, cancer and stroke.

The background against which these assumptions and premises are set includes a number of trends and influences which have been affecting the nature of medical service, education, and research for some years. The opportunities created by the impact of science on modern medicine have already been mentioned. Along with the creation of opportunities, however, the increasing impact of science has changed the nature and shape of modern medicine, raising a number of situations which are very difficult to manage, including increased specialization. increasing complexities and costs of diagnosis and treatment, and the difficulties in transmitting a rapidly expanding body of knowledge. The tremendous growth of knowledge through large scale research efforts is a characteristic of our times, not just in medicine but in most aspects of our society. Wherever this phenomenon is seen. it calls for the development of new means of coping with steady and dynamic change if the benefits of the knowledge are to be realized.

The forces of change can be viewed as part of a continuum existing over many years. rather than a revolutionary or radical alteration of current patterns. This trend calls for the development of Regional Medical Programs which create an effective environment for continuing adaptation, innovation, and modification. The development of a great medical research effort is the product of a deliberate national policy to stimulate and support the development of new medical knowledge at a rapid rate. The passage of the legislation authorizing Regional Medical Programs represents a corresponding commitment to assist the development of necessary measures to bring the benefits of this new knowledge to the patient in the field of heart disease, cancer, stroke, and related diseases.

The process of medical education in all its aspects has also been undergoing a change under the impact of the growth of knowledge. The development of great medical centers built around education, research, and high-quality patient care has taken place

throughout the Nation. The consequence of rapid expansion in the body of medical knowledge is increased specialization, resulting in the prolongation of the educational process. A continuing process of education throughout the career of a physician is therefore of great importance.

The continued evolution of medical education and the growth of the medical centers carries with it increased problems in maintaining an effective linkage between the medical center and the practicing physician, Recent reports have emphasized the need for those concerned with medical education to assume responsibilities in meeting national needs for improved health care. It has become clearly apparent that the medical center represents an indispensable resource for improving health in its area of influence. In the environment of medical education, new attention is being given to the need to cope effectively with the problems brought about by the developments in modern scientific medicine.

Many medical leaders are stressing that those involved in health care must maintain a continuous relationship to the educational process and that medical schools and hospitals should have an increasing involvement in the process of continued learning. The very forces that have tended to separate the centers of medical knowledge from the practicing physician are creating an ever greater need to bring physicians into continuing contact with the environment of teaching and research.

Another trend is usually described as the regionalization of medical services. There have been numerous regionalization proposals during the past 35 years and efforts have been made to implement various approaches to regionalization. The concept of Regional Medical Programs includes the regional approach to the provision of highly specialized services involved in the diagnosis and treatment of heart disease, cancer, stroke, and related diseases. The legislation provides a very flexible framework for the implementation of a regional approach which is appropriate to the voluntary nature of our medical institutions.

The Regional Medical Programs present the medical interests within a region with an instrument of synthesis that can capitalize on and reinforce the various trends and resources seeking to make more widely available the latest advances in diagnosis and treatment of these diseases. It is the interaction of these trends at this time, rather than an abstract conceptualization, which not only justifies but requires a synthesizing force such as the Regional Medical Programs. The Regional Medical Programs represent a general concept, rather than a specific blueprint. The opportunity is presented to go beyond concept into specific planning and implementation of programs which represent pragmatic steps toward the achievement of the overall goals of the legislation. It is an opportunity to mix creative ideas and specific actions in developing improved means for advancing the health standards of the American people.

- II. COMPOSITION OF A REGIONAL MEDICAL PROGRAM
- A. Definition of a Regional Medical Program
- B. The National Advisory Council on Regional Medical Programs
- C. Categorical Emphasis
- D. The Region
- E. Cooperative Arrangements Among Resources Within The Region
- F. Interregional Cooperation
- G. The Regional Advisory Group
- H. Relation of Regional Medical Programs to Programs of Other Health Agencies
- A. Definition of a Regional Medical Program The Act defines a regional medical program as a cooperative arrangement among a group of public or private nonprofit institutions or agencies engaged in research, training, diagnosis, and treatment relating to heart disease, cancer, or stroke, and at the

option of the applicant, related disease or diseases; but only if such group

- ♦ is situated within a geographic area, composed of any part or parts of any one or more states which the Surgeon General determines, in accordance with regulations, to be appropriate for carrying out the purposes of the Act:
- consists of one or more medical centers, one or more clinical research centers, and one or more hospitals; and
- has in effect cooperative arrangements among its component units which the Surgeon General finds will be adequate for carrying out effectively the purposes of this program.

## B. The National Advisory Council on Regional Medical Programs

The National Advisory Council on Regional Medical Programs consists of the Surgeon General, who is the chairman, and 12 members, not otherwise in the regular fulltime employ of the United States, who are leaders in the fields of the fundamental sciences. the medical sciences, or public affairs, In particular, one of the twelve council members must be outstanding in the field of heart disease, one in cancer, and another in stroke, and two must be practicing physicians. The role of the Council is to advise and assist the Surgeon General in the formulation of policy and regulations regarding the regional medical programs, and to make recommendations to him concerning approval of applications and amounts of grant awards. No grant may be awarded unless it has been recommended for approval by the Council.

## C. Categorical Emphasis

The focus of the Regional Medical Programs under the authorizing legislation is on problems of heart disease, cancer, stroke, and related diseases. This rather broad categorical approach must be a consideration in the development of specific program elements under a Regional Medical Program. Heart disease, cancer, and stroke are appropriate targets because of their prevalence as killing and disabling diseases. These diseases present a complex challenge to the research

investigator, and the advances which are being made require diagnostic and treatment techniques of great sophistication. Because of the broad scope of heart disease, cancer, and stroke it would be difficult and perhaps detrimental to some types of medical services and educational activities if a rigidly categorical approach were adopted for all relevant program elements. However, the emphasis of the program does require that the program elements be shown to have significance for combating heart disease, cancer, stroke and related diseases.

#### D. The Region

A region is a geographic area composed of part or parts of one or more states which the Surgeon General determines to be appropriate for the purposes of the program. It should be an economically and socially cohesive area taking into consideration such factors as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; and presence and distribution of educational and health facilities and programs. The region should be functionally coherent; it should follow appropriate existing relationships among institutions and existing patterns of patient referral and continuing education; it should encompass a sufficient population base for effective planning and use of expensive and complex diagnostic and treatment techniques.

## E. Cooperative Arrangements Among Resources Within the Region

It is recognized that the full development of a Regional Medical Program, which involves potentially all medical institutions, organizations, and personnel within the region, could take a number of years in many areas. The program emphasizes the development of cooperative arrangements which are effective in making the latest scientific advances in these diseases more widely available. Considerable flexibility is provided for the development of cooperative arrangements that are appropriate to the needs, resources, and patterns of the region. The cooperative arrangements should:  $\Diamond$  Encourage a coopera-

tive attitude and stimulate participation and initiative among the program elements: Provide for the necessary decision-making framework for the activities conducted under the Regional Medical Program grant; O Include administrative and fiscal arrangements. which provide for adequate program coordination and fiscal accountability: O Provide for effective administration of central program elements which serve the entire region; ♦ Include mechanisms for the evaluation of the effectiveness of the Regional Medical Program, including the acquisition of uniform data for the use in evaluating effectiveness and the means to evaluate specific program elements of the Regional Medical Program: O Provide for continual planning and implementation of the further development of the Regional Medical Program.

## F. Interregional Cooperation

The definition of a particular region necessarily requires consideration of relationships to adjoining regions. Interregional cooperation is to be encouraged, especially in program elements where a uniform approach is desirable. Some examples where interregional cooperation might be beneficial include: Development of standardized criteria for data gathering and analysis; Continuing education programs drawing on the educational resources of more than one region; Referral of patients for highly specialized diagnosis and treatment not available in every region; Program planning and coordination between regions.

Regional boundaries should not cut off existing relationships and patterns and should not operate to the detriment of the objectives of the legislation.

## G. The Regional Advisory Group

The Act specifies that an applicant for a planning grant must designate a Regional Advisory Group. The Act also specifies that the Advisory Group must approve an application for an operational grant under Section 904. The Advisory Group must include practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, other health

professions, voluntary health agencies, and representatives of other organizations, institutions, and agencies and members of the public familiar with the need for the services provided under the program. It should be broadly representative of the geographic areas and of the social groups who will be served by the Regional Medical Program.

The Regional Advisory Group should provide overall advice and guidance to the grantee in the planning and operational program from the initial steps onward. It should be actively involved in the review and guidance and in the coordinated evaluation of the ongoing planning and operating functions. It should be constituted to encourage cooperation among the institutions, organizations, health personnel, state and local health agencies, and with the state Hill-Burton agencies. It should be concerned with continuing review of the degree of relevance of the planning and operational activities to the objectives of the Regional Medical Program and particularly with the effectiveness of these activities in attaining the objective of improved patient care. Therefore, Advisory Group members should be chosen who will provide a broad background of knowledge, attitudes and experience.

The grantee institution named on the face page of the application is legally and administratively responsible for the conduct of the Regional Medical Program. The Advisory Group does not have direct administrative responsibility for the program, but the clear intent of the Congress was that the Advisory Group would insure that the Regional Medical Program is planned and developed with the continuing advice and assistance of a group which is broadly representative of the health interests of the region. The' Advisory Group, therefore, is an inherent element of a Regional Medical Program that helps to accomplish the basic objective of broadly based regional cooperation.

In order to serve these purposes the Advisory Group should operate under established procedures which insure continuity and appropriate independence of function and advice. The Advisory Group is expected to prepare an annual statement giving its evalu-

ation of effectiveness of the regional cooperative arrangements established under the Regional Medical Program.

## H. Relation of Regional Medical Programs to Programs of Other Health Agencies

An essential function of Regional Medical Programs is to plan and to provide an environment for coordinating the health resources of the Nation in order to assure the availability of the best of medical care to all persons, it is not the intent of a Regional Medical Program grant to supplant other sources of support for the various program elements that are related to achieving its purpose. The Regional Medical Program provides an opportunity to introduce program activities which draw upon and effectively link activities already supported, or supportable in the future, through other sources. Current examples of other Federal programs that provide essential inputs into the health resources of the region are: O The Bureau of States Services: 
 The Bureau of Medical Services;  $\Diamond$  The National Institutes of Health, particularly the National Heart Institute, National Cancer Institute and National Institute of Neurological Diseases and Blindness;  $\Diamond$  Other constituents of the Department of Health, Education, and Welfare, particularly the Social Security Administration, the Office of Education, the Vocational Rehabilitation Administration and the Welfare Administration; and Other government agencies, particularly the Office of Economic Opportunity and the Veterans Administration. The Regional Medical Program grants should concentrate on catalyzing and synthesizing efforts in achieving more effective communication among all of the health related elements in the region. New sources of possible support for activities related to the Regional Medical Programs should also be considered during both the planning and operational phases. For example, the reimbursement principles for hospitals and other providers of Medicare services should make available to these institutions additional amounts of capital funds, which may contribute to accomplishing the objectives of the Regional Medical Programs through a cooperative approach to the use of medical resources in the region.

In order to assure coordination within the Federal Government, the Division of Regional Medical Programs is developing an active exchange of information with these agencies to assure that all pertinent activities are effectively interrelated.

#### III. POLICIES AND DEFINITIONS

- A. Policies
- 1. General Responsibilities
- 2. General Assurances
- 3. Surveys and Questionnaires
- 4. Systems Analysis
- 5. Publications
- 6. Patents and Inventions
- 7. Other Public Health Service Grant Policies
  - a. Clinical Research and Investigation Involving Human Beings
  - b. Protection of Individual Privacy in Research and Investigation
  - Administration of Personality Tests, Inventories or Questionnaires
  - Investigation of Persons Below the College Age Level
  - c. Animal Care
- B. Definitions
- 1. Approved Program
- 2. Budget Period
- 3. Clinical Research Center
- 4. Construction
- 5. Grant
- 6. Grantee
- 7. Hospital
- 8. Medical Center
- 9. Non-Profit
- 10. Practicing Physician
- 11. Program Period
- 12. Related Diseases

#### III. POLICIES AND DEFINITIONS

#### A. Policies

- 1. General Responsibilities The named grantee is obligated, both for itself and coperating institutions, to administer the grant in accordance with regulations and policies of the Division of Regional Medical Programs. Where a policy is not stated or where the institutional policy is more restrictive than the Regional Medical Program policy, institutional policy prevails.
- 2. General Assurances—Specific attention is directed to the requirement to honor the assurances provided in the Act.

The recipient of a planning grant must comply with the assurances in Section 903 (b), namely:

- a. reasonable assurances that Federal funds awarded to any grantee will be used only for the purposes for which awarded and in accordance with the applicable provisions of the Act and the regulations thereunder,
- b. reasonable assurances that the grantee will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement in the accounting for such Federal funds,
- c. reasonable assurances that the grantee will make such reports in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports, and
- d. a satisfactory showing that the grantee has designated an advisory group to advise it (and the institutions and agencies participating in the resulting regional medical program) in formulating and carrying out the plan for the establishment and operation of such regional medical program. The advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives from other organizations, institutions and agencies concerned with activities of the kind to be carried on under

the program and members of the public familiar with the needs for the services provided under the program.

The recipient of an operational grant must comply with the assurances under Section 904 (b), namely:

- a. Federal funds awarded to any grantee (1) will be used in accordance with applicable provisions of the Act and the regulations thereunder and (2) will not supplant funds that are otherwise available for establishment or operation of the Regional Medical Program with respect to which this grant is made.
- b. The grantee will provide for such fiscal control as fund accounting procedures as are required by the Surgeon General to assure proper disbursement of an accounting for such federal funds.
- c. The grantee will make such reports in such form and containing such information as the Surgeon General may from time to time reasonably require and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports, and
- d. Any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pursuant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 USC 276a-276a-5); and the Secretary of Labor shall have with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15FR 3176; 5 USC 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 USC 276c).
- Surveys or Questionnaires—Surveys or questionnaires arising from and supported by a grant should include a positive statement clearly setting forth that the contents are in no way the responsibility of the Public Health Service.
- 4. Systems Analysis—This policy statement is to be used by those applicants who de-

sire to incorporate systems analysis methodologies into their applications.

The use of systems analysis methodologies in regional medical programs is encouraged, but only to such an extent as it is considered applicable as an essential integral component of the individual program proposed by the applicant. The applicant should emphasize the development of innovative, adequately formulated studies of realistically restricted problems involving the application of "systems" methodologies rather than submit an application dominated by general proposals for the utilization of large scale "systems" approaches for the design of a regional medical program.

The Division of Regional Medical Programs will explore through contracts and selective studies the applicability of systems analysis to the planning and implementation of a regional medical program. One approach to the use of systems analysis in current grant applications, within the framework of this policy, is the incorporation of limited numbers of personnel with such analytic skills into the planning process. These personnel may come from university departments or schools of industrial engineering, schools of public health, commercial systems firms, those with experience in program planning and budgeting, and a variety of other sources. It is expected that from such a beginning areas worthy of more detailed activity may well become apparent and qualify for subsequent additional grant support. Applicants are encouraged to direct any questions they may have relative to the use of systems analysis to the Division of Regional Medical Programs.

- 5. Publications—Grantees may publish materials relating to their regional medical program without prior review provided that such publications carry a footnote acknowledging assistance from the Public Health Service, and indicating that findings and conclusions do not necessarily represent the views of the Service.
- 6. Patents and Inventions—The Department of Health, Education, and Welfare regulations (945 F.R., Part 6 and 8) provide as a condition that all inventions arising out of the

activities assisted by Public Health Service grants must be promptly and fully reported in the Public Health Service. Any process, art or method, machine manufacture or improvement thereof, may constitute an invention if it is new and useful and would not have been obvious to a person having skill in the art to which it relates.

In order for the Public Health Service to carry out its responsibility under these patent regulations, it is essential that the Service be advised before awarding Government funds of any commitments or obligations made by the institutions or by the professional personnel to be associated with the activities carried on under the grant which would be in conflict with the inventions agreement. When submitting an application for Regional Medical Programs, the grantee must provide in letter form either:

- a. a statement indicating no previous commitments or obligations have been made, or
- b. a detailed explanation of such commitments or obligations where they do exist.

One such letter will suffice for the named grantee and all cooperating institutions receiving support under the grant. It is the responsibility of the institution named as the grantee on the application to ascertain the facts relating to patents and to report these on behalf of all entities participating in the Regional Medical Program.

In subsequent years an annual invention statement Form PHS-3945 must be filed whether or not an invention has occurred. Where there are no inventions to report, a single form PHS-3945 is all that is required for the institution named on the application as the grantee and for all cooperating institutions. Where there are inventions to report, a separate annual invention statement must be filed for each one. Here again, it is the responsibility of the grantee to report on behalf of itself and all other entities participating in the Regional Medical Program. The Regional Medical Program grant for the following year will not be issued until the invention statement form PHS 3945 has been received by the Division of Regional Medical Programs.

- 7. Other Public Health Service Grant Policies
  —The following Public Health Service grant
  policies are also applicable to any such
  activities supported through a regional medical program grant:
- a. Clinical Research and Investigation Involving Human Beings—This policy statement is currently being revised by Public Health Service.
- b. Protection of Individual Privacy in Research and Investigation—
- (1) Administration of personality tests, inventories or questionnaires. No grant or award of the Public Health Service Extramural Programs in support of research or investigation involving the administration of personality tests, inventories or questionnaires shall be awarded by the Public Health Service unless the application includes a description of the manner in which the rights and welfare of the subjects are assured, that is, how their informed consent is obtained or why this consent is deemed unnecessary or undesirable in the particular instance.
- (2) Investigations of persons below the college age level. No grant or award of Public Health Service Extramural Programs in support of research or investigation involving administration of investigational procedures to persons below the college age level shall be awarded by the Public Health Service unless the application includes a description of the manner in which the rights and responsibilities are respected, that is, how the informed consent of the parents or guardians is obtained, or why this consent is deemed unnecessary or undesirable in this particular instance.

The professional judgment of the grantee will determine what constitutes respect for the rights and responsibilities of parents or guardians, what constitutes informed consent, and what constitutes a validation for deeming this consent to be unnecessary or undesirable in a particular instance.

#### c. Animal Care

Each person assigned or appointed to a project receiving any Public Health Service support is required to exercise every pre-

caution to assure proper care and humane treatment of research animals. The booklet, Guide for Laboratory Animals, Facilities and Care (PHS Publication #1024) should be obtained from the Division of Research Grants, Information Office, National Institutes of Health, Bethesda, Maryland, 20014.

The Public Health Service endorses the following guiding principles in the care and use of animals:

- Animals should be acquired, retained, and used in compliance with applicable state and local law.
- Animals should receive every consideration for their bodily comfort, be kindly treated and properly fed, be kept in sanitary facilities, and be provided with suitable medical care.
- ♦ With any operation likely to cause greater discomfort than that attending anesthetization, the animal should first be rendered incapable of perceiving pain and should be maintained in that condition until the operation is ended. Exceptions should be made only when anesthesia would defeat the objective of the experiment. In such cases, the anesthesia should be discontinued only so long as it is absolutely essential for the necessary observations.
- ♦ If the nature of the study requires survival of the animal, aseptic precautions should be observed during the operation, and care should be taken to minimize discomfort during convalescence comparable to precautions taken in a hospital for human beings. If the animal is severely incapacited and survival is not a requirement of the experiment, the animal should be sacrificed in a humane manner immediately following final observation.
- B. Definitions
- Approved Program—An approved program is an identified activity approved by the Division of Regional Medical Programs for support for a specific period of time.
- 2. Budget Period—The budget is the period of time within a program covered by a specific budget, usually 12 months.

- 3. Clinical Research Center—A Clinical Research Center is an institution (or part of an institution), the primary function of which is research, training of specialists, and demonstrations and which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatients and outpatients. The clinical research center may be a part of the medical center or it may be a separate institution.
- 4. Construction—Construction means alteration, major repair (to the extent permitted by regulations), remodeling and renovation of existing buildings with prior approval (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.
- 5. Grant—A grant is the total amount of direct and indirect costs which is awarded to a grantee for support of an approved program for a specific period of time.
- 6. Grantee—The grantee is the applicant institution who is named on the face page of the application and who assumes responsibility for the grant.
- 7. Hospital—The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, outpatient departments (nurses' home facilities), central service facilities operated in connection with hospitals, and other health facilities in which local capability for diagnosis and treatment is supported and augmented by the program established under this Act. It does not include institutions furnishing primarily domiciliary care. Proprietary hospitals may participate in the Regional Medical Program but may not be funded under the Act.
- 8. Medical Center—Medical Center is a medical school or other medical institution involved in postgraduate medical training and one or more hospitals affiliated therewith for teaching, research, and demonstration purposes.
- Non-Profit—Non-profit as applied to any institution or agency means an institution or agency which is owned and operated by

one or more non-profit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

- Practicing Physician—A practicing physician is any physician licensed to practice medicine in accordance with applicable state laws.
- 11. Program Period—The program period is the time for which new or continuing support has been recommended. The initial grants may be for any period up to June 30. 1969.
- 12. Related Diseases—Related diseases are those diseases which can reasonably be considered to bear a direct relationship to heart disease, cancer or stroke.

#### IV. GENERAL GRANT INFORMATION

- A. Types of Grants
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- 3. Supplemental
- B. Relationship of Planning Grant to Operational Grant
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- 1. Under a Planning Grant (including Feasibility Studies)
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- ♦ Demonstration of Patient Care
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- ♦ Computers
- O Diagnostic and Treatment Equipment
- Support of Staff in Cooperating Institutions
- ♦ Consultant Services
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- D. Relationship to Other Sources of Support
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#### IV. GENERAL GRANT INFORMATION

## A. Types of Grants

- 1. Planning—Section 903 of the Act authorizes the Surgeon General, upon the recommendation of the National Advisory Council on Regional Medical Programs, to make grants to assist in the planning and development of Regional Medical Programs.
- 2. Operational—Section 904 authorizes the Surgeon General, also upon recommendation of the National Advisory Council on Regional Medical Programs, to make grants to assist in the establishment and operation of the Regional Medical Programs. The initial authorization of this program through fiscal year 1968 indicates that operational grants under Section 904 will be considered pilot projects for the establishment and operation of Regional Medical Programs. The designation of operational programs as pilot projects emphasizes the exploratory nature of the first period of authorization.
- 3. Supplemental-The exploratory and developmental aspects of a Regional Medical Program, both in the planning and operational phases, lead to the expectation that the grantee will wish to add additional program elements or to expand existing program elements subsequent to the award of the initial grant. The practice of submitting requests for supplemental funds is encouraged insofar as the submission of a supplemental request is preferable to the inclusion in the initial application of program elements which represent only very preliminary ideas or for which it is difficult to justify particular budget requests. Supplemental grant requests will be submitted on the same form as the initial application and will go through a similar review and award process.

## B. Relationship of Planning Grant to Operational Grant

The Act does not provide a specific sequential relationship between planning grants

under Section 903 and operational grants under Section 904. The operation of a Regional Medical Program obviously should be based upon sound planning. For example, one purpose of planning for a region is to help establish the geographic boundaries that are necessary for effective and efficient operation of the region. Planning also provides an opportunity for the advisory group to participate in the initial stages of the program. In some areas of the country, much relevant planning may have taken place before passage of this legislation. In such instances the grantee may request an operational grant without having first applied for a planning grant under Regional Medical Programs.

A grantee who has received a planning grant need not wait for the completion of that planning grant before applying for an operational grant under Section 904. The grantee may wish to request funds under Section 904 to finance operational activities which represent the first elements of a complete Regional Medical Program. Such grants for the partial implementation of a Regional Medical Program will be awarded, however, on the condition that the planning for implementation of additional phases of the Regional Medical Program will proceed. Grants for partial implementation will be awarded for limited time periods and the continuation of such a grant will be conditioned upon the submission, review, and approval of additional elements of the complete Regional Medical Program by the end of the initial period of award. The purpose of these conditions is to allow initial steps in the implementation of a Regional Medical Program, while at the same time, insuring progress toward the full development of the Regional Medical Program.

Planning should continue after the initiation of an operational program under Section 904. This continued planning may be financed either by continuing the planning grant under Section 903, or by the inclusion of the support of planning activities under the operational grant. Conversely, however, operational activities may not be supported from planning grant funds.

#### C. Eligible Activities

This section gives examples of types of activities which would be eligible for support under a Regional Medical Program grant. The intent of the program is to encourage innovations and creativity in the development through cooperative efforts of program elements to be included in the Regional Medical Program. The listing therefore is intended to be helpful in the understanding of the scope of a regional medical program, rather than to be definitive.

Many different types of activities can be supported under a Regional Medical Program grant. Special attention must be given to the functional interrelationships among the various program elements, and how they relate to the goals of the Regional Medical Program.

Certain program elements deserve special discussion. Applications for a Regional Medical Program grant, both planning and operational, must include specific reference to program plans for education and training of health personnel. Continuing education should receive particular emphasis as an integral part of the total Regional Medical Program. However, meritorious programs of continuing education presented in the absence of, or unrelated to, plans for the fuller development of a Regional Medical Program cannot be supported through grants under this program. Therefore, the relationship of continuing education to other aspects of the proposed planning or operational activity must be indicated.

Both the planning and operational phase of a Regional Medical Program should stress the development of more effective relationships between ongoing research activities in the fields of heart disease, cancer, stroke, or related diseases and the other proposed activities of an educational or service nature under the Regional Medical Program. The Regional Medical Program should seek to maintain an effective interaction between ongoing research activities and other aspects of the Regional Medical Program, so as to assure that the activities specifically directed toward the goal of improved diagnosis and

reatment may receive the benefit of future research advances.

1. Under Rlanning Grant (including Feasibility Studies)—The scope of planning activities which are related to accomplishing the objectives of the Regional Medical Programs can be quite broad. However, planning and conceptualization concerned with general health matters but not related to development of a Regional Medical Program should not be included.

In general, planning should include studies of resources, distribution of services, patient flow, and program elements that are needed, design of specific program elements that includes a mechanism for program evaluation, planning for cooperation among institutions, and planning toward the more effective distribution and utilization of all types of medical resources.

The development and operation of regional medical programs, individually and collectively, can be aided by well conceived, properly implemented, and continuous communication and public information techniques and activities which are designed to provide a maximum of understanding, participation and support among cooperating organizations and individuals, as well as among lay publics for whom the programs will be established.

To plan and implement such activities, provision for including professional staffing and budgetary support for a communication and public information component may be included in grant applications.

The emphasis on continuing education in the Act deserves particular mention. Creative approaches in the development and management of cooperative arrangements to achieve high quality education programs as well as new ways of applying educational research findings are vital. Indeed the history of the legislation itself stimulates this aspect of regional medical programs.

Examples of activities for consideration in planning in the area of continuing education and training are: identification of existing

educational and training programs within the region; evaluation of additional educational and training needs in the region; projections of methods of meeting those needs including specification of appropriate curriculum content, etc.; preliminary thoughts relative to the mechanism of evaluating the effectiveness of future programs in meeting the needs; the relationship of continuing education and training programs to the overall objectives of the Regional Medical Program including their anticipated effectiveness in bringing about cooperative arrangements between the various health institutions and personnel within the region.

 Under an Operational Grant—Pilot projects for the establishment and operation of a Regional Medical Program can cover a great variety of activities.

♦ Continuing Education and Training It is assumed that before applying for an operational grant in this area, certain activities will have been undertaken during the planning process (see above). Operational grant funds can support costs of programs including teaching staff, equipment, educational materials, transportation, rental or renovation of space and related demonstrations of patient care. However, the grant may not supplant previous support for ongoing activities in this area. Documentation of the additive nature of the proposed program should be made. Stipends for trainees and participants in the program will be considered only when it is fully documented that such funds are not available from other sources and their expenditure is absolutely necessary for the implementation of the program.

In instances where major expenditures for equipment and supplies are requested special emphasis should be given to measurement of effectiveness of the program including measurements in change in performance of participants, numbers of participants, and degree information produced might be applicable to other regional medical programs. There should also be acknowledgement of related efforts already accomplished by others with indications of how the

proposed project will extend those efforts. It is anticipated that such major investments for equipment and supplies will more appropriately be in pilot projects or operational grants rather than in feasibility studies or planning grants.

Considerations under the Regional Medical Programs will be given to continuing education and training programs for medical, allied health personnel and associated professions. However, it should be emphasized that the primary intent of the legislation in this area is the support of those activities that are beyond those normally accepted as basic preparation for work in the health field. Thus, support of basic programs in medical education, residency training, and basic education and training in allied health areas is not normally anticipated. If, however, the applicant can demonstrate that funds are not available from other sources and the particular basic educational program is essential to the success of the Regional Medical Program then consideration will be given to such a request.

Applicants are encouraged to explore innovative training approaches and the development of new types of health personnel to meet the manpower needs of the region as identified in the planning process.

#### ♦ Research

Research into better means of accomplishing the purposes and objectives of the Regional Medical Program is supportable under an operational grant. Since other Public Health Service grant mechanisms provide excellent means for the support of biomedical research, the grantee under a Regional Medical Program is required to look to these and other sources of support as well. The support of research activities through other Public Health Service research support mechanisms does not lessen the importance of planning and implementing a Regional Medical Program in a manner which insures a close and continuous linkage between all of the activities of the regional program and the environment of research and teaching.

However, if special justification exists for the support of research which is essential to the effective accomplishment of the objectives of the Regional Medical Program, and if it can be demonstrated that the other sources of support are not appropriate, a limited amount of research activity could be supported under the Regional Medical Program grant.

O Demonstrations of Patient Care

Demonstrations of patient care may be supported when related to the research, training, and continuing education activities of the program. The Act provides that the costs of patient care may be supported only when such care is incident to research, training, or demonstration activities encompassed by the purposes of the program and only if the patient has been referred by a practicing physician. Grant funds could be used to pay the other costs incident to the demonstration activity, including staff and equipment.

♦ Support of Administrative Core

The grant may be used to pay the costs for the central administration of the total Regional Medical Program. This could include the salaries of a program coordinator and other administrative staff as well as the other costs incident to the central coordination of the Regional Medical Program.

♦ Alteration and Renovation

Ninety percent of the costs of alteration and renovation may be charged to operational grants. No such charges are permitted to planning grants.

♦ Communication Systems

A grant may support the purchase or rental of communication systems to be used for educational, diagnostic or other purposes. However, if such requests represent major funding investments, they should include (as mentioned under Continuing Education and Training above) documentation of: the measurements of effectiveness of the program; the numbers of people affected by the system; the degree to which the information produced might be generalized to other Regional Medical Programs; and knowledge of related efforts already accomplished by others with indications of the manner by which the proposed project will extend those efforts.

♦ Communications and Public Information A communication and public information component as an integral part of the proposed regional medical program might include:

Utilization of a qualified communication and public information specialist, and necessary supporting staff, in both planning and operational activities.

Development of studies to evaluate professional and public attitudes toward the programs.

Development and maintenance of a flow of professional and general information to all special and general interest groups and publics, among other existing regional medical programs, and between them and the Division of Regional Medical Programs.

Preparation and distribution of printed, visual and other information material for professional and lay publics.

Participation of this component in planning and conducting programs, seminars, conferences and other means of exchanging professional general information.

Plans that do not specifically further understanding, participation and support as previously defined, or which would appear to provide only for publicity for the program and aggrandisement of its officials, should not be included.

Questions related to these aspects of a proposed program may be directed to the Division of Regional Medical Programs for answers or special consultation.

## **♦** Computers

Grant funds may be used to purchase computer time, or if the needs of the program are sufficient, the rental of a computer. As with all other activities, the costs of acquiring computer capability must be measured against the benefits to be derived for the program.

♦ Diagnostic and Treatment Equipment Funds may be used to purchase diagnostic and treatment equipment which is identified, through the planning process, as being a specific need of the region in carrying out the purposes of the program. The location of such equipment should be planned with its efficient and effective use in mind.

♦ Support of Staff in Cooperating Institutions
The grant can be used to pay the salary of
staff involved in the conduct of the Regional
Medical Program, not only in the grantee
institution but also in the other institutions
cooperating in the program. The level of
salary support must be consistent with the
salary policies of the institution concerned.
The staff might be engaged in supervising
and coordinating the activities of the Regional Medical Program in the institution or
be involved in specific program elements,
such as those discussed above.

♦ Consultant Services

The grant could pay for consultant services related to any program element of the Regional Medical Program and justified as the most effective means of accomplishing a particular purpose to be served.

♦ Transportation of Patients

When justified as the most efficient means of carrying out the purpose of the program, grant funds may be used to pay the costs of transportation of patients referred for diagnosis and treatment in other institutions as part of a research, training or demonstration program. The use of grant funds to pay transportation costs should be carefully weighed against the use of funds for other activities within the Regional Medical Program.

D. Relationship to Other Sources of Support It is expected that no institutional funds formerly devoted to these activities will be displaced by the use of the Regional Medical Program grant. Not only should the grantee avoid substituting these grant funds for other sources of support, but he should also continue to seek additional resources for carrying out the objectives of the Regional Medical Program.

## E. Single Grant Approach

Planning as well as operational grants will each be single instruments of support for activities under the Regional Medical Programs. The single grant approach is intended to insure an appropriate degree of cohesiveness in the cooperative approach.

# V. PREPARATION AND REVIEW OF APPLICATION

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- 5. Invention
- O. Miscellaneous
- 1. Safety Precautions
- 2. Federal Income Tax
- 3. Military Service

# V. PREPARATION AND REVIEW OF APPLICATION

### A. Eligible Applicants

The following are eligible applicants for bot planning and operational grants: public, o private non-profit universities, medica schools, research institutions, and othe public, or non-profit private agencies and institutions located in any state, the Distric of Columbia, Puerto Rico, or the Virgi Islands. The applicant must be authorized to represent the participating institutions who propose to be involved in the planning and operation of the Regional Medical Program The applicant must be able to exercise pro gram coordination and fiscal responsibility in assuring the effective use of the gran funds. The applicant is legally responsible for expenditure of funds both by itself and cooperating institutions.

### B. Method of Obtaining Application

Application form NIH-925, which is used both for planning and operational grants, whether they are new, continuation, or supplemental may be obtained by writing the Division or Regional Medical Programs, National Institutes of Health, Bethesda, Maryland, 20014

## C. Method of Preparing Application

Applications should be prepared in accordance with information contained in these

guidelines and with the specific instructions included with the application.

### D. Review of Application

Applications will be reviewed by the staff, by consultants to the Division of Regional Medical Programs, and as required by statute, by the National Advisory Council on Regional Medical Programs. Under terms of the law, a grant may not be awarded unless it has been recommended for approval by the National Advisory Council.

The rigorous review process requires that sufficient information be provided in the application to enable the reviewers to reach considered and informed judgments concerning the nature, feasibility and soundness of the proposal and to weigh the use of grant funds for the particular proposal against benefits to be gained from the use of grant funds elsewhere.

A complete, informative application will facilitate and expedite the review of an application. When necessary in the judgment of the staff or consultants, additional information or justification may be required either by supplemental documents or by conferences and visits.

#### E. Notification of Applicant

Copies of a Notice of Grant Awarded are sent to the grantee. This notice indicates the program period, the amount being awarded (including the budget period covered), and any special conditions under which the grant is awarded.

#### F. Financial Management

1. General Requirements—Funds granted may be used only for services, materials and other items required to carry out the approved program. Circular A-21 of the Bureau of the Budget should be used to the extent practicable in determining allowable costs related to the grants for Regional Medical Programs. Where the Division of Regional Medical Programs requires prior approval for items not listed in the approved budget, a written request must be made by the grantee to the Division of Regional Medical

Programs in advance of the performance of the act which requires the obligating or expenditure of funds.

- 2. The Amount Awarded—There is no fixed limitation on the amount of funds that may be awarded. The budget must have a direct relationship to the activities proposed. The size of the various program elements included in the budget should be carefully considered in terms of the relative effectiveness in accomplishing the purposes of the Regional Medical Program. The budget should also have a direct relationship to the reasonable expectations for the rate of implementation of the proposed programs.
- 3. Direct Costs—The following are examples of direct costs that may be charged to a Regional Medical Program grant:

#### Personnel

Salaries, wages, and fringe benefits of personnel in proportion to the time or effort expended on the program and in accordance with institutional policy, may be charged to this category. Adequate time and effort records must be maintained in order to substantiate these costs.

## ♦ Consultant Costs

Grant funds may be used to pay consultant fees for services related to any program element of the Regional Medical Program providing that these services are the most effective means of accomplishing a particular purpose, and that the consultant is not on the staff of the grantee or cooperating institution. If consultation is obtained from a staff member of the grantee or cooperating institution, a proportionate amount of his regular salary may be paid by the grant. In either case, consultant costs must be supported by a clear statement of services performed and if appropriate, the number of man days of service.

### ♦ Hospitalization Costs

The method of determining hospitalization costs is still under consideration by the Division of Regional Medical Programs. It will be distributed at a later date.

### ♦ Travel

Per diem reimbursements to travelers, personal transportation charges, and reimbursements for authorized use of personally owned automobiles are chargeable under this category.

Less than first class travel accommodations shall be used except in extenuating circumstances. Automobile mileage and any foreign travel must be in accordance with institution policy. Any foreign travel must receive prior approval from the Division of Regional Medical Programs.

#### ♦ Rent

The expenses for rental of facilities not owned by the grantee or participating institution may be charged in proportion to the space actually utilized for the program. Rental costs may not be in excess of comparable rentals in the particular locality, and must be in accordance with institution policy.

#### ♦ Communication

That portion of communication charges necessary to the planning or implementation of the program or project may be charged to this category. In no case may institutional local and regular monthly telephone costs and normal postage charges not related to the Regional Medical Programs be charged to the grant.

## Printing and Reproduction

Printing of pamphlets, brochures and other materials necessary for this program may be charged to this category.

## ♦ Equipment

Rental and purchase of equipment for the planning or implementation of a program may be charged to this category. When acquiring equipment, consideration of the relative advantages of lease versus purchase should be considered.

♦ Alteration and Renovation ("Construction")
Under the Act "construction" means alteration, restoration to a sound state, remodeling and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete built-in equipment of existing buildings. Built-in equipment is equipment affixed to the facility and customarily included in a building contract. The applicant is required to furnish in sufficient detail plans and specifications, as well as a narrative description, to indicate the need, nature and purpose of the proposed "construction."

Operational grant funds may not support more than 90% of the cost of such "construction" or equipment,

New facilities may not be constructed under this program. Where construction of new facilities is considered necessary for furthering the program, the applicant may seek construction funds under other applicable Federal programs, such as the Hill-Burton, Health Research Facilities, and the Health Professions Educational Assistance programs.

#### ♦ Direct Costs not Permitted

The following direct costs or charges are not allowable:

- Honoraria as distinguished from consultant fees
- Entertainment (cost of amusement, social activities, entertainment and incidental costs thereto, such as meals, lodging, rentals, transportation and gratuities)
- · Payment to Federal employees
- · Petty cash funds
- Subgranting (a subgrant is any allocation of grant funds by the grantee to other individuals or organizations for purposes over which the grantee institution named on the application does not maintain scientific and financial responsibility. A grantee may contract for services, but may not subgrant.)
- 4. Indirect Costs—Institutional indirect cost rates will be based on the percentage relationship that total institutional indirect cost is to the total direct salaries and wages paid by the institution (not just the research indirect cost pool).

Data taken directly from the grantee or cooperating institutions most recent annual financial report and immediately available supporting information will be utilized as a basis for determining the indirect cost rate applicable to a Regional Medical Program grant at the institution.

Total expenditures as taken from the most recent annual financial report will be adjusted by eliminating from further consideration the following items or categories of expenditure:

♦ The costs of equipment, buildings, and repairs which materially increase the value or useful life of buildings or equipment. However, depreciation and use charges may be included in determining total expenditure.

- ♦ Advertising other than for recruitment of personnel, procurement of scarce items or the disposal of scrap or surplus material.
- ♦ Bad debts
- ♦ Contingency reserves
- ♦ Commencement and convocation costs
- ♦ Entertainment costs
- Fines and penalties
- Interest, fund raising and investment management costs
- ♦ Losses on other agreements or contracts
- Profits and losses on disposition of plant, equipment, or other capital costs
- ♦ Public information services costs
- Scholarships and student aid costs
- ♦ Special services costs incured for general public relations
- ♦ Student activity costs
- Student dormitory costs
- ♦ Student services costs
- ♦ Costs used in arriving at a hospitalization rate or interdepartmental charge
- Unrelated hospital costs
- ♦ Other inappropriate costs

Where any types of expense ordinarily treated as general administration and general expenses or departmental administration expenses are charged to a Division of Regional Medical Programs grant as direct costs, the similar type of expenses applicable to other activities of the institution must, through separate cost groupings, be excluded from the indirect costs allowable to a Division of Regional Medical Programs grant.

The indirect cost rate will then be computed by dividing the total direct salaries and wages paid by the institution into the total adjusted indirect cost incurred by the institution.

When, under an operational grant, the cooperating institutions are preparing their budgets for submission to the grantee, the institutions' indirect cost rates, 'based on salaries and wages, should be stated in the budget. To substantiate this rate, the cooperating institutions should supply the grantee with adequate substantiating data, such as documents certifying that the over-

all institutional indirect cost rate has been audited and approved by the PHS, another Government agency, or an independent accounting firm. In addition, the total institutional indirect cost, and direct salaries and wages should be stated as separate amounts. The institution should indicate whether fringe benefits are included in the salary and wage base or not. A detailed indirect cost proposal should accompany each new or continuing grant application. When an applicant is submitting a planning grant application to the Division of Regional Medical Programs, the above procedures also apply.

Indirect costs are those which, because of their incurrence usually for common or joint objectives, are not readily Identified with individual projects. All costs representing charges associated with the activities of the grantee or cooperating institutions which are supportive of the conduct of the Regional Medical Program, except those which are specifically approved by the Division of Regional Medical Programs as direct costs, are classified as indirect costs. The general types of indirect costs are:

♦ General administration and expenses which are incurred for the executive and administrative offices of an institution receiving grants, and other expenses of a general character which do not relate solely to any specific unit in the institution, or to any specific project in the institution;

♦ Program administration expenses which apply to program activities administered in whole or in part by a separate organization or an identifiable administrative unit. Examples of work relating to grant programs which is sometimes performed under such organizational arrangement are: grant administration, purchasing, personnel, accounting, etc.;

♦ Operation and maintenance expenses incurred for operating and maintaining an institution's physical plant, including expenses normally incurred for administration or supervision of the physical plant; janitorial service; utilities, including telephone installation and maintenance costs; and other expenses customarily associated with the operation, maintenance, preservation,

and protection of the institution's physical facilities;

♦ Reimbursements and other receipts from the Federal Government which are used by the institution to support directly, in whole or in part, any of the administrative or service (indirect) activities received pursuant to an institution's base grant or any similar contractual arrangement with the Federal Government shall be treated as a credit to the total indirect cost pool. Such set-off shall be made prior to the determination of the indirect cost rate submitted to the Division of Regional Medical Programs. These credits include indirect cost reimbursements contained in payments for hospitalization, interdepartmental charges and centralized facilities operated by the institution.

5. Rebudgeting of Funds—The grantee or cooperating institutions may depart from the approved budget and use the funds for other items required for the project, except for the following restrictions:

♦ Grant funds may not be used for any purpose contrary to the regulations and policies of the Division of Regional Medical Programs or the grantee or the cooperating institutions.

♦ Grant funds may be transferred between budget categories to the extent that no category is increased or decreased by more than 20% of the approved budget. Increases or decreases in a budget category in excess of 20% must be approved by the Division of Regional Medical Programs.

6. Refunds—During the program period, refunds and rebates should be credited to the account. Credits received after the termination of the program period shall be returned to the Public Health Service. Checks should be made payable to National Institutes of Health, PHS, DHEW, Bethesda, Maryland, 20014.

♦ Interest and other income Interest or other income earned on grant

Interest or other income earned on grant funds must be returned to the Public Health Service.

A Royalties and Profits

When the costs of publishing material are provided from Public Health Service grants, any royalties or profits up to the amount charged to the grant for publishing the

material shall be refunded to the Public Health Service.

7. Unexpended Balance-Continued use of any unobligated or unexpended funds remaining in the grant account at the end of the budget period should be justified by the grantee when the Expenditures Report is submitted to the Division of Regional Medical Programs. If adequate justification is received, the Division of Regional Medical Programs will advise the grantee that such funds may be used during the subsequent budget period. If inadequate justification, or no justification is presented, unexpended funds will be used toward payment of the total amount requested for the subsequent budget period. The unexpended balance as shown in the final Expenditures Report must be returned to the National Institutes of Health, PHS, DHEW, Bethesda, Maryland, 20014.

8. Obligations or Expenditures-Obligations. commitments, encumbrances, or expenditures will normally be made within the period indicated on the notice of grant award. Grant funds may not be used to reimburse any such obligations, commitments or expenditures made prior to the beginning date of the initial grant for a new or renewal project. In exceptional instances the grantee may, at its own risk, prior to the beginning date of a continuation award, incur expenditures which exceed existing Division of Regional Medical Programs authorization but which are considered essential to the conduct of the project. The Division of Regional Medical Programs may allow reimbursement of such expenditures from the continuation grant,

## 9. Accounting Records and Audit-

♦ Accounting

Accounting for the grant funds will be in accordance with the grantee and/or cooperating institution accounting practices consistently applied regardless of the source of funds. Itemization of all supporting expenditures must be recorded in sufficient detail to show the exact nature of expenditures. Each recipient of grant funds shall keep such records as the Surgeon General may prescribe, including records which fully disclose the amount and disposition by such

recipient of the proceeds of such grant, the total cost of the program or undertaking in connection with which such grant is made or used, and the amount of that portion of the cost of the program or undertaking supplied by other sources, and to make such records available as will facilitate an effective audit by authorized personnel. Such a system must meet the following criteria:

- A special grant account must be established for each Regional Medical Program grant and be maintained at the grantee institution designated on the application. Responsibility for expenditure of funds by participating institutions must be assumed by the named grantee institution.
- The accounting records at the grantee institution shall provide the information needed to identify the receipt and expenditure of all program funds separately for each grant. Expenditures shall be recorded by the component program and budget cost categories shown in the approved budget.
- Each entry in the accounting records at the grantee or cooperating institution shall refer to the documentation which supports the entry and the documentation shall be filed in such a way that it can be readily located.
   The accounting records shall provide accurate and current financial reporting information.
- The accounting system shall possess an adequate means of internal control to safeguard the assets, check the accuracy and reliability of the accounting data, promote operational efficiency, and encourage adherence to prescribed management policies.
   Records

The financial records, including all documents to support entries on the accounting records, must be kept readily available for examination by authorized personnel. No such records shall be destroyed or otherwise disposed of within three years after the termination of the program. Unless written approval is obtained from the Public Health Service to dispose of the records, they must be retained until the audit has been completed and all questions about the expenditures are resolved.

## Audit

The Division of Regional Medical Programs follows generally accepted auditing practices

in determining that there is a proper accounting in use of grant funds. Failure of a grantee to appeal a proposed audit disallowance within thirty days after receipt of a written notification will make the action of the Division of Regional Medical Programs conclusive.

## 10. Equipment (Title and Accountability)

Title to equipment purchased with grant funds resides in the grantee institution and accountability may be waived at the termination of the grant by the Division of Regional Medical Programs as long as the equipment is used to further the objectives of the Public Health Service. The Division of Regional Medical Programs, however, reserves the right under unusual circumstances to transfer title of equipment to the Division of Regional Medical Programs or to another grantee.

Excess materials and supplies retained by the grantee upon termination of the program may be accounted for under the same terms as equipment.

#### G. Additional Funds

To obtain additional funds for support of a program, the procedures vary according to the need as follows:

- 1. For continued support—An application form requesting support for the next budget period of the program period (continuation grant) will be mailed to the grantee institution about 4 months before the beginning date of the next budget period. It is the responsibility of the grantee to request this application form if it is not received. The application should be submitted in accordance with the instructions accompanying the form.
- 2. For supplemental funds—If additional funds to conduct the program are required within any portion of the program period over those budgeted and approved, and such funds are not available within the institution receiving support for the program, a supplemental application may be submitted. A face sheet, budget page, and justification are required for a supplemental award. A

supplemental grant forms a part of the initial award and only one report of expenditures is required.

Supplemental applications are processed in the same manner as new applications and must compete for available funds, except those applications to meet increased administrative costs, such as fringe benefits or salary increases, may be administratively approved.

3. Support beyond the Program Period—If additional support beyond the program period is required, a new application must be submitted. This application will go through the normal review process and will compete with other applications for available funds. If approved, an initial grant for a new program period will be awarded.

## H. Program Evaluation

The grantee should make a special effort to incorporate into all aspects of the planning and operational activities appropriate mechanisms for evaluating the effectiveness of all aspects of the Regional Medical Program. The concern with the evaluation should begin in the planning process so that the planning process may include planning for evaluation mechanisms. The exploratory nature of the Regional Medical Programs makes the need for the realistic evaluation mechanisms especially important. Particular attention to the evaluation process will provide the means for the grantee to assess his progress and accomplishments and will also provide the basis for the preparation of progress reports which can be used by the Division of Regional Medical Programs in evaluating the accomplishments of the total national program.

## I. Changes in Approved Program

The Division of Regional Medical Programs does not intend to interfere with administrative or program flexibility which serves the objectives of the Regional Medical Programs. If, however, a change is determined by the grantee to be desirable, and if that change would constitute a substantial change in the nature of the program originally approved, the grantee should consult with the Division of Regional Medical Programs staff.

### J. Change of Grantee

If the grantee expects to relinquish active direction of the program, the Division of Regional Medical Programs must be notified immediately. The grantee may request that the grant be terminated, in which case a terminal progress report, an expenditures report, and invention statement (PHS-3945) must be submitted. The grantee may request that the program be continued under the direction of another institution.

If the grantee terminates its responsibility for the program, the new institution may submit a new grant application for the remainder of the program period. The application should include the reasons for transferring the program and the probable effect of the move on the program. Administrative approval may be given by the Division of Regional Medical Programs to continue the program at the new institution. Applications, however, that reflect major changes will be referred to the National Advisory Council on Regional Medical Programs for recommendation.

## K. Change of Program Coordinator

The program coordinator named in the application shall be responsible for coordination of the program during the period for which the grant was awarded.

A change of program coordinator or other key official directing the program requires approval by the Division of Regional Medical Programs. The grantee is required to notify the Division of Regional Medical Programs if such a change is necessary.

### L. Change in Program Period

The program period may be extended up to 12 months (but not beyond June 30, 1969) without additional funds, if requested by the grantee before the end of the program period.

# M. Early Termination of Grant

1. By the Grantee—A grant may be terminated or cancelled at any time by the grantee upon written notification to the

Division of Regional Medical Programs stating the reasons for termination.

2. By the Public Health Service—A grant may be revoked or terminated by the Surgeon General, in whole or in part, in any time within the program period whenever it is determined that the grantee has failed in a material respect to comply with the terms and conditions of the grant. The grantee will be promptly advised of the reasons for termination of the grant in writing.

#### N. Reports

All reports required to be submitted to the Public Health Service should be sent to the Division of Regional Medical Programs, Public Health Service, Bethesda, Maryland, 20014.

- 1. Progress Reports-The grantee is required to submit an annual progress report. This report should contain sufficient detail to inform the reader of the accomplishments with particular respect to the objectives originally set forth. These progress reports must be submitted with the application for a continued support. In addition, grantees may be required to supply other information needed for guidance and development of the national program and are encouraged to report significant developments promptly at any time. A terminal progress report must be submitted to the Division of Regional Medical Programs within three months of the termination of the program period.
- 2. Regional Advisory Group—The Regional Advisory Group is expected to prepare an annual statement on the effectiveness of the regional cooperative arrangements established under the Regional Medical Program. The report should be submitted to the Division of Regional Medical Programs by the grantee along with the annual progress report. Periodic reviews of grants by the staff of the Division and the Advisory Council will include consideration of the effectiveness of the Advisory Group in serving its essential purpose.
- 3. Expenditures Report (Form NIH-925-3)—A single expenditures report and a single narrative progress report is required to be

submitted by the named grantee on behalf of all cooperating institutions to the Division of Regional Medical Programs for each budget period of the program period. If the grantee fails to submit an expenditures report within 120 days after the end of each budget period, future awards for that project may be withheld.

A supplemental grant forms a part of the existing grant and only one expenditure report need be submitted on the combined grants.

- 4. Time or Effort Report—Charges for salaries and wages of individuals other than members of the professional staff will be supported by time and attendance and payroll distribution records. For members of the professional staff, quarterly estimates of the percentage distribution of their total effort must be used as support in the absence of actual time records. Time and effort reports are not to be sent to the Division of Regional Medical Programs but must be retained by the grantee and must be made available for inspection by the Public Health Service staff.
- Invention Report—Immediate and full reporting of all inventions to the Public Health Service is required.

#### O. Miscellaneous

- 1. Safety Precautions—The Public Health Service assumes no responsibility with respect to accident, claims or illness arising out of any work undertaken with the assistance of a Public Health Service Grant. The grantee institution is expected to take necessary steps to insure or protect itself and its personnel.
- 2. Federal Income Tax—Determination of a tax status of an individual receiving compensation in any form from the Public Health Service grant is the responsibility of the Internal Revenue Service.
- 3. Military Service—The Public Health Service will not intercede on behalf of an individual in relation to military status.

Public Law 89-239 89th Congress, S. 596 October 6, 1965

## AN ACT

To amend the Public Health Service Act to assist in combating heart disease, cancer, stroke, and related diseases.

Heart Disease, Cancer, and Stroke Amendments of 1965.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Heart Disease, Cancer, and Stroke Amendments of 1965".

Sec. 2. The Public Health Service Act (42 U.S.C., ch. 6A) is amended by adding at the end thereof the following new title:

"TITLE IX—EDUCATION, RESEARCH, TRAIN-ING, AND DEMONSTRATIONS IN THE FIELDS OF HEART DISEASE, CANCER, STROKE, AND RELATED DISEASES

#### "Purposes

"Sec. 900. The purposes of this title are—
"(a) Through grants, to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions, and hospitals for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases;

"(b) To afford to the medical profession and the medical institutions of the Nation, through such cooperative arrangements, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases; and

"(c) By these means, to improve generally the health manpower and facilities available to the Nation, and to accomplish these ends without interfering with the patterns, or the methods of financing, of patient care or professional practice, or with the administration of hospitals, and in cooperation with practicing physicians, medical center officials, hospital administrators, and representatives from appropriate voluntary health agencies.

## "Authorization of Appropriations

"Sec. 901. (a) There are authorized to be appropriated \$50,000,000 for the fiscal year ending June 30, 1966, \$90,000,000 for the fiscal year ending June 30, 1967, and \$200,000,000 for the fiscal year ending June 30, 1968, for grants to assist public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private institutions and agencies in planning, in conducting feasibility studies, and in operating pilot projects for the establishment, of regional medical programs of research, training, and demonstration activities for carrying out the purposes of this title. Sums appropriated under this section for any fiscal year shall remain available for making such grants until the end of the fiscal year following the fiscal year for which the appropriation is made.

- "(b) A grant under this title shall be for part or all of the cost of the planning or other activities with respect to which the application is made, except that any such grant with respect to construction of, or provision of built-in (as determined in accordance with regulations) equipment for, any facility may not exceed 90 per centum of the cost of such construction or equipment.
- "(c) Funds appropriated pursuant to this title shall not be available to pay the cost of hospital, medical, or other care of patients except to the extent it is, as determined in accordance with regulations, incident to those research, training, or demonstration activities which are encompassed by the purposes of this title. No patient shall be furnished hospital, medical, or other care at any facility incident to research, training, or demonstration activities carried out with funds appropriated pursuant to this title, unless he has been referred to such facility by a practicing physician.

#### "Definitions

"Sec. 902. For the purposes of this title—
"(a) The term 'regional medical program'
means a cooperative arrangement among a
group of public or nonprofit private institutions or agencies engaged in research, training, diagnosis, and treatment relating to
heart disease, cancer, or stroke, and, at the
option of the applicant, related disease or
diseases; but only if such group—

"(1) is situated within a geographic area, composed of any part or parts of any one or more States, which the Surgeon General determines, in accordance with regulations, to be appropriate for carrying out the purposes of this title;

"(2) consists of one or more medical centers, one or more clinical research centers, and one or more hospitals; and

"(3) has in effect cooperative arrangements among its component units which the Surgeon General finds will be adequate for effectively carrying out the purposes of this title.

"(b) The term 'medical center' means a medical school or other medical institution involved in postgraduate medical training and one or more hospitals affiliated therewith for teaching, research, and demonstration purposes.

"(c) The term 'clinical research center' means an institution (or part of an institution) the primary function of which is research, training of specialists, and demonstrations and which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatients and outpatients.

"(d) The term 'hospital' means a hospital as defined in section 625(c) or other health facility in which local capability for diagnosis and treatment is supported and augmented by the program established under this title.

"(e) The term 'nonprofit' as applied to any institution or agency means an institution or agency which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"(f) The term 'construction' includes alteration, major repair (to the extent permitted by regulations), remodeling and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

#### "Grants for Planning

"Sec. 903. (a) The Surgeon General, upon the recommendation of the National Advisory Council on Regional Medical Programs established by section 905 (hereafter in this title referred to as the 'Council'), is authorized to make grants to public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist them in planning the development of regional medical programs.

"(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any such application may be approved only if it contains or is supported by—

"(1) reasonable assurances that Federal funds paid pursuant to any such grant will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder;

"(2) reasonable assurances that the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

"(3) reasonable assurances that the applicant will make such reports, in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

"(4) a satisfactory showing that the applicant has designated an advisory group, to advise the applicant (and the institutions and agencies participating in the resulting regional medical program) in formulating and carrying out the plan for the establishment and operation of such regional medical program, which advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives of other organizations, institutions, and agencies concerned with activities of the kind to be carried on under the program and members of the public familiar with the need for the services provided under the program.

## "Grants for Establishment and Operation of Regional Medical Programs

"Sec. 904. (a) The Surgeon General, upon the recommendation of the Council, is authorized to make grants to public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist in establishment and operation of regional medical programs, including construction and equipment of facilities in connection therewith.

"(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any such application may be approved only if it is recommended by the advisory group described in section 903(b)(4) and contains or is supported by reasonable assurances that—

"(1) Federal funds paid pursuant to any such grant (A) will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder, and (B) will not supplant funds that are otherwise available for establishment or operation of the regional medical program with respect to which the grant is made;

"(2) the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

"(3) the applicant will make such reports, in such form and Records containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may

find necessary to assure the correctness and verification of such reports: and "(4) any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pursuant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a-276a-5); and the Secretary of Labor shall have, with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176: 5 U.S.C. 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c).

# "National Advisory Council on Regional Medical Programs

"Sec. 905. (a) The Surgeon General, with the approval of the Secretary, may appoint, without regard to the civil service laws, a National Advisory Council on Regional Medical Programs. The Council shall consist of the Surgeon General, who shall be the chairman, and twelve members, not otherwise in the regular full-time employ of the United States, who are leaders in the fields of the fundamental sciences, the medical sciences, or public affairs. At least two of the appointed members shall be practicing physicians, one shall be outstanding in the study, diagnosis, or treatment of heart disease, one shall be outstanding in the study. diagnosis, or treatment of cancer, and one shall be outstanding in the study, diagnosis or treatment of stroke.

"(b) Each appointed member of the Council shall hold office for a term of four years, except that any member appointed to fill a vacancy prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term, and except that the terms of office of the members first taking office shall expire, as designated by the Surgeon General at the time of appointment, four at

the end of the first year, four at the end of the second year, and four at the end of the third year after the date of appointment. An appointed member shall not be eligible to serve continuously for more than two terms.

"(c) Appointed members of the Council, while attending meetings or conferences thereof or otherwise serving on business of the Council, shall be entitled to receive compensation at rates fixed by the Secretary, but not exceeding \$100 per day, including traveltime, and while so serving away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (5 U.S.C. 73b-2) for persons in the Government service employed intermittently.

"(d) The Council shall advise and assist the Surgeon General in the preparation of regulations for, and as to policy matters arising with respect to, the administration of this title. The Council shall consider all applications for grants under this title and shall make recommendations to the Surgeon General with respect to approval of applications for and the amounts of grants under this title.

## "Regulations

"Sec. 906. The Surgeon General, after consultation with the Council, shall prescribe general regulations covering the terms and conditions for approving applications for grants under this title and the coordination of programs assisted under this title with programs for training, research, and demonstrations relating to the same diseases assisted or authorized under other titles of this Act or other Acts of Congress.

## "Information on Special Treatment and Training Centers

"Sec. 907. The Surgeon General shall establish, and maintain on a current basis, a list or lists of facilities in the United States equipped and staffed to provide the most advanced methods and techniques in the diagnosis and treatment of heart disease, cancer, or stroke, together with such related information, including the availability of ad-

vanced specialty training in such facilities, as he deems useful, and shall make such list or lists and related information readily available to licensed practitioners and other persons requiring such information. To the end of making such list or lists and other information most useful, the Surgeon General shall from time to time consult with interested national professional organizations.

#### "Report

"Sec. 908. On or before June 30, 1967, the Surgeon General, after consultation with the Council, shall submit to the Secretary for transmission to the President and then to the Congress, a report of the activities under this title together with (1) a statement of the relationship between Federal financing and financing from other sources of the activities undertaken pursuant to this title, (2) an appraisal of the activities assisted under this title in the light of their effectiveness in carrying out the purposes of this title, and (3) recommendations with respect to extension or modification of this title in the light thereof.

## "Records and Audit

"Sec. 909. (a) Each recipient of a grant under this title shall keep such records as the Surgeon General may prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is made or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such records as will facilitate an effective audit.

"(b) The Secretary of Health, Education, and Welfare and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of any grant under this title which are pertinent to any such grant."

"Sec. 3. (a) Section 1 of the Public Health Service Act is amended to read as follows: "Section 1. Titles I to IX, inclusive, of this Act may be cited as the 'Public Health Service Act'."

(b) The Act of July 1, 1944 (58 Stat. 682), as amended, is further amended by renumbering title IX (as in effect prior to the enactment of this Act) as title X, and by renumbering sections 901 through 914 (as in effect prior to the enactment of this Act), and references thereto, as sections 1001 through 1014, respectively.

Approved October 6, 1965, 10:15 a.m.

#### LEGISLATIVE HISTORY:

HOUSE REPORT No. 963 accompanying H. R. 3140 (Comm. on Interstate & Foreign Commerce).

SENATE REPORT No. 368 (Comm. on Labor & Public Welfare).

CONGRESSIONAL RECORD, Vol. 111 (1965):
June 25: Considered in Senate.

June 28: Considered and passed Senate.

Sept. 23: H. R. 3140 considered in House. Sept. 24: Considered and passed House, amended, in lieu of H. R. 3140.

Sept. 29: Senate concurred in House amendments.

# Appendix 8—Regulations of Regional Medical Programs

March 18, 1967

# SUBPART E-GRANTS FOR REGIONAL MEDICAL PROGRAMS 1

Authority: The provisions of this Subpart E issued under sec. 215, 58 Stat. 690, sec. 906, 79 Stat. 930; 42 U.S.C. 216, 299f. Interpret or apply secs. 900, 901, 902, 903, 904, 905, 909, 79 Stat. 926, 927, 928, 929, 930, 42 U.S.C. 299, 299a, 299b, 299c, 299d, 299e, 299i.

## ♦ 54.401 Applicability.

The provisions of this subpart apply to grants for planning, establishment, and operation of regional medical programs as authorized by Title IX of the Public Health Service Act, as amended by Public Law 89-239.

- ♦ 54.402 Definitions.
- (a) All terms not defined herein shall have the meaning given them in the Act.
- (b) "Act" means the Public Health Service Act, as amended.
- (c) "Title IX" means Title IX of the Public Health Service Act, as amended.
- (d) "Related diseases" means those diseases which can reasonably be considered to bear a direct relationship to heart disease cancer or stroke.
- (e) "Title IX diseases" means heart disease, cancer, stroke, and related diseases.
- (f) "Program" means the regional medical program as defined in section 902(a) of the Act.
- (g) "Practicing physician" means any physician licensed to practice medicine in accordance with applicable State laws and currently engaged in the diagnosis or treatment of patients.
- (h) "Major repair" includes restoration of an existing building to a sound state.
- (i) "Built-in equipment" is equipment affixed to the facility and customarily included in the construction contract.
- (j) "Advisory group" means the group designated pursuant to section 903(b)(4) of the Act.

- (k) "Geographic area" means any area that the Surgeon General determines forms an economic and socially related region, taking into consideration such factors as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; presence and distribution of educational, medical and health facilities and programs, and other activities which in the opinion of the Surgeon General are appropriate for carrying out the purposes of Title IX
- ♦ 54.403 Eligibility.
- In order to be eligible for a grant, the applicant shall:
- (a) Meet the requirements of section 903 or 904 of the Act;
- (b) Be located in a State;
- (c) Be situated within a geographic area appropriate under the provisions of this subpart for carrying out the purposes of the Act.
- ♦ 54,404 Application.
- (a) Forms. An application for a grant shall be submitted on such forms and in such manner as the Surgeon General may prescribe.
- (b) Execution. The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant all of the obligations specified in the terms and conditions of the grant including those contained in these regulations
- (c) Description of program. In addition to any other pertinent information that the Surgeon General may require, the applicant shall submit a description of the program in sufficient detail to clearly identify the nature, need, purpose, plan, and methods of the program, the nature and functions of the participating institutions, the geographic area to be served, the cooperative arrangements, in effect, or intended to be made effective, within the group, the justification supported by a budget or other data, for the amount of the funds requested, and financial or other data demonstrating that grant

- funds will not supplant funds otherwise available for establishment or operation of the regional medical program.
- (d) Advisory group; establishment; evidence. An application for a grant under section 903 of the Act shall contain or be supported by documentary evidence of the establishment of an advisory group to provide advice in formulating and carrying out the establishment and operation of a program.
- (e) Advisory group; membership; description. The application or supporting material shall describe the selection and membership of the designated advisory group, showing the extent of inclusion in such group of practicing physicians, members of other health professions, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary agencies, representatives of other organizations, institutions and agencies concerned with activities of the kind to be carried on under the program, and members of the public familiar with the need for the services provided under the program.
- (f) Construction; purposes, plans, and specifications; narrative description. With respect to an application for funds to be used in whole or part for construction as defined in Title IX, the applicant shall furnish in sufficient detail plans and specifications as well as a narrative description, to indicate the need, nature, and purpose of the proposed construction.
- (g) Advisory group; recommendation. An application for a grant under section 904 of the Act shall contain or be supported by a copy of the written recommendation of the advisory group.
- ♦ 54.405 Terms, conditions, and assurances.
- In addition to any other terms, conditions, and assurances required by law or imposed by the Surgeon General, each grant shall be subject to the following terms, conditions, and assurances to be furnished by the grantee. The Surgeon General may at any time approve exceptions where he finds that such exceptions are not inconsistent with the Act and the purposes of the program.
- (a) Use of funds. The grantee will use grant

funds solely for the purposes for which the grant was made, as set forth in the approved application and award statement. In the event any part of the amount paid a grantee is found by the Surgeon General to have been expended for purposes or by any methods contrary to the Act, the regulations of this subpart, or contrary to any condition to the award, then such grantee, upon being notified of such finding, and in addition to any other requirement, shall pay an equal amount to the United States. Changes in grant purposes may be made only in accordance with procedures established by the Surgeon General.

- (b) Obligation of funds. No funds may be charged against the grant for services performed or material or equipment delivered, pursuant to a contract or agreement entered into by the applicant prior to the effective date of the grant.
- (c) Inventions or discoveries. Any grant award hereunder in whole or in part for research is subject to the regulations of the Department of Health, Education, and Welfare as set forth in Parts 6 and 8 of Title 45, as amended. Such regulations shall apply to any program activity for which grant funds are in fact used whether within the scope of the program as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Surgeon General to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligation. Laboratory notes, related technical data, and information pertaining to inventions or discoveries made through activities supported by grant funds shall be maintained for such periods, and filed with or otherwise made available to the Surgeon General or those he may designate at such times and in such manner as he may determine necessary to carry out such Department regulations.
- (d) Reports. The grantee shall maintain and file with the Surgeon General such progress, fiscal, and other reports, including reports of meetings of the advisory group convened before and after award of a grant under

<sup>&</sup>lt;sup>1</sup> Subpart E added 1/18/67, 32 FR 571.

section 904 of the Act, as the Surgeon General may prescribe.

- (e) Records retention. All construction, financial, and other records relating to the use of grant funds shall be retained until the grantee has received written notice that the records have been audited unless a different period is permitted or required in writing by the Surgeon General.
- (f) Responsible official. The official designated in the application as responsible for the coordination of the program shall continue to be responsible for the duration of the period for which grant funds are made available. The grantee shall notify the Surgeon General immediately if such official becomes unavailable to discharge this responsibility. The Surgeon General may terminate the grant whenever such official shall become thus unavailable unless the grantee replaces such official with another official found by the Surgeon General to be qualified.

#### ♦ 54.406 Award.

Upon recommendation of the National Advisory Council on Regional Medical Programs, and within the limits of available funds, the Surgeon General shall award a grant to those applicants whose approved programs will in his judgment best promote the purposes of Title IX. In awarding grants, the Surgeon General shall take into consideration, among other relevant factors, the following:

- (a) Generally, the extent to which the proposed program will carry out, through regional cooperation, the purposes of Title IX, within a geographic area.
- (b) The capacity of the institutions or agencies within the program, individually and collectively, for research, training, and demonstration activities with respect to Title IX
- (c) The extent to which the applicant or the participants in the program plan to coordinate or have coordinated the regional medical program with other activities supported pursuant to the authority contained in the Public Health Service Act and other Acts of Congress including those relating to plan-

ning and use of facilities, personnel, and equipment, and training of manpower.

- (d) The population to be served by the regional medical program and relationships to adjacent or other regional medical programs.
- (e) The extent to which all the health resources of the region have been taken into consideration in the planning and/or establishment of the program.
- (f) The extent to which the participating institutions will utilize existing resources and will continue to seek additional nonfederal resources for carrying out the objectives of the regional medical program.
- (g) The geographic distribution of grants throughout the Nation.

## ♦ 54.407 Termination.

- (a) Termination by the Surgeon General. Any grant award may be revoked or terminated by the Surgeon General in whole or in part at any time whenever he finds that in his judgment the grantee has failed in a material respect to comply with requirements of Title IX and the regulations of this subpart. The grantee shall be promptly notified of such finding in writing and given the reasons therefor.
- (b) Termination by the grantee. A grantee may at any time terminate or cancel its conduct of an approved project by notifying the Surgeon General in writing setting forth the reasons for such termination.
- (c) Accounting. Upon any termination, the grantee shall account for all expenditures and obligations charged to grant funds: Provided, That to the extent the termination is due in the judgment of the Surgeon General to no fault of the grantee, credit shall be allowed for the amount required to settle at costs demonstrated by evidence satisfactory to the Surgeon General to be minimum settlement costs, any noncancellable obligations incurred prior to receipt of notice of termination.

## ♦ 54.408 Nondiscrimination.

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that

no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing the statute have been issued as Part 80 of Title 45, Code of Federal Regulations. The regional medical programs provide Federal financial assistance subject to the Civil Rights Act and the regulations. Each grant is subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 F.R. 12319, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

## ♦ 54.409 Expenditures by grantee.

- (a) Allocation of costs. The grantee shall allocate expenditures as between direct and indirect costs in accordance with generally accepted and established accounting practices or as otherwise prescribed by the Surgeon General.
- (b) Direct costs in general. Funds granted for direct costs may be expended by the grantee for personal services, rental of space, materials, and supplies, and other tiems of necessary cost as are required to carry out the purposes of the grant. The Surgeon General may issue rules, instructions, interpretations, or limitations supplementing the regulations of this subpart and prescribing the extent to which particular types of expenditures may be charged to grant funds.
- (c) Direct costs; personal services. The costs of personal services are payable from grant funds substantially in proportion to the time or effort the individual devotes to carrying out the purpose of the grant. In such proportion, such costs may include all direct costs incident to such services, such as salary during vacations and retirement and workmen's compensation charges, in accordance with the policies and accounting practices consistently applied by the grantee to all its activities.
- (d) Direct costs; care of patients. The cost of hospital, medical or other care of pa-

tients is payable from grant funds only to the extent that such care is incident to the research, training, or demonstration activities supported by a grant hereunder. Such care shall be incident to such activities only if reasonably associated with and required for the effective conduct of such activities, and no such care shall be charged to such funds unless the referral of the patient is documented with respect to the name of the practicing physician making the referral, the name of the patient, the date of referral, and any other relevant information which may be prescribed by the Surgeon General. grant funds shall not be charged with the cost of-

- (1) Care for intercurrent conditions (except of an emergency nature where the intercurrent condition results from the care for which the patient was admitted for treatment) that unduly interrupt, postpone, or terminate the conduct of such activities.
- (2) Inpatient care if other care which would equally effectively further the purposes of the grant, could be provided at a smaller cost.
- (3) Bed and board for inpatients in excess of the cost of semiprivate accommodations unless required for the effective conduct of such activities. For the purpose of this paragraph, "semiprivate accommodations" means two-bed, three-bed, and four-bed accommodations.

#### ♦ 54.410 Payments.

The Surgeon General shall, from time to time, make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses to be incurred or incurred to the extent he determines such payments necessary to carry out the purposes of the grant.

- $\diamondsuit$  54.411 Different use or transfer; good cause for other use.
- (a) Compliance by grantees. If, at any time, the Surgeon General determines that the eligibility requirements for a program are no longer met, or that any facility or equipment the construction or procurement of which was charged to grant funds is, during its useful life, no longer being used for the

purposes for which it was constructed or procured either by the grantee or any transferee, the Government shall have the right to recover its proportionate share of the value of the facility or equipment from either the grantee or the transferee or any institution that is using the facility or equipment. The Government's proportionate share shall be the amount bearing the same ratio to the then value of the facility or equipment, as determined by the Surgeon General, as the amount the Federal participation bore to the cost of construction or procurement.

- (b) Different use or transfer; notification. The grantee shall promptly notify the Surgeon General in writing if at any time during its useful life the facility or equipment for construction or procurement of which grant funds were charged is no longer to be used for the purposes for which it was constructed or procured or is sold or otherwise transferred.
- (c) Forgiveness. The Surgeon General may for good cause release the grantee or other owner from the requirement of continued eligibility or from the obligation of continued use of the facility or equipment for the grant purposes. In determining whether good cause exists, the Surgeon General shall take into consideration, among other factors, the extent to which—
- (1) The facility or equipment will be devoted to research, training, demonstrations, or other activities related to Title IX diseases.
- (2) The circumstances calling for a change in the use of the facility were not known, or with reasonable diligence could not have been known to the applicant, at the time of the application, and are circumstances reasonably beyond the control of the applicant or other owner.
- (3) There are reasonable assurances that other facilities not previously utilized for Title IX purposes will be so utilized and are substantially the equivalent in nature and extent for such purposes.

#### ♦ 54.412 Publications.

Grantees may publish materials relating to their regional medical program without prior review provided that such publications carry a footnote acknowledging assistance from the Public Health Service, and indicating that findings and conclusions do not represent the views of the Service.

#### ♦ 54.413 Copyrights.

Where the grant-supported activity results in copyrightable material, the author is free to copyright, but the Public Health Service reserves a royalty-free, nonexclusive, irrevocable license for use of such material.

#### ♦ 54.414 Interest.

Interest or other income earned on payments under this subpart shall be paid to the United States as such interest is received by the grantee.

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