POSITION STATEMENTS (ITEMS 25-28) 1971 FD " 6

AR.GOV.01 AAMC Series 6: Position statements Box 1 Folder 6

A Policy for Biomedical Research

Report of an Ad Hoc Committee
of the Council of Academic Societies
of the Association of American Medical Colleges

A Supplement

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ASSOCIATION OF AMERICAN MEDICAL COLLEGES

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Introduction

In February of 1970, the Council of Academic Societies of the Association of American Medical Colleges held a meeting in Chicago at which aspects of the problems related to research and research funding were aired. It was decided that the Council should formulate a policy for the support of biomedical research which would reflect the AAMC position. Accordingly, a committee was formed which was representative of most of the conventional disciplines in a school of medicine, with geographic breadth as well.

The Committee on Biomedical Research Policy met several times. In addition, it held interviews with various branches of the executive government, with individuals high in scientific components of the federal establishment, with nonfederal groups concerned with national science policy, with legislative assistants, and with others. On October 31, 1970, the Committee's chairman presented a comprehensive summary of the present report to the Council of Academic Societies in Los Angeles, California.

Our charge was to survey certain problems. One of these was the issue of levels of support for biomedical research. First, is it reasonable to ask how much should be spent nationally for this purpose? Then, because the question, reasonable or not, had been raised (and we should certainly be prepared to say something more definitive than "more"), we were to examine the questions, how much and by whom? Another object was to develop a perspective for a long-range look at the evolving biomedical scene, taking into account that there must be shifts in the emphases to be placed on areas of investigation and in the manner of funding. Lastly, we were to consider means for creating an atmosphere cordial to the examination of relevant problems by the citizenry at large and their elective representatives.

This report is an attempt to define our position at this time. It expresses a consensus of the Committee based on its conferences and communications.

Before proceeding with comments on the report itself, we should like to relay some information we obtained that calls for the most serious attention. This concerns the manner in which trainees in the biomedical sciences may be supported in the future.

In a letter to our Committee, Dr. Thomas J. Kennedy, associate director for program planning and evaluation, National Institutes of Health, stated:

> The Department of Health, Education, and Welfare and the Office of Management and Budget have asked the National Institutes of Health to examine the effects of altering present Federal policies for support to research training in the biomedical sciences. The central problem is to assess the consequences of substituting guaranteed loans for stipends to graduate students and postdoctoral trainees.

NIH has planned a penetrating study of this and related problems.

We recognized that such a study must be done in great detail with meticulous documentation. Nevertheless, we felt an urgency concerning this matter which

prompted us to conduct a simpler, less sophisticated study that would give us some idea of how many prospective trainees might be lost through a change from stipends to loans. Toward this end, we developed a brief questionnaire which was sent to every medical school in the country. Every department chairman was asked to help in administering the questionnaire to fellows whose training would be completed as of June 1970. Since those queried were completing their training, they would be expected to show little or no bias in terms of secondary gain.

There were 4,000 respondents. A variety of questions were asked concerning scientific discipline, career goals, age, sex, indebtedness, and occupation of father. The final question was, "If no stipend had been available to support your training, but a long-term, low-interest loan had been available, would you have been able to continue your plans for training?" The answer to this question was "no" from 62 percent of the respondents. Further data from the study are given in Chapter 3.

There are some interesting cross-correlations, but the overriding issue is that over three-fifths would not have taken the additional training—and this number is exceedingly significant in terms of fostering young talent to advance knowledge leading to better modalities of therapy.

Furthermore, this is the pool from which future teachers will arise, both as replacements and for the larger classes of students in existing schools and the new schools that are contemplated.

The respondents appear to us to represent a national resource of limited cost and tremendous potential for social benefits. To erect monetary restrictions on their training would be foolhardy. Moreover, the argument that training for research in the health sciences diminishes the health manpower pool is pale when one notes the small number of respondents who were M.D.s as compared with the 300,000 physicians or the total of 3 million persons employed in all phases of health care in this country.

We, therefore, urge that everything possible be done to bring this matter to the attention of the lay public, the Congress, and the Administration toward the end that training programs shall be expanded rather than curtailed. Obviously, if we are to continue to enjoy the fruits of biomedical research, we must continue to train young men and women in the health sciences. The diversion of any significant number from research careers, even for a few years, would measurably weaken biomedical science and education and retard the advancement of the nation's health. It is imperative that this threat be avoided.

We mention this development concerning NIH training programs at an early point because it indicates the urgency of our task—to help formulate and further the adoption of a national policy on biomedical research.

Such a policy should take into account the role of research, both basic and applied, in the control of disease, in the promotion of health, and in the education of investigators and practitioners. These considerations are discussed in the following pages.

We wish to make it clear at the outset that our use of the term "biomedical research" includes research in health care delivery. Modalities of disease prevention and therapy are of little value unless they can be made available to the consumers of the health industry in ways that are sound, expeditious, and comfortable for them. On the other hand, investigations in health care delivery could be extended at the expense of the rest of biomedical science. Conceivably, one could learn

quite well how to deliver but in a short time have little to deliver that was new or better.

The second chapter of the report concerns where the research policy should be implemented in terms of research institutes, industrial laboratories, and the universities. Attention is given to the role of medical centers, schools of arts and sciences, engineering schools, and institutions concerned with pharmacy, nursing, public health, and other aspects of the broader health scene.

The third chapter deals with the means of support—the sources of funds, public and private; the funding instruments that can be employed, such as grants and contracts to institutions and individuals; and the importance of rounded programs that include the support of research training, special resources, and the institutions themselves.

The fourth chapter takes up the question of support levels. It discusses the various ways in which the problem could be approached. Here, we develop the proposition that the only prudent response to the question "how much" relates, in the last analysis, to the quantity of qualified, motivated brainpower available to do research. This, of course, begs the question of training-support levels—the question of how much more brainpower should be developed to exploit widening research opportunities.

The last chapter is addressed to the need and means for implementing biomedical research policy. It stresses the role of communications, particularly those required to inform the public and its representatives of the nature, the aims, and the achievements of biomedical research, with a view to increasing comprehension and acceptance.

This report is intended to set forth our understanding of the problems as we see them, the premises upon which further studies should continue, and the questions that must be answered to provide appropriate data.

We gratefully acknowledge the cooperation of the National Institutes of Health, particularly the Office of Program Planning and Evaluation and the Division of Research Grants, in generously supplying the Committee with charts and data from their publications and records.

Louis G. Welt, M.D., Chairman
Biomedical Research Policy Committee

Chapter 1

The Necessity for Making Biomedical Research a National Goal

The primary aim of biomedical research is to increase the understanding of man and his disorders and to provide the means for the prevention and treatment of disease. Today this goal is threatened with failure. Although biomedical research has been a large-scale enterprise in this country for only 20 years, its very existence is compromised by a number of unfortunate attitudes and circumstances.

Critics of biomedical research claim that advances in the laboratory have not been translated into practical medicine. Alleged evidence of this failure includes a leveling off of life expectancy in recent years, at least for males, and a relatively high neonatal mortality rate. While further discussion of these views would be too digressive here, it might be pointed out that only sweeping progress against the social conditions underlying this country's excessive infant mortality rate could be realistically expected to bring a further impressive extension of the average life span in the foreseeable future.

The technology derived from biomedical research has been blamed for much of the increased cost of health care. This argument, while true in part, does not take cognizance of the dramatic strides that have been made in almost every branch of medicine. The investigation and diagnosis of disease, the complicated techniques of the modern surgeon, the diagnostic and therapeutic progress in radiology, and many other curative advances have undeniably increased medical costs.

The critical attitude toward science and technology in general encompasses biomedical research. This attitude blames technology, and by association the science that has made it possible, for pollution, transportation problems, and the slums, not to mention the development of biological, chemical, and nuclear weapons. In short, the lay public tends to confuse science and technology, and both are blamed for the side-effects of the latter.

In an era of stringent fiscal constraints, funding for biomedical research is in competition with other major national needs, such as the restoration of the environment, improvement of housing, and control of inflation. Above all, the demands on our national resources occasioned by costly involvement in Southeast Asia have curtailed funds available for domestic programs, including biomedical research.

In such an atmosphere, a vigorous defense of biomedical research seems necessary. It may be well to review briefly some of medical science's important contributions and to cite a few of its benefits to mankind.

Historical Perspective

Prior to World War II, health-related research was a sporadic phenomenon.

There were major successes—for example, the control of tetanus, diphtheria, and smallpox—but they were comparatively few and far between. Then the war itself and tremendous advances in other fields of science spurred progress in medicine. This included the development of antimicrobial and antimalarial agents, the life-saving therapy for shock and trauma, the benefits of fractionation and storage of blood and blood products, and the control of certain diseases through effective pesticides.

At the beginning of this era, only a quarter of a century ago, hospitals in the United States were filled with patients afflicted with infectious and nutritional diseases. Infantile diarrhea, epidemic meningitis, typhoid fever, tuberculosis, typhus, trachoma, scarlet fever, pneumonia, poliomyelitis, and measles, to mention only a few, were major causes of illness and death. Prevalent in certain parts of the country were pellagra, rickets, sprue, goiter, and iron-deficiency anemia —still major health problems in many regions of the world.

The fact that these diseases have not been eliminated in this country can hardly be ascribed to a lack of medical knowledge but rather to political, economic, and sociologic problems that have not been solved at the same pace as biology has advanced. Effective systems have not evolved to reap fully the harvest of biomedical research. The cost of this failure can only be suggested through analogy.

Without attempting here a strict cost-benefit analysis, one might cite the great saving in lives and dollars from the virtual eradication of polio. There were an estimated 10,000 quadriplegic patients institutionalized with poliomyelitis in 1960. Assuming hospitalization costs at 1970 figures, the prevention of this disease alone yields an annual saving of one-third of a billion dollars—or roughly one-fifth of the total 1970 federal budget for medical research and development.

It should be emphasized that this simply refers to the direct expenditure for the care of patients; it does not take into account the implications of the eradication of polio which affect many other areas of our economy. These include the benefits to tourism, resorts, summer camps, and all the intangible economic correlates. And this still leaves a benefit to the quality of life which is associated with the removal of this single threat—a benefit that cannot be equated in dollars.

The list of diseases that have been almost wholly conquered through biomedical research is impressive in itself. Even more significant is the fact that the resulting health measures have been largely preventive rather than curative, and as such are far less visible. Tuberculosis and rheumatic fever provide excellent examples. Research has produced effective chemotherapy for the former and effective chemoprophylaxis for the latter. Thanks largely to modern drug treatment, the tuberculosis sanitariums that dotted the countryside until a decade years ago have virtually disappeared. Similarly, the specialized institutions that cared for children with rheumatic fever and its aftermath have been shut down or are being used for patients with other illnesses. The savings in pain and anguish occasioned by the prevention and treatment of these two diseases are incalculable, but the savings in dollars could probably be counted in the billions.

It is certainly true that there are many diseases whose causation we understand only partially or not at all and for which therapy is at best incomplete. These include cancer, stroke, coronary artery disease, cirrhosis, glomerulonephritis and other renal diseases, rheumatoid arthritis

and the collagen disorders, asthma, multiple sclerosis, most of the psychoses, emphysema, muscular dystrophy, cystic fibrosis, a number of inborn disorders of metabolism, and the virus infections that are not preventable by early immunization. For the most part indolent and chronic, these diseases sorely tax the health resources demanded for the care of their victims.

While many facets of these diseases remain to be elucidated, significant progress has been made against most of them. For example, a comparatively rare but formerly lethal cancer, choriocarcinoma, can be cured in many patients with early, adequate anti-cancer drugs. Likewise, improved surgical and radiotherapeutic methods have improved the state of health, and in some instances have prolonged life, for patients with leukemia, Hodgkin's disease, and cancer of the breast, lung, and rectum. Improved understanding of pulmonary physiology has led to the development of respiratory assistance devices that have increased comfort and lengthened the lives of patients with chronic lung disease, including emphysema.

Significant progress has been made against other chronic diseases in terms of a better understanding of their mechanisms and their prevention and cure. One cannot ignore, however, that even the advances have brought with them new sets of problems, such as the acute need for improved health-care facilities and for more professional and auxiliary health personnel. But this is hardly a reason to diminish biomedical research. Rather, it argues for wholehearted support with a view to furthering the march of progress now well under way.

The biomedical research endeavor of this nation constitutes a resounding success story. Science should not be attacked because it has failed to solve many of our social dilemmas. These are not the consequence of too much research but of insufficient information and awareness on the part of the community at large—information on the nature of the problems and awareness of how science and society must interrelate to provide solutions leading to the fullest possible life. These social dilemmas, as well as the unsolved problems of health, require new knowledge. Translated into practical terms, this means we need more and not less biomedical research.

Basic Versus Applied Research

It is no longer adequate to state that knowledge for the sake of knowledge is a noble end in itself. The public wants to see the fruits of science—that is, technology—and is little interested in science *per se*. It is essential to point out, however, that science is the *sine qua non* for the development of a new technology and, hence, is highly relevant to medical care.

To ignore this principle is to ignore the developments of the immediate and more remote past. One need only trace the roots of any so-called breakthrough to find the essence of the scientific adventure which, in its day, would surely have been considered "irrelevant" or at least unrelated to the disease for which better therapies would evolve from the early discoveries.

A few examples are described in detail in a report prepared for the National Science Foundation by the Illinois Institute of Technology Research Institute. The title, *TRACES*, is an acronym for "Technology in Retrospect and Critical Events in Science" (1). This is a most interesting and provocative document dealing with many of the important tools we have today. Certain products of

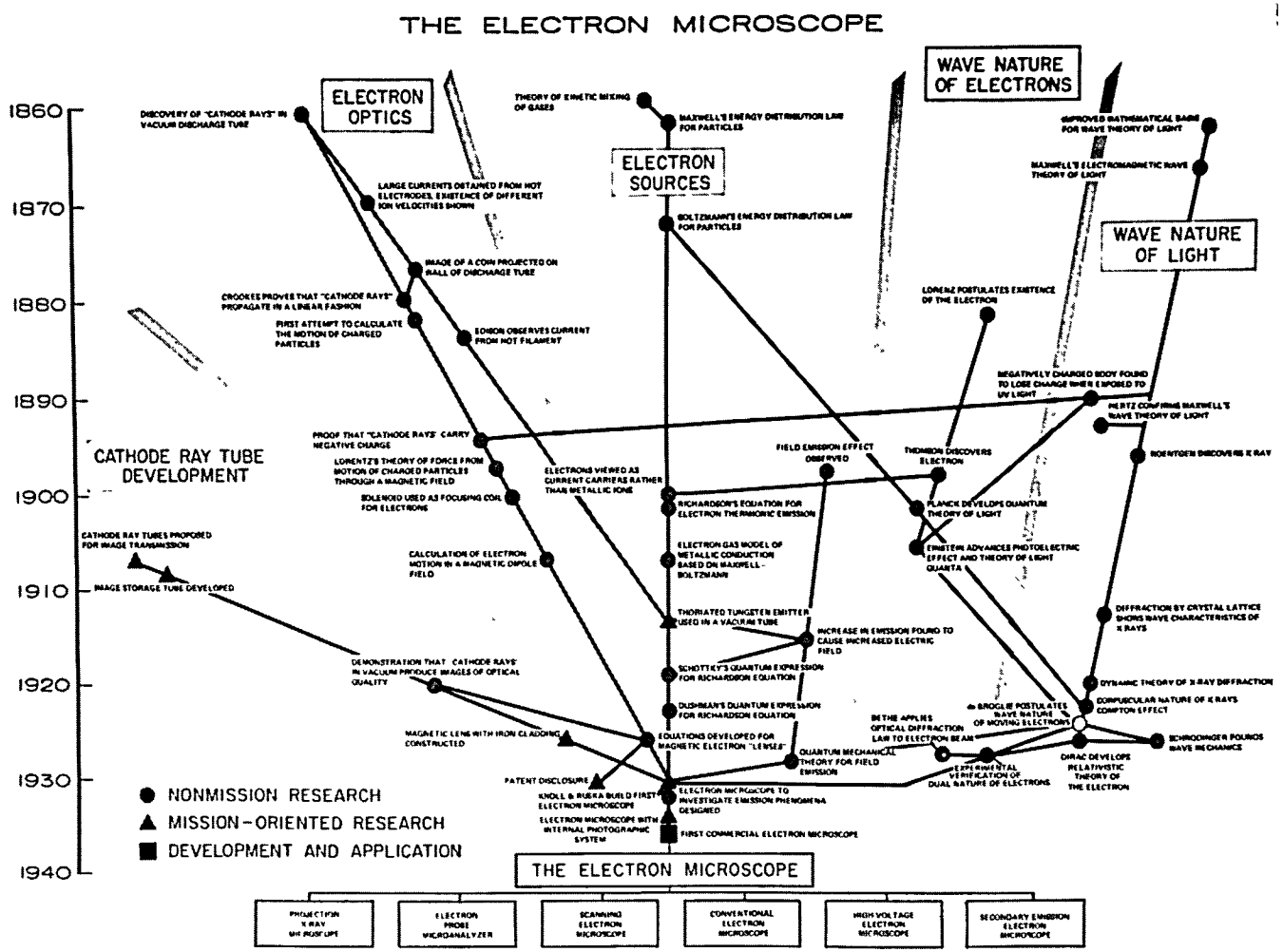


FIGURE 1

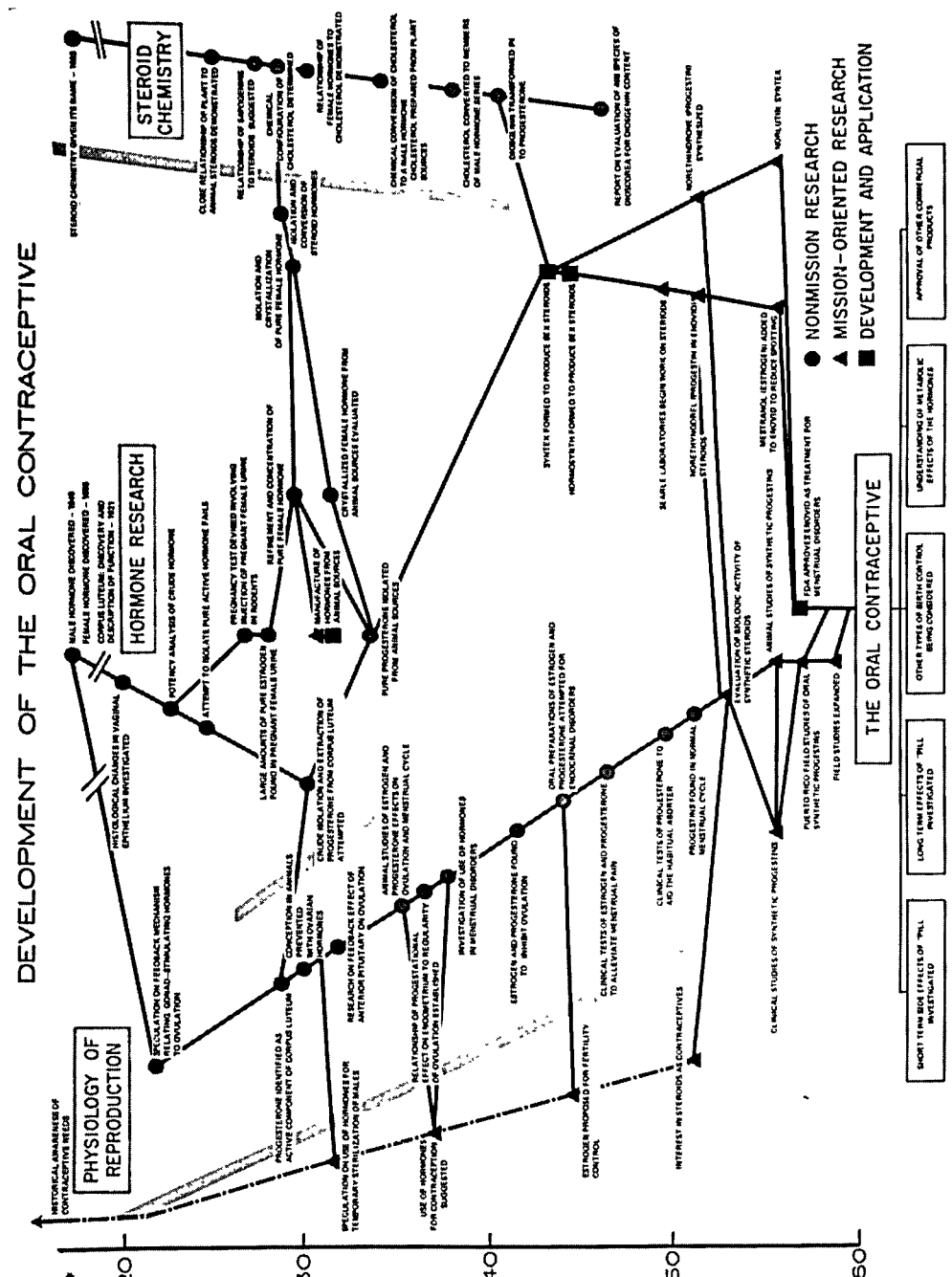


FIGURE 2

science and technology, such as the electron microscope and "the pill," are traced back to their origins in basic investigation. Figures 1 and 2 are abridged versions of *TRACES* diagrams directly related to medicine.

Several contributions of basic science to clinical medicine are cited in Appendix A, submitted by Dr. Petersdorf. It should be quite clear that the numerous examples described therein are but a small fraction of those possible. Indeed, the practical solutions to most problems in biology and medicine have originated in the basic laboratory.

It should also be pointed out that many of the discoveries that have resulted in practical applications to the practice of medicine are not the product of directed research but of chance observations. This emphasizes that at least some creative scientists must be left the freedom to pursue uncharted paths wherever these may lead. Finally, it should be clear from the examples (Appendix A) that the border between applied and basic research is often narrow or blurred.

The aim of basic research should be the eventual application of all new knowledge to man and his problems, though there may be a long hiatus before some discoveries can find their way to the patient. It should be clear, however, that applied research and the derivative technology, unless well grounded in a scientific base, are sure to falter.

In summary, there are more than enough data available to permit the conclusion that basic research has found a great many practical applications resulting in the prevention of untold suffering and of countless deaths. It has clearly demonstrated its value in improving the health of the American people.

Research and Education

At the present time in this country, most biomedical research is carried out in medical schools. Although it has been argued that there is no relationship between medical research and the quality of medical education, the weight of the evidence is to the contrary. The aims in fusing research and education are straightforward and clear. When medicine is taught by individuals with a research background, the scientific method is translated to the bedside. Each patient is, after all, a "research problem," and teaching a student to think about disease in scientific terms is a cornerstone of the educational process.

Biomedical research has profoundly affected the curriculum offerings of medical schools. It is difficult to imagine what would have happened to the American health establishment—including its schools—if the era of active research, both basic and applied, that has gained such momentum during the last decades were simply erased. American medical schools would find themselves like those in developing parts of the world where medicine, taught entirely in a nonresearch environment, is years behind the times or like those that have adhered rigidly to the Germanic *Geheimrat* method of disseminating information. The contrast between the type of student turned out by those schools and by American medical schools is striking, and the loss to health care in those parts of the world is obvious.

The development of a research enterprise in a medical center caring for patients has permitted early application of basic laboratory findings. This bridge between preclinical and clinical investigators has paid many dividends and is

particularly appropriate to the university setting.

It should also be recognized that the leaders in medicine and medical education have come, for the most part, from a research environment.

The modern practitioner of medicine knows the value of biomedical research and can cite how the products of research have influenced his practice. Moreover, he is avid for knowledge that has been gained in the laboratory. This interest on the part of the practitioner is illustrated by the content of the annual scientific programs of the American College of Physicians, the largest organization of internists in this country. The themes of these programs during recent years have been the application of computers to medicine—including a fair amount of background mathematics to aid in understanding the workings of computers—and bioengineering, including some lectures in basic physics. The most recent theme is medical genetics and includes some presentations in molecular biology and biochemistry.

Closely related to this subject is the vital relationship of biomedical research to health manpower. The research atmosphere has provided better educated practitioners and has attracted creative people to the teaching and practice of medicine and to other areas of the health field.

A National Science Policy

In April of 1970, a report of the President's Task Force on Science Policy, *Science and Technology: Tools for Progress*, was published (2). The importance of scientific leadership was emphasized:

> The Task Force believes that one of the important national goals for which this nation should strive is leadership and excellence in science itself—as a long-range investment in achieving the nation's other goals, as a precursor to more directly applicable and controllable technology, and as a contribution to the culture, spirit, and inspiration of our people.

The Task Force recommends that the President explicitly enunciate as a national policy the need for vigorous, high-quality science and technology focusing on our national goals and purposes and recognizing the cultural and inspirational values in man's scientific progress.

The Task Force also recommends that the President, as one of the national goals, call for continuing leadership in the science and technology relevant to our national goals and purposes.

Finally, it recommends that the President direct "that increasing emphasis be given to using our scientific and technological capabilities quantitatively to develop and project long-range requirements in support of our national goals."

This charge encompasses biomedical science. What is needed, however, is an unequivocal statement concerning the federal commitment to biomedical research. Such a statement should contain the following points:

1. That basic biomedical research represents the foundation of applied science related to health.

2. That the ultimate application of basic biomedical research may be unpredictable but that practical applications, as the record shows, will be found in most cases.

3. That the application of biomedical research to improve the health of the nation is among the primary concerns of the U.S. government.

4. That the federal government should be the principal sponsor of research and education in the biomedical sciences.

5. That it be the intention of the Congress to maintain the progress that has been made in the biomedical sciences by providing adequate long-range funding.

It is only through such an unambiguous statement of policy that the momentum gathered in the past two decades will be sustained and the health care of our citizens improved. The remainder of this report will deal with the details of such a biomedical research policy.

Chapter 2

Location of Biomedical Research Facilities

The distribution of biomedical research activities must be guided by the principle of maximum yield for funds invested. Both long- and short-term yield must be considered. The immediate gain from the location of research facilities in particular areas might be significantly different from the long-term yield to be obtained. For example, the conduct of research on antibiotics in a hospital setting might lead to the rapid testing of agents and their immediate use in the treatment of disease; but the conduct of such research in a basic biomedical setting, such as a university department of microbiology, might lead to the discovery of certain principles from which could arise a whole new family of useful antibiotics.

Individual Creativity

In general terms, maximum yield for a given investment in research occurs in an environment where there is optimal encouragement of the creative mind. The creative aspect of research—aimed at original discovery or the original use of existing knowledge—is emphasized here because the objectives are in sharp contrast to those of research in other fields. In law, for example, "research" may be the review of past actions for the purpose of establishing precedence, but creativity in legal research is exceptional.

The environments in which research is conducted can vary greatly. Because of the enormous range of human interests and motivations, a single, established, ideal pattern for research units is impossible and undesirable.

There is no one way to organize research facilities and activities. A range is required, from the lone investigator operating in a small, isolated facility to large, interrelated teams working together. Each may represent an optimal environment for the individual scientist, affording sufficient stimulation and intellectual feedback. In a society that emphasizes free choice of careers and residence, it is essential that multiple approaches to the location and organization of research be made possible so that investigators can have a reasonable opportunity to suit their life style.

Creative Interaction

At the same time as individual freedom of action is considered in the development of research allocations, the importance of creative interaction cannot be neglected. Maximum productivity must be sought through attainment of a "critical mass" of investigators, equipment, ideas, and techniques—a combination through which more can be accomplished than through solitary action. For example, the elucidation of a genetic defect might best be accomplished by the interaction of an expert in cell biology, a biochemist, and a geneticist. Each operating alone would not attain the same result. This multiplier effect of bringing individuals

or groups together dictates a general principle in the distribution of research facilities.

Diversity of Research Problems

Research problems, likewise, have almost as great a diversity and range as human capability and need. There would seem to be no ideal pattern for all research ventures. Some call for a minimum of equipment; others demand major resources that cannot be duplicated in a single country.

Again, the range of problems constituting a research project can vary considerably. Just as there may be interaction of individuals to attain an optimal capability, so there may be interrelationship of problems, so that the approach or solution of one contributes to that of another. Here, too, those who allocate resources must recognize this phenomenon in order to attain maximum yield.

Historically, research has been conducted with multiple options of a wide range, from the monastery of Mendel to the research metropolis of the Argonne Laboratories. Also, in general, there has been no systematic plan for distribution of resources. Rather, the governing factors have been largely human interest or particular geographic benefits, as in respect to marine laboratories. The deployment has also been influenced to a greater or lesser degree by economic or political pressures.

Occasionally, there have been highly directed, monolithic approaches which have gained certain applied objectives, such as the Manhattan Project or the placing of a man on the moon. Yet such ventures can stifle creativity and even lead to major blunders as a result of adhering to a solitary but erroneous point of view.

Because the distribution of resources and effort in research is predominantly human-oriented, duplication and gaps are inevitable. To some minds, this human approach, in contrast with an orderly, systematic one, might be considered wasteful. Yet productivity in research, as in other human endeavors of a complex and little understood *modus operandi* —merchandizing, politics, artistic creation—calls for highly individualized styles.

Classification of Research Locations

A classification of research facilities can be made in the traditional way as profit and nonprofit.

PROFIT

Historically, the industrial sector of our economy has invested very little in basic biomedical research. And except for the development of drugs it has invested a relatively small amount in applied research. Even here, most of the major advances have resulted from research in nonprofit laboratories, with some assistance from pharmaceutical companies. A considerable part of pharmacologic and efficacy studies, and essentially all drug reaction studies, are carried out by the nonprofit sector with or without support from the profit group.

The report of the President's Task Force on Science Policy extols the competitive, free-enterprise system as a major research resource. Yet the rate of progress of the private sector, speaking of research and development generally, has been relatively slow and the costs high. For example, the rate of improvement of the internal combustion engine over the past half century has been extremely small in comparison with the rate of progress of medicine in the elimination of nutritional and infectious diseases.

We might digress here briefly to illustrate a measure of medical progress

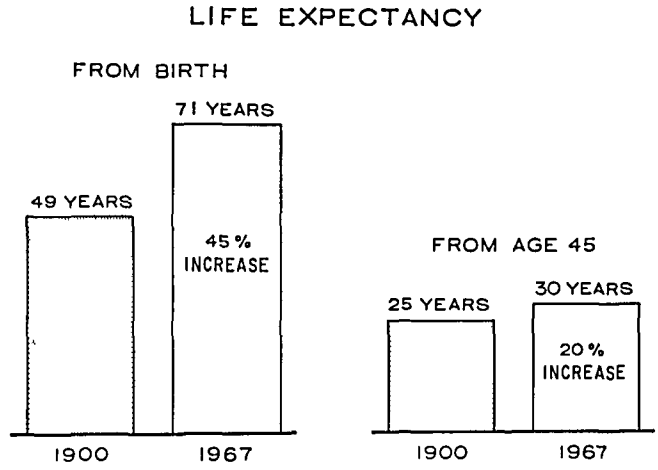


FIGURE 3

against these ancient scourges. As shown in Figure 3, the average life expectancy from birth increased in the United States from 49 years in 1900 to 71 years in 1967—45 percent. This was due largely to decline in infectious diseases. The increase in life expectancy from age 45 has been less spectacular—20 percent—because progress against the chronic, degenerative diseases, particularly heart disease, cancer, and stroke, has been slower.

The 10 leading causes of death in 1900 and in 1967 are ranked in Figure 4. This further delineates and quantifies the areas of greatest medical impact. Medical science, social changes, and improved medical practice have all contributed to the life-prolonging transformations reflected here.

Returning to the subject of research locations, it might be pointed out that there is a role for private industry, particularly the health industry, in respect to investment in and reimbursement for medical care. Industry not only would benefit tremendously from reduction of illness, disability, and premature death but also could derive considerable savings from more economical delivery of health measures. The nation's total health cost is an estimated $60 billion a year; yet research and development dollars to improve the delivery system are almost negligible. Hospitals and medical centers alone are multimillion dollar ventures but have almost no research and development money to improve their services.

Inadequate capitalization of nonprofit ventures remains a major problem. The inclusion of research and development funds that may lead to cost reduction is essential in the health industry's delivery corporations. Blue Cross and Blue Shield, for example, should have extensive funds for support of research in health-care delivery. In addition, private industry involved in the development of chemical agents and health appliances should be encouraged. Because the profit feedback is delayed, a major investment by private industry in these areas is highly unlikely. The encouragement of private industry, moreover, should not be used as a smoke screen for the limitation of public funds.

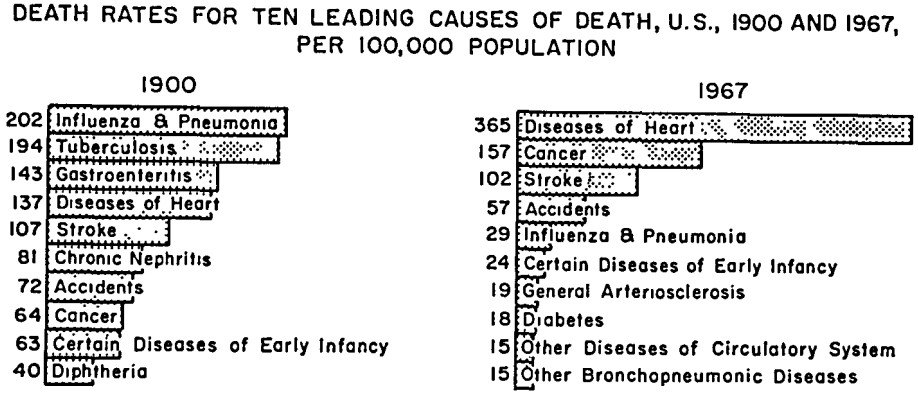


FIGURE 4

NONPROFIT

The nonprofit research facilities can be divided into federally operated and nonfederal activities, in accordance with the report of a survey (3) conducted in 1968 for the Department of Health, Education, and Welfare. In the nonfederal nonprofit sector, research facilities fall into five broad categories: academic institutions, independent hospitals, independent research institutions, state and local health departments, and other institutions. This grouping accounted for 97 percent of all U.S. Public Health Service grants and hence, to a major degree, for the biomedical research capability of the country. Altogether, a total of 1,093 institutions were considered.

The academic sector contained 82 percent of the space. This was subdivided into medical schools, with 42 percent; other health professional schools, 8 percent; and other academic institutions, 32 percent. Independent hospitals accounted for approximately one-sixth as much space as medical schools, and independent research institutions accounted for approximately the same amount as independent hospitals. State and local health departments accounted for somewhat less.

This classification does not clarify the enormous diversity of organization within each of these categories. University research facilities may present extraordinarily different patterns—some with goal-directed research institutes within the academic framework, others that follow very clear-cut departmental lines, and still others that are widely interdepartmental, even interschool, and occasionally interinstitutional. Likewise, other health professional schools and other academic institutions may have surprisingly varied research arrangements.

In general, basic, or preclinical, research is carried out somewhat apart from the day-to-day clinical problems involving patients. Clinical research is conducted in university or affiliated hospitals in the proximity of the medical school. Occasionally, clinical departments or divisions have rather extensive basic science components. Independent hospitals may also develop extensive basic research activities to complement more commonly accepted clinical research.

Generally, the amount of research space in hospitals is relatively low for the manpower involved. Laboratory needs may be somewhat less for clinical problems, and

the associated medical school may meet such needs for the hospital staff.

Federal research facilities have a considerable degree of diversity. Veterans Administration hospitals, for instance, have extensive clinical and occasionally basic research facilities. Public Health Service hospitals also have clinical research facilities. The Clinical Center and other installations of the National Institutes of Health constitute an enormous public resource for all levels of biomedical research activity. In general, the federal sector operates with personnel who are full-time or part-time employees of the government. They are rated in a service corps, such as the U.S. Public Health Service, or are Civil Service employees.

A somewhat new pattern is the government-operated, as well as supported, facility within a university complex or independent hospital. In essence, the government leases space and access to the research environment of the university or independent hospital to pursue some directed research by its own staff. The Gerontology Research Center at Baltimore City Hospitals is an example.

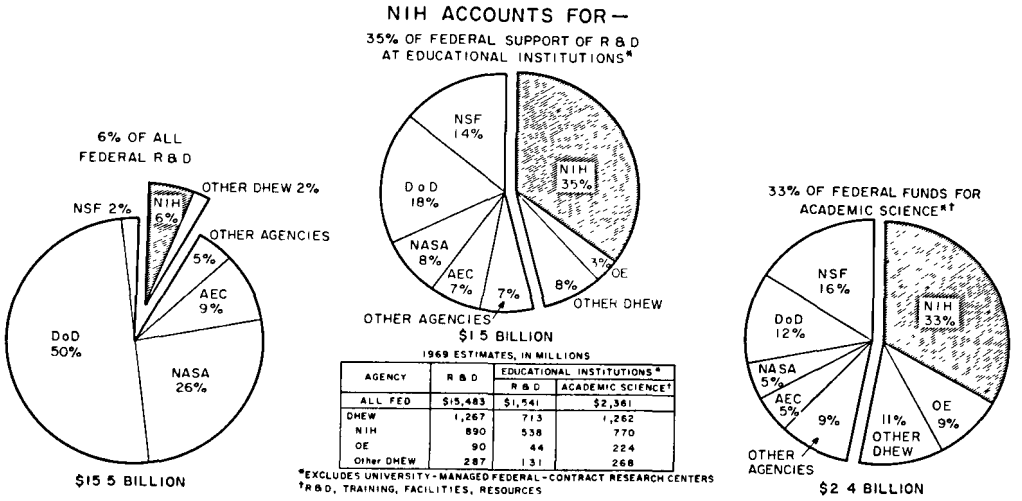
It would be almost impossible for any study group to ascertain the best approach to research facilities, as indicated above. Each arrangement described has certain advantages, such as ease of recruitment, availability of support, access to equipment, and presence of scientific knowledge.

The university or other academic institution offers some advantages, at least superficially. Staff recruitment is often easier because of certain academic benefits—tenure, access to colleagues, stimulation through student interaction, and a tradition of encouragement of scholarship without interference. Traditionally, the university has symbolized the optimal environment for nurture of the creative mind. Creativity, though often difficult to measure, has been rewarded by promotion. Finally, university life has been regarded as a highly desirable feature, though this is probably not true of the modern urban university, which often plays only a small part in the community.

University research has received generous support from a combination of private donations and research grant programs of the federal government. The agency contributing the largest share of federal support of all research and development at educational institutions is the National Institutes of Health. Figure 5 shows that NIH in fiscal year 1969, though funding only 6 percent of all federal research and development, supported fully 35 percent of that conducted at educational institutions. In the larger universe of academic science—training, facilities, and resources—NIH again funded the largest share—33 percent. And its parent organization, the Department of Health, Education, and Welfare, accounted for over half of all federal aid to science in the schools.

Federal support of biomedical science, however, has been seriously limited since about 1966, and private philanthropy has not been able to command enough new money to compensate for the rising cost of research. On the other hand, stability from year to year and freedom from political interference have made recruitment possible. These advantages seem tenuous at the present time. There is growing concern in public institutions about legislative interference and even some concern on private campuses about federal interference through indirect means.

The presence of scientific capability in the university is of course a major asset, but this has probably not been adequately exploited. Departmental and other artifi-



AGENCY	R & D	EDUCATIONAL INSTITUTIONS*	
		R & D	ACADEMIC SCIENCE†
ALL FED	$15,483	$1,541	$2,361
DHEW	1,267	713	1,262
NIH	890	538	770
OE	90	44	224
Other DHEW	287	131	268

*EXCLUDES UNIVERSITY-MANAGED FEDERAL-CONTRACT RESEARCH CENTERS
†R&D, TRAINING, FACILITIES, RESOURCES

FIGURE 5

cial barriers have prevented the full participation of basic scientists in clinical problems. Likewise, scientific equipment in the university may not be fully utilized, as protective and sometimes isolationist measures are maintained. In some schools, limitation of funding has brought greater dissemination of equipment and better interdigitation of resources.

The strongest argument for location of research in universities is the benefit of research to the educational process and of education to research. Unless some students are exposed to research and become interested in scientific careers, progress must cease. Furthermore, the student's inquisitive mind may stimulate and augment the pursuit of important new knowledge.

The independent hospital has one distinct advantage—namely, the presence of extensive clinical material. This serves as an attraction for the clinically oriented scientist, who may or may not have an interest in teaching. The individual with clinical inclinations and a desire to improve patient care can work in an independent hospital environment without the distraction of students or administration which marks a university or medical school. However, the isolation of such a hospital can be a serious deterrent to recruitment. The lack of a stable support policy, and particularly the lack of colleagues, significantly handicap such an operation. Many independent hospitals are developing much closer affiliation with universities so that the latter's capability, its access to students, and other advantages for research can be realized.

The problems of the independent research institution are exactly the same whether in the nonfederal or federal sector. The great advantage is the freedom from distraction and the opportunity for concentrated research unrelated to the service needs of patients or the training needs of students. Such institutes may have the problem of being dependent upon outside financing that requires relatively spectacular advances for continued funding. Hence, such research institutes may be rather heavily goal-directed and, therefore, short on basic science accomplishments.

State and local health departments are

a small part of the total in terms of dollar support, even though the numbers are relatively high. The research activities are frequently under a state civil service which draws upon part-time consultants. The laboratories, to a great degree, are directed toward very narrow goals that serve immediate public interests. Longer-term goals, however highly desirable, particularly in the preventive health areas, are generally not subsidized because the yield is too remote for the administration delivering the support.

In this regard, the development of regional laboratories to carry out activities of a part-service, part-research nature—such as the working out of new diagnostic approaches—would be of considerable value. Such facilities would reduce duplication in state laboratories and tend to centralize particular capabilities that could not be reproduced in every state.

The federal research institutes and the federal-university complexes have distinct advantages in regard to funding support and may offer some features of the university setting. Thus, investigators who are heavily committed to basic problems may be attracted into such environments when long-term support is assured through federal commitment.

In addition to considering the diverse needs of a free society, future allocations of research facilities must take two current transformations into account. The first is the technological revolution in audio-visual media. The second is the greater degree of mobility of the investigator and of research teams as improved transportation markedly shortens distances between research installations. Particularly in the face of dwindling research dollars, serious consideration should be given to the development of collaboration among universities.

By this, it is not intended that emphasis should be placed unduly on large, cooperative, multiuniversity endeavors but rather that various aspects of a problem should be shared on a voluntary basis with other universities that have a particular capability. It might then be possible to maintain a creative environment in multiple settings, with improved communication and transportation providing a critical mass. For example, problems of immune deficiencies are being investigated simultaneously in a number of laboratories, with one group or another undertaking various portions of the task. Information is distributed rapidly to other groups so that the progress of each can be accelerated. Thus, the university consortium has been hailed as an advance for the future.

The consortium concept has been tried out in a few isolated instances, particularly among universities or colleges in close geographic proximity. There seem to be some advantages, but also disadvantages because of the necessity for rather extensive formalities in developing these arrangements. At the moment, informal arrangements among universities and institutes should be strongly encouraged.

The need for the federal research establishment to work cooperatively cannot be overemphasized. Here again, the pooling of capabilities may lead to considerable acceleration of progress without increased cost. The granting agencies of the federal government should be encouraged to develop shared awards so that various institutions can work together on integral parts of research projects. For example, the study of growth failure in one institution might be advanced by the simultaneous awarding of grants to other institutions for studies on specimens from a particular patient.

The distribution of funds to these various localities has been generally dictated by the quality of research proposals and of past performance, as determined by peer judgment. The research market has been largely a free-enterprise venture with competition among investigators. On the other hand, directed research is now accepted as a necessity for meeting certain high-priority problems. But here also quality of research must determine the allocation of funds, rather than formulae based on geographic, demographic, or political jurisdictions.

In conclusion then, emphasis in future allocation must be placed on a variety and diversity of facilities and locations, emphasizing especially the university because of the need to produce investigators for the future. Emphasis must also be given to the creation of closer ties between universities, and between other sectors of the research community, so that the full scientific capability of the institutions can be realized.

Chapter 3

Sources and Instruments of Support

Over the past 20 years, the funding of biomedical research in this country has derived mainly from the federal government and industry. Universities have not seen fit, either financially or philosophically, to support the research endeavors of their faculty members, other than to provide salaries and working space. Conservative estimates place the federal government's share of all U.S. support of biomedical research over the 60 percent level.

Trends

Figure 6, based on an annual survey of federal agencies and other studies by the National Institutes of Health,* illustrates the absolute and relative growth of federal support for biomedical research and development from 1950 to 1970. (See also Appendix B, Table 3.)

Prior to World War II—in 1940, for instance—the total national support was on the order of $45 million, of which the federal government provided only $3 million. The remainder came largely from industry—$25 million—and from foundations and health agencies—$12 million. By 1947 the emerging role of the government was clear. Federal support of $27 million now slightly exceeded that of private philanthropy—$25 million. Industry spent $35 million, almost entirely in its own laboratories.

In 1952, when the nation's total cost of biomedical research and development was about $197 million, federal funds for the first time exceeded all private—profit and nonprofit—by $9 million. Subsequent trends were well defined. Nonfederal as well as federal expenditures continued to rise, probably through mutual stimulation of public interest. Today they stand at an estimated $1.7 billion in federal support and $1 billion in nonfederal.

Only a small proportion of the government's funds for biomedical research and development are expended in government laboratories. In Figure 7 the $2.7 billion total estimated for 1970 is allocated by source and by performer. Whereas the federal government provides 62 percent, it spends only 18 percent in its own laboratories and clinics. Academic institutions are the principal performers, accounting for about 35 percent of all funds.

A close analysis of the past and present patterns of medical science funding shows quite clearly that the federal government has become the major and indispensable source of support.

NIH alone obligated about $870 million in support of biomedical research and development in fiscal 1970. By contrast, the nation's foundations and voluntary health agencies spent only $112 million. Although the private sector is an important and appreciated patron, it is much overshadowed by the government in the support of biomedical research and development. Further, the demise of the Life

* Figures 6–9 are based on data published under the associate director for program planning and evaluation, NIH.

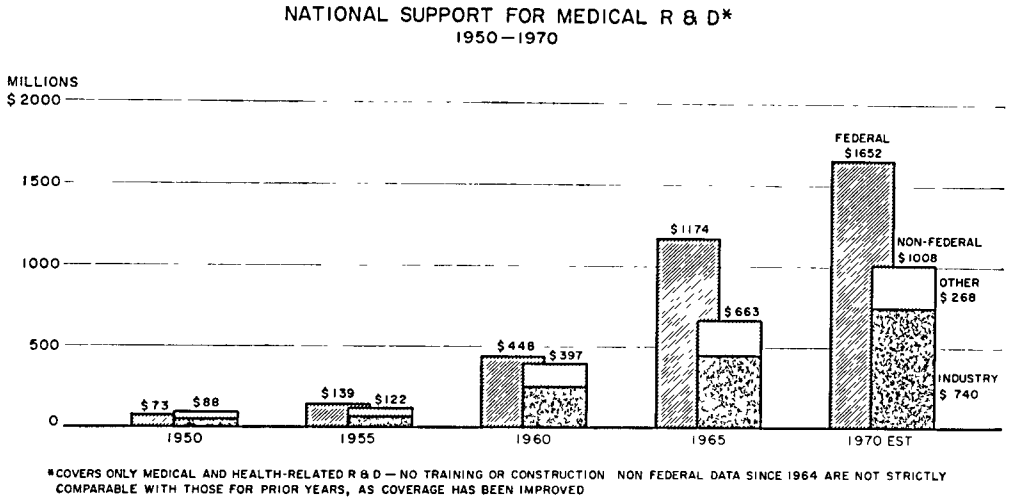


FIGURE 6

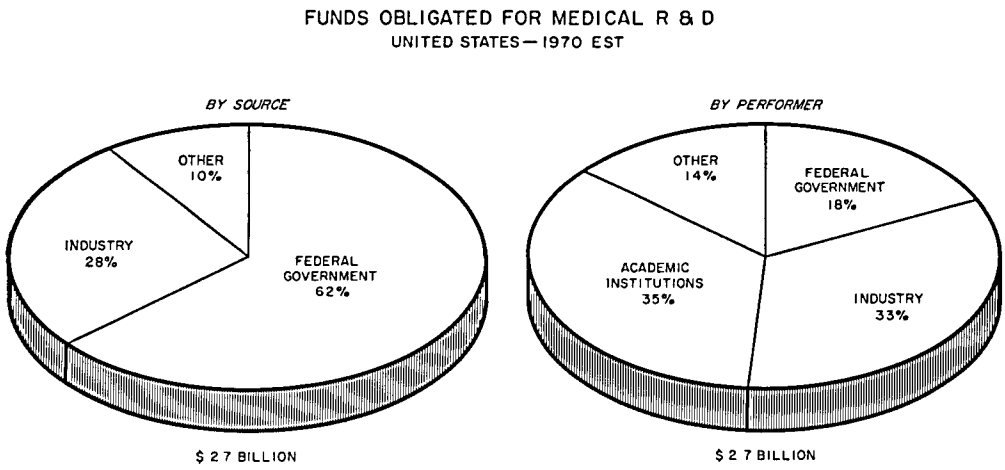


FIGURE 7

Insurance Medical Research Fund indicates that support from the private sector may have begun to decline, boding ill for scientists who seek aid from these sources.

The conclusion, then, that funds for research in the health sciences must come largely from the federal government is inescapable if this country is to maintain its prowess in biomedical research and preserve a valuable national resource for the future.

Before leaving the subject of national expenditures for biomedical research, it seems important to interject a note on economic trends. Figure 8, combining the federal and nonfederal sectors for 1966–70, represents total obligations in current and constant dollars, with the latter values based on the conservative gross national product deflator. Only in such a light can we approach a realistic view of today's trend in research support.

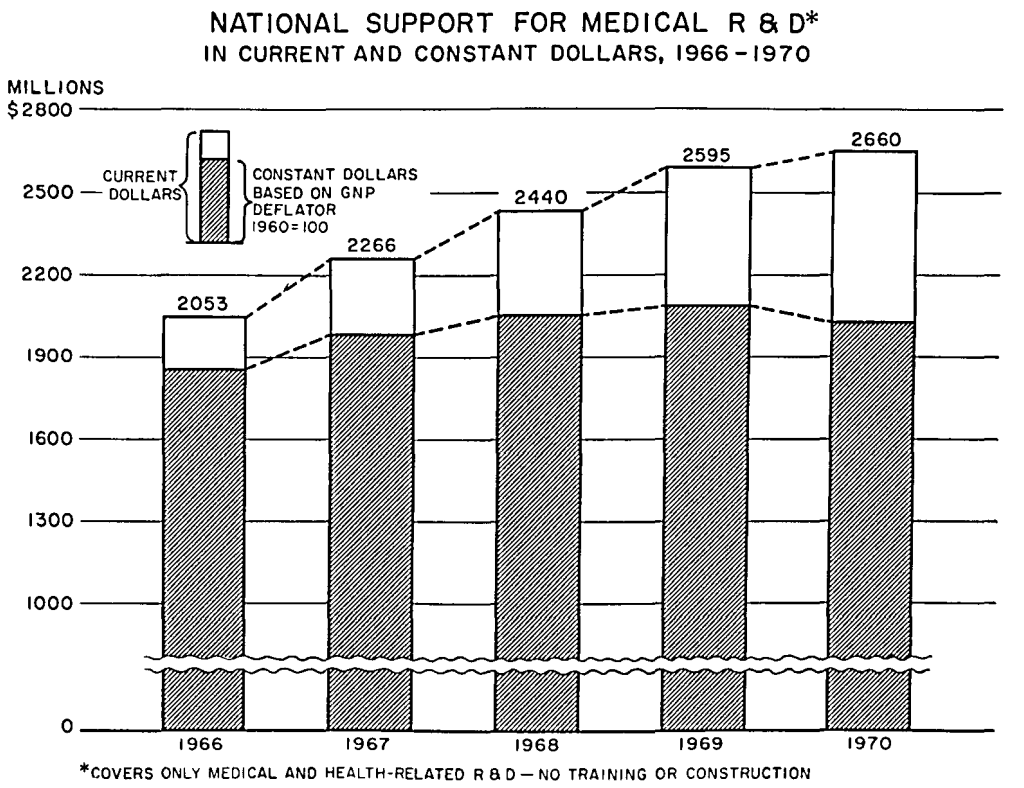


FIGURE 8

Instruments of Support

With regard to the mechanisms of support, several avenues are possible—for example, research project grants, institutional support grants, and contracts. The predominant and generally preferable instrument is the research project grant to the individual investigator, made available through a program to which he submits a proposal of the research he desires to undertake. This is the type of support that offers the most latitude for the scientist to explore the frontier of knowledge in his own field, accountable primarily to his peers and guided by results and his own individual style. The project grant has furthered the development of one of the most productive biomedical research efforts in the world.

Closely related to the regular project grant is the program-project grant, which permits the support of closely related interests of a group of scientists. This is a most reasonable type of funding and should be expanded in the future. Similar awards fund research centers and resources.

Institutional support has also been provided by NIH research construction grants, though these have been discontinued. Since the inception of the program in 1957, 1,483 grants totaling $473 million have been awarded on a matching basis for the construction of biomedical research facilities.

To underpin the research and research training programs of nonprofit institutions, general research support grants are

awarded on a formula basis. NIH grants of this type were authorized by a 1960 amendment of the U.S. Public Health Service Act. In the peak year 1969, they represented about 6 percent of NIH support for research and research training.

Institutional grants *per se* are widely viewed with a degree of scepticism, since their allocation within the institution can be biased and a source of ill will. This view is in conflict with the Carnegie Commission on Higher Education's 1970 report, *Higher Education and the Nation's Health: Policies for Medical and Dental Education* (4). The Commission recommends that "not less than 10% and not more than 25% of the research grants to any university health science center take the form of institutional grants rather than grants for specific research projects." It is the Committee's view that such grants can be used effectively for certain types of construction, for salary support in research programs, and as seed funds for young investigators before they are able to compete successfully on the national scene; but the percentage of the biomedical research dollar allocated in this fashion should be closer to 10 than 25 percent.

Lastly, the research contract has made a definite entry into the funding pattern of the country. Few investigators in biomedical research have operated under contract support, and thus its impact is difficult to assess. While the instrument has its place, particularly in developmental research, most biomedical investigation is too complex and unpredictable to be handled easily within a contract form.

An impression of the relative magnitude of these various types of support may be gained from the following data on NIH awards.† In fiscal 1970, the institutes and research divisions awarded 11,203 research grants and 872 research contracts. Dollar totals were $353.6 million in research project grants; $185.4 million for program projects, centers, and resources; $57.7 million for general research support; and $97.4 million in research contracts. Most NIH contracts finance the extramural portion of "collaborative research" as an extension of direct research operations.

Importance of Graduate Training

The mechanisms by which funding is accomplished must cover not only the research project *per se* but also the training of scientists. Regarding the latter objective, one need only consult a 1969 report of the National Institute of General Medical Sciences to realize the impact of one federal program on the supply of trained basic investigators. *Effects of NIGMS Training Programs on Graduate Education in the Biomedical Sciences* describes the largest of the research training programs conducted in 1958–1967 by the several National Institutes of Health (5).

In fiscal year 1967 alone, all NIH programs together obligated $133 million for training grants, not to mention additional sums for research fellowships, research career awards, and general research training support.‡ These are programs that must be maintained at a viable level, since they are vital to the future of biomedical research in this country. A decrease in graduate training support, even for a period of one to two years, would cause an

† From the Division of Research Grants, NIH. See also Appendix B, Tables 5 and 6, showing NIH research grants by kind of program and kind of recipient institution. Differences between text and tables are due to the inclusion in the latter of a few research grants from the manpower development and library programs (BEMT and NLM).

‡ NIH education as well as training awards for fiscal 1967–69 are summarized in Table 7, Appendix B.

estimated five-year delay in providing newly trained personnel for the health sciences.

In addition to the instruments of support for graduate training that have evolved successfully since World War II—the individual research fellowship and clinical traineeship, the departmental training grant, and the training stipend under institutional awards—the guaranteed student loan is now receiving serious consideration in federal circles.

Training Stipends Versus Student Loans

The introduction to this report states that the National Institutes of Health has been requested by the Office of Management and Budget (formerly the Bureau of the Budget) to examine the probable effects of altering present federal policies for support of research training in the biomedical sciences. More specifically, NIH was to assess the consequences of substituting guaranteed loans for stipends to graduate students and postdoctoral trainees. Such a move is said to be favored by the present Administration and by many members of the Congress. It was further stated that NIH has planned a searching study of training support and related problems. The study is to be done in two parts, the the first utilizing available data and the second reporting on a survey of institutions and trainees.

The Committee's reaction to the question posed by the OMB—a question that seemed both ominous and exigent—was to seek an immediate estimate of the number of prospective trainees that might be lost as a result of a change from stipends to loans. Toward this end, a very simple questionnaire was developed and sent to every medical school in the country. All department chairmen were asked to help in its administration to graduate and postdoctoral fellows and trainees who were completing their training as of June 1970.§

The essence of the results lies in the responses to the final question: "If no stipend had been available to support your training, but a long-term, low-interest loan had been available, would you have been able to continue your plans for training?" The answer was "no" from 62 percent of the 4,000 respondents.

Of those who were U.S. citizens, 58 percent responded negatively; of the noncitizens, 68 percent responded negatively. There was no difference between the sexes.

With relation to current training status, 61 percent of the answers were negative among the predoctoral Ph.D.'s, 75 percent among the postdoctoral Ph.D.'s, and 70 percent among the postdoctoral M.D.'s interested in research. Of the postdoctoral M.D.'s interested in clinical careers, only 51 percent were negative.

Half of the respondents were receiving support from the National Institutes of Health. Of those, 68 percent said "no," whereas only 51 percent said "no" when their support was from some other source. In respect to their career plans, 68 percent said "no" when the career goal was research and/or teaching, but only 46 percent answered "no" among those who planned a life goal in specialty practice. Negative answers totaled 67 percent among those who took training in basic science departments and 56 percent among those in clinical departments.

About half of the respondents were already in debt, some in excess of $15,000. The percentage of negatives was not particularly different when correlated with the size of the debt, the number of dependents, or the trainee's age.

Only 51 percent of those with physicians as parents said "no," in contrast with 64

§ Copies of the questionnaire and the printout of the data compilation are available from the AAMC.

percent of those whose parents worked in the services or trades.

There are some telling points in these data. First, 62 percent of the respondents said they could not have taken the extra training if they had had to depend on loans in lieu of stipends; and this figure rises to 68–70 percent of those whose career goals were research and teaching. What are some of the implications of these findings?

It has been argued that research diminishes the professional manpower pool for health care. The survey data, however, reveal that only 2,500 of the 4,000 respondents possess the M.D. degree and that only 654 of those contemplate research and teaching careers. Seventy percent of this number represents fewer than 500 M.D.'s who would have been diverted into nonresearch and teaching activities if loans rather than stipends had been offered. This seems a puny increment in the health manpower pool for direct service in the face of the 3 million employed in all phases of health care in this country.

On the other hand, the number is most significant in terms of continuing the production of new scientists and new teachers, particularly in view of the larger classes of students anticipated in existing and projected schools. It should also be stressed that the extra training undoubtedly enhanced the professional capabilities of those who will enter medical practice.

Another argument that is sometimes heard is that the trainee should pay for his own added training because it augments his earning power. This is hardly true in a career of research and teaching, but it may well be the case for those who know from the outset that their goal is practice, particularly in a specialty. It may be noted that only 46 percent of those whose career plan was a specialty practice said that a loan would not have enabled them to continue. Perhaps additional training aimed at a career in practice as we know it today should indeed employ loans in lieu of stipends.

However, the stipends—and increased stipends at that—should certainly be maintained for those whose career goals are teaching and research. The value to the citizenry from this small investment is truly large, and society can ill afford not to develop this resource. Lastly, it should be pointed out from the data concerning the parents' financial status that a shift to loans would tend to restrict the career in research and teaching to the very well-to-do or exceedingly motivated. Many whose parents could ill afford to borrow for their children's education would be forced into other occupations.

This point has already been made, but it will bear repeating: the threat implicit in the OMB's query must be countered and the potentially ruinous shift from training grants to loans averted.

Federal Health Funding

Returning to the broader theme of the importance of federal support to the nation's biomedical research and development effort, some estimates of the government's total health expenditures, by agency and program, are shown in Figure 9. This indicates the extent to which research must compete with less "controllable" costs for the federal health dollar. We have already seen in Figure 7 a measure of the degree to which the nation's medical research is dependent on the success of its advocates in this competition.

In conclusion, then, the major source of funding for biomedical research in this country must originate with the federal government. The form of support should

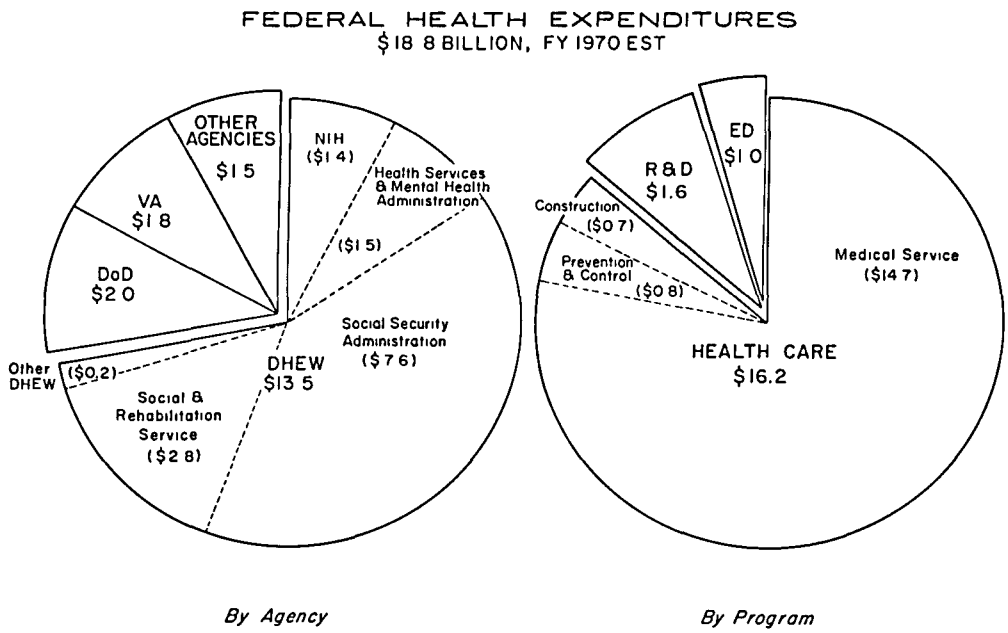


FIGURE 9

retain the elements of the individual research grant in order to nurture the unique and individual talents so important to solution of biological problems and maintenance of scientific excellence. Further, training grant programs for producing a constant supply of highly capable, original investigators must be continued.

An expanded system of program-project type grants would serve to focus scientific attention on problems of high "relevance." Contracts and institutional grants, on the other hand, appear to be a less desirable route to the support of biomedical science.

Federal policies guiding the support of health programs have not been clearly enunciated. To the extent that policies exist, they find expression through the Office of Management and Budget and the essentially compliant actions of the Congress. These bodies must be persuaded that federal appropriations for research and research training are vital to the nation's biomedical research effort, present and future, and thus to the significant advancement of the nation's health.

Chapter 4

Determining the Levels of Support

The question of how much should be spent on biomedical research is clearly a most important and difficult one. At first glance, it may seem imponderable; and perhaps for this reason one is tempted to offer simplistic answers. These would at best be expedient reactions to an exceedingly critical set of problems. One must guard against this type of approach, since it may, if not basically valid, provide not only immediate relief from those problems but also long-term misunderstandings that will sooner or later become detrimental to the health of our nation.

At the extreme of the simplistic reactions would be the tendency to state simply that appropriations are currently inadequate and that "more" should be provided. Aside from the essential importance of preparing a more thoughtful response, the mood of the people and their legislators is not cordial to providing "more" without a convincing justification.

Indexes

Some may suggest that the level of research expenditure should bear a certain relation to the gross national product or the federal budget or the total cost of the health industry. The problem was intensively reviewed at a meeting of the Association of American Medical Colleges' Council of Academic Societies in Chicago, Illinois, February 1970. For an excellent summary of various approaches to establishing appropriate research levels, see "National Expenditures for Biomedical Research" by Robert W. Berliner and Thomas J. Kennedy in the *Journal of Medical Education* (6).

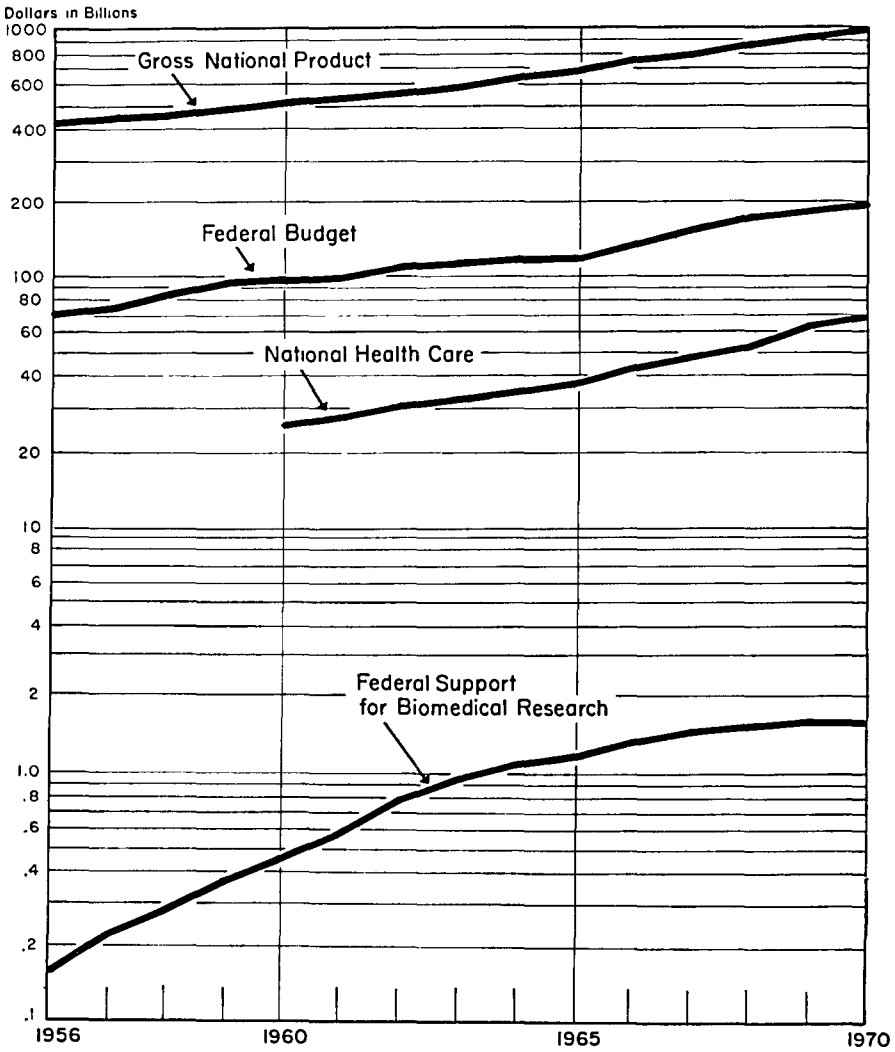
It is most difficult to see how there could be a formulation or equation that could possibly be applied to any of the above denominators for any number of successive years. To cope meaningfully with the complexities and inter-relationships involved is far beyond the Committee's ability. The approach would appear to be unproductive for even so short a period as five to 10 years. What can be stated with confidence, however, is that the gross national product, the total federal budget, and the total cost of the health industry have each increased out of proportion to the availability of funds for biomedical research. This may be observed in the curves of Figure 10 and the supportive tables of Appendix B.

The current inadequacies can be readily documented in terms of approved research and training grants that remain unfunded. In this regard, it should be emphasized that the allusion here is not to those approvals with low priorities and perhaps differences of opinion concerning their value. Rather, the reference is to grants that have passed a peer and dual review, with close scrutiny, and have been awarded a high priority rating.

Sources of Medical Advances

There is an alternative approach that can be made in an effort to answer the question of how much. The achievement of a

GNP, FEDERAL BUDGET, NATIONAL HEALTH CARE, AND FEDERAL BIOMEDICAL RESEARCH



Sources GNP: Office of Business Economics
Federal Budget · U S Office of Management and Budget
National Health Care · NIH - OPPE - Office of Resources Analysis

FIGURE 10

new therapeutic modality is rarely a *de novo* "breakthrough." The new advances, when examined in historical perspective, are seen to be dependent on observations that have preceded the final triumph by scores of years. Some clearly date back over centuries. Many examples of these should be carefully traced to their roots.

Such an exercise, which calls for meticulous documentation, would demonstrate several fundamental features of the research process.

First, it would reveal that many of the data leading to the treatment of disease X had nothing to do with disease X when the individual studies were done which provided the essential bits of information. It would emphasize that no society in its day was necessarily capable of predicting what was to become, years later, a key datum in an amazingly complicated puzzle.

This fact cannot be overemphasized in terms of its importance to our society's understanding of the major implications of the biomedical research effort. Such an understanding is essential if we are to expect an informed willingness to support studies that appear at a given point in time to have no relevance to a current health problem.

Second, the best measures for justifying support of a particular research venture have to do with the integrity of the investigator, the scientific meaning of the question he proposes to explore, and the elegance of the experimental design with which he plans to examine his hypothesis. The quantity of money to be awarded must then relate to the tools, supplies, personnel, and capital investment necessary to implement his studies effectively.

Cost-Benefit Analysis

Third, valid data, in the long run, will be useful somewhere, sometime, somehow. With the data that might be collected from an in-depth history of a few advances, it should be easy to demonstrate that the total cost of the endeavors that ultimately led to a given breakthrough actually represents a saving in dollars, let alone the incalculable values to the quality of life, to life itself, and to a healthy population.

In this regard, it is of interest to refer to some of the data from a study performed by Mr. Owen McCrory, a consultant in medical economics at Ann Arbor, Michigan, at the request of Mrs. Mary Lasker (7). McCrory estimates that owing to the declining death rate, attributable at least in part to new therapies, 554,066 lives were "saved" in 1967. The income of the wage earners in that population was an estimated $13.8 billion and the excise and income taxes they paid was $1.69 billion. The National Institutes of Health appropriation for that year (fiscal 1967) was $1.4 billion.* McCrory concludes:

> . . . from the analysis, it appears that the Federal Government receives more from the individuals who have been saved than the National Institutes of Health appropriate. This is true for 1967 alone or for the cumulative period of 1945 through 1967.

Now, one may argue that the lower mortality rate is not all due to developments through NIH programs. Without challenging this, let us quickly point out that the data refer simply to prevention of deaths and take no account of the enormous cost of illness.

Another reference is a monograph entitled, *Estimating the Cost of Illness*, by Dorothy P. Rice. This is designated as Report No. 6 of the U.S. Public Health Service Health Economics Series, dated May 1966 (8). A perusal of this document gives astounding information on the cost of illness and the savings that are real and anticipated through improved modalities of therapy.

A Practical Criterion

The premises suggested above might be formulated as follows:

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* Including National Institute of Mental Health, which became a separate bureau in the Department of Health, Education, and Welfare on January 1, 1967.

1. That recent therapeutic advances should be viewed in historical perspective and the costs of those advances be compared with the economic gains.

2. That the decision to award a particular grant must rely on the intrinsic scientific qualities expressed in the request.

3. That at some point in time, valid data collected for a host of different reasons will ultimately contribute to new and better modes of care.

Then if it can be demonstrated with a careful series of cost-benefit analyses (anticipating from McCrory's and Rice's reports) that these advances more than pay for themselves, the following proposition presents itself: *that the only reasonable ceiling to be placed on the cost of biomedical research should be fixed by the quantity of the qualified and motivated brainpower available to do the research.*

It is recognized that an opportunity for a tautology presents itself, since the quantity of funds that society is willing to make available in the first instance may modify the intensity of the motivation. Moreover, the question of training-support levels to produce additional brainpower must enter the long-range picture as research opportunities expand. But all in all, this proposition appears to be the most rational premise from which to operate.

Restricted Versus Unrestricted Research

From this point, one can legitimately go at least one step farther and state that the research to be supported can be divided into two main categories:

1. Research *qua* research—that is, unfettered and unrestricted.

2. Target, or mission-oriented, research.

Some suggest a third category, namely the research that serves as a teaching tool. This subject was discussed at some length at the second Fogarty International Symposium held in July 1970. It seems unnecessary to stipulate this third category separately, since research conducted in an institution that is dedicated to education and research will readily have its impact on the educational process.

The amounts (or percentages) to be assigned to these categories cannot be stipulated for all time. They should have flexible constraints and moving boundaries within those constraints. The best investment would almost invariably be to assign the largest percentage of funds to the first category, namely unrestricted research. Here, the qualified and independent investigator, guided by the dictates of good science and accountable primarily to his peers, finds his own way into the unknown, seeking new knowledge irrespective of immediate practical problems.

There are occasions, however, when it is deemed appropriate in terms of available data to innovate and, mobilizing funds and personnel, attack areas where, with a few more critical pieces of information that may well be within our grasp, a probability can be made a reality. Or one may examine the general health picture and, assessing the various needs, make priority judgments—decide that a given area is badly in need of research if we hope to minimize hazards to health and improve the quality of life. Frequently the research opportunity and the need act together as effective inducements to support a particular line of endeavor.

Paul Kotin, in referring to our environment, comments that for almost the first time in the history of science, we are in a position to study new diseases prospectively.

Another example of target research relates to the field of cancer—specifically to tumor-producing viruses. Distinguished

and well-trained molecular biologists are anxious to work in this area; but the techniques for studying viruses, and particularly these viruses, are difficult, and funds to accelerate the marriage of the conceptual frameworks and the technology would be well spent. Facilities are needed in which to prepare pure, genetically identifiable, virus-free tissue cultures, for the field of cancer research awaits these tools in bulk.

There are many other areas where mission-oriented investigations supported by contracts are not only valid but also urgent. Plans and proposals for both basic and applied research against all the major health problems are presented in *The Advancement of Knowledge for the Nation's Health—A Report to the President on the Research Programs of the National Institutes of Health*, dated July 1967 (9).

Modes of Administration

The Committee has resolved that new ways of ministering to these demanding problems of biomedical research and training must be sought. It would be worthwhile to develop a task force that would address itself explicitly to these problems, including questions of the need for a department of health—an organization responsive to the needs of NIH, NSF, and other federal agencies—or a department of science and education, which would be divorced from the delivery of health care itself. These are complicated problems worthy of considerable thought.

There is need to streamline the review mechanism. The Committee strongly endorses the system of peer review as the best known way to ensure high quality in research, and as the most democratic way to permit flexibility of approach through a variety of pathways, in contrast to the biased course of single individuals. Serious questions might be raised today as to whether all grants should be reviewed at the federal level or whether some portion might best be reviewed at regional or institutional levels. There are benefits and costs related to each system which should be examined with care.

The question of dual review may be less urgent in the 1970s than it was in the 1950s, and the role of the National Advisory Councils may need redefinition. It is probable that their most effective role would be a consideration of the state of the art in the several areas and an in-depth review of what has happened, what is happening, what ought to happen, and what might be important that no one is examining.

The Task Ahead

Finally, in the light of these considerations, it is suggested that the general proposition previously expressed for determining "how much" should be translated into dollars for the support of biomedical research over the next 10 years. One might well start from a baseline year, perhaps 1967, and extrapolate, with at least these issues in mind: (*a*) inflation due to the general state of the economy; (*b*) inflation due to the use of more sophisticated equipment; (*c*) inflation due to the need for more highly skilled technicians; (*d*) additional faculty for each medical school, in relation to anticipated growth of the population of medical students and other health-care personnel; (*e*) new schools of medicine; (*f*) capital investment in grounds and buildings; (*g*) training of new investigators to meet the growing demand in quantity and quality; (*h*) new approaches on a large scale which relate to the manner in which advances in health care can be delivered to all citizens—and again, studies in health-care delivery

should be viewed as intrinsic to the program of biomedical research.

The material presented in this report is a first step in formulating the future needs for biomedical research. It suggests a whole series of tasks and questions that must be addressed. Some of these are as follows:

1. An analysis of the costs of biomedical research over the next 10 years, as outlined above.

2. Detailed study of a few diseases for which new therapies are available, with a view toward tracing the routes of the ultimate achievements, the costs involved, the number of people benefited in terms of morbidity and mortality, and the financial consequences. These studies will provide an understanding of the nature of "breakthroughs" as well as an opportunity for cost-benefit analyses.

3. An examination in depth of the McCrory and the Rice reports on research economics as well as other documents on the subject. References follow to papers by Mushkin, Cole and Felton, the AMA Commission on the Cost of Medical Care, Klarman, and the Office of Resources Analysis, NIH (10–14).

4. An examination of areas in which mission-oriented research performed under contract might be of value today and in the near future at an estimated cost.

5. A realistic approach to the cost of research in the delivery of health care over the next decade.

6. An examination of granting mechanisms, with a view toward expediting without unfavorably modifying quality.

7. A consideration of the needs for a new department of health or a department of science and education which might deal with these problems more directly, responsibly, and constructively.

Chapter 5

Implementation of Biomedical Research Policy

The ultimate purpose of biomedical research is the eradication of disease and the advancement of health and well-being. All of its knowledge and findings tend toward these ends, directly or indirectly. And history clearly shows that the effort has been richly rewarding in prolongation of life and relief from suffering. Thus, all society has an interest in the health and well-being of biomedical research. The very extent of the effort and its beneficiaries, however, raises the questions of how and by whom research policy should be implemented.

General Considerations

Biomedical research, it must be emphasized, is not merely a desirable choice among alternative ways to better health. It is the only sure road to medical progress. The greatest conquests of disease have proceeded from an understanding of their nature and causes; and such understanding, except in minute part and rare instances, does not come by accident but through deliberate search.

This search is expensive. It requires expert manpower, well-equipped facilities, and ample funds. It requires leadership and organization of a high order. And it produces certifiable results and returns on the nation's investment. This last fact is far from widely enough known. Nor is it generally appreciated that further significant advances in the prevention of disease and the promotion of optimum health can only be expected to come about through further scientific endeavor.

Biomedical research is an essential component of medical education. It can and should be conducted so as to enrich in the future, as indeed it has in the past, the nature and nurture of education in medicine and allied fields. This refers to both basic and applied research, and to those largely corresponding poles, noncategorical (discipline-oriented) and categorical (mission-oriented) or preclinical and clinical research. Educational institutions, though traditionally identified with fundamental investigation, share today with industry and government the responsibility for "targeted" research and practical medical advancement.

Biomedical research is thus the ally of the medical student, the physician, and their fellow workers on the health team. It should enlist them as colleagues or informed supporters. The ivory tower is largely a myth; modern medical advancement depends strongly on diversified interaction and effective feedback of information from the medical community.

From the point of view of the American people in general, biomedical research should be an investment in their individual and collective health, happiness, and future. It should be so guided and administered by its trustees—in particular, the medical schools—that it will produce results which, in the long or short run, will pay desired dividends. This report

describes elsewhere an impressive and still-paying harvest of contributions to medical care. The viral vaccines and a wide range of drugs have alone yielded benefits that greatly exceed all the investments ever made in the life sciences.

To continue to make such advances for human health, biomedical research cannot be relegated to the position of "poor relative," and no informed citizen should want to see it poorly nourished. The funds, facilities, and manpower that will make possible great new advances can and should be made available, with due respect to other needs of medicine and medical education, and in due proportion.

Biomedical research is supported, as has been described, from a variety of sources public and private. Its sustenance is not the prerogative of any single group or sector. Multiple support not only ensures the freedom of research from controls favoring a particular group but also provides for participation by the many in an endeavor that should be shared by all: the search for health.

Moreover, the enterprise is a partnership one, not solely possessed in its planning, administration, or operations by any particular interest—not even the medical schools, though they are prime leaders and performers. It is an endeavor of public and private people and agencies from all walks of life and all levels of organization and society.

Biomedical Communications

Among the principal policies for biomedical research, the importance of communications should be firmly established. Communications, full and free, should be recognized—and provided for—as a vital, integral part of the total research effort and program. This has never been done, though many effective channels of communication exist.

The reference here is to communication at all levels and among all peoples. There must be communication and interchange between scientists. There must be communication between scientists and health workers. There must be communication among scientists, health workers, and the public, both individually and collectively.

Communication with the public should utilize all available methodologies and media. It must be carried out on a continuing, sustained, regularized basis, as well as on *ad hoc*, or special campaign, bases. Both of these avenues are imperative if communications are to succeed in conveying the nature and values of biomedical research and its goals and achievements.

Goals of Communication

Communication of findings from biomedical research is a *sine qua non* of scientific exploration and medical practice. Moreover, communication is necessary to ensure widespread understanding of biomedical research and the appropriate application of knowledge derived from it. Thus, communication to the public, as individuals and special groups, is requisite to the prevention and treatment of illness and to the promotion of individual, family, and community health.

The major goals of communication in biomedical research are:

1. To exchange research findings and other useful information among research workers and the health professions.

2. To assist in carrying out the obligation, incumbent upon biomedical research as a public trust, of accounting for its stewardship of private and public funds.

3. To report upon activities and plans of biomedical research widely, freely, and accurately.

4. To carry out informational and edu-

cational activities concerning the aims, methods, people, and programs of biomedical research with the ultimate objective of health improvement.

5. To produce and disseminate materials, soundly based on research and the current state of knowledge, for the same objective.

6. To work with all interests, organizations, and institutions concerned with health—scientific, professional, civic, etc., of both private and public character—with a view to assisting in the wider spread of biomedical research information and health knowledge.

7. To convey to the public, as individuals and as members of families and other groups, information on biomedical research and on health and illness which will be interesting or useful to them.

8. To use all media (established, developmental, or experimental) to collect, prepare, and disseminate information on biomedical research and health, both specifically and broadly.

Special Considerations

A number of salient problems and needs face those concerned with communications programs in biomedical research. One problem is the malaise ensuing from a belated and rueful recognition that communications with the general public and its elective representatives have been insufficient and to a large degree unsuccessful. The plateau in research appropriations despite rising costs, the willingness of public officials to resort to trade-offs between research and health services, the neglect of the public and the press to urge exploitation of exciting research opportunities, and the doubts of "relevance" of basic science even among medical students all evince our failure to establish biomedical research as a stable, intrinsic aspect of the American culture.

Although some of the problems of biomedical research may loom too large in the eyes of the prophets of its near-doom, they are serious. They include a lack of evidence that the general clamor for a reordering of national priorities implies a reasonable priority for basic science. They include a halt to federal research construction support on grounds that new space would call for new scientists. They include the denial of science as a national resource in the proposal that scientists should pay for their own graduate training through loans. And they include demands for immediate "results" despite the recent strides in conquering poliomyelitis, heart defects, measles, hypertensive heart disease, uterine cancer, choriocarcinoma, childhood leukemia, renal diseases, and many other major disorders.

The problems also involve such things as the opinion of some that scientists are too political; are corrupted in maneuvering for research funds; are high-living, far-traveling, ivory-tower impracticals; or are not sufficiently concerned with the relevant social issues of the times. The overall effect of these and other aspersions is, of course, a climate in which solid research progress fails to receive the attention it deserves, and the voices of the friends of science fall on deaf ears. James A. Shannon's words* to the effect that the story of biomedical research cannot be told in "daily bulletins of little science spectaculars" have come home to roost.

This unfortunate public image, however, is most probably capable of modification through sound communications, but not by hollow publicity, phony diversions, or slick propaganda. Rather, there must be authentic, studied, multilevel communication based on fact.

* At a meeting of the American Association for the Advancement of Science, Dallas, Texas, December 27, 1968

This brings us to the question of needs facing the public information aspects of the communications program. For example, there is an acute need:

1. To further establish the relevance of biomedical research to the public interest.
2. To inculcate understanding of researchers, that is, to show that they are real men and women, not "mad scientists" or misty-eyed dreamers or haughty untouchables.
3. To show that the benefits and values of biomedical research far outweigh the undesirable effects.
4. To show how the results of biomedical research are saving lives and preventing suffering.
5. To demonstrate that these results are returning vast dividends from the investment.
6. To implant understanding of the methods and facilities of medical researchers, with exposition in comprehensible ways of their daily tasks.
7. To help avert an age of stagnation and unreason, in which medical research could even become the victim of persecution, and to generate instead an age of reason and enlightenment.

Such needs and objectives as these are postulated upon the ground that biomedical research in our times is a success story in which the American medical college has been almost completely unknown and ignored. It is incumbent upon the medical schools to increase their efforts to join the community and make their needs and goals understood.

There are many other tasks concerning the "image" of biomedical research which call for better communications. There are fallacies about biomedical research, for example, that can be the subject of immediate and long-range efforts. The full picture would also include the story of what research does for medicine—and thus controvert the misimpression that biomedical research is confusing physicians and warping medical practice.

Methods and Media

Among the methods that might be considered in implementing a new, invigorated, purposeful communications program for biomedical research is the establishment of a national council, perhaps sponsored or initiated by the Association of American Medical Colleges. Such a council—or if a continuing body is not feasible or desirable, an *ad hoc* national meeting of interested groups—could serve to launch a nationwide communications program, making it clear from the outset that the endeavor is not to consist merely in fund-raising or propagandizing activities.

Here are suggested some of the methods that might be employed:

1. Exploration of the virtually untapped potential of television for explaining and dramatizing biomedical research—a task requiring new formulas if the degree of success is to approach that of sports, news, variety, or advertising.
2. Use of films, newspapers, trade books, textbooks, magazines, and other media to educate the public to the values of research.
3. Involvement of science editors, citizens' associations, labor unions, churches, and executives and legislators at all levels of government.
4. Use of "case" material—vignettes—of research projects and their results.
5. Preparation and use of data, where feasible, on the costs of a disease or medical problem and their relation to the costs of solutions.
6. Involvement of government and industry in the communications effort.
7. More dynamic roles for the medical schools, singly and collectively, in re-

search communications—presenting, for example, an exhibit, a research case, a personality, a team approach, or other illustration conveying the true story of medical science.

8. More active support and interest of medical students, encouraged through the Student American Medical Association and its local chapters and through involvement of individual students in communications projects and activities.

9. Attention to the matter of private interest and support on the part of foundations, voluntary health agencies, and the like.

10. Encouragement of regional organizations, such as the Southern Regional Education Board and the Western Interstate Commission for Higher Education, to play a role in promoting the understanding of biomedical research.

11. Enlistment of the teachers of science, physical education, and other subjects in elementary and high schools and in nonmedical colleges and universities.

12. Promotion of understanding of biomedical research on a nonpartisan basis by political parties, and development of mechanisms for providing full, factual information on request.

13. Many other projects and activities that could be planned and undertaken on various levels, with a view to encouraging and implanting the understanding of biomedical research—for instance, open houses at research institutes, medical school demonstrations, participation in health and science fairs for the public, and full cooperation with the media.

The above are only examples of the kinds of activities and projects, some broad and some quite specific, that should be implemented as parts of a well-rounded, aggressive public communications program.

A word should be added here about the various media of communication, some of which have been mentioned above. From the short talk with slides before a local club to the television spot or full-length film, each and all have a role. The experience and expertise of the National Institute of Mental Health in such endeavors as its nationwide information program on drug abuse indicate that all techniques and media can be brought to bear.

In conclusion, it should be pointed out that many of the suggested projects should be undertaken through contracts with the highly skilled agencies and firms of today's communications field. It would cost money, but there is no other way to secure the quality and kind of materials—films, exhibits, publications—needed to do the job.

Emphasis should also be given to the necessity for staff, in addition to those presently available, whose full-time responsibility is to carry out the programs in biomedical research communications. Many others, indeed all interested parties, must contribute to the program both at national and local levels. But an adequate endeavor cannot be carried out if new professional resources, as well as funds and materials, are not engaged to aid those already in the field of biomedical research and medical education.

Summary of Conclusions and Recommendations

Conclusion: That biomedical research has contributed in substantial ways to longer life and better health for all Americans. Impressive progress continues to be made against the formidable health problems remaining. Nevertheless, biomedical research is under attack, sharing with all science much of the blame for problem-causing technologies and for failure to cure social ills.

1. Recommendation: That the nation adopt a policy of supporting more, rather than less, biomedical research, in full recognition of the fact that no other course can offer hope for ultimate solutions to health problems.

That the public supports science as a means to an end, not as an end in itself. But applied research leading to practical results, it should be made clear, can go only so far without new knowledge from basic research and will falter if it exceeds its science base.

2. That the public be made aware of the payoffs from basic research through cost-benefit analyses in which life-saving results are traced to their origins.

That biomedical research and medical education are mutually dependent and mutually beneficial.

3. That medical schools and their affiliated hospitals continue to be the principal sites of biomedical research effort in this country, thus enhancing the training of physicians and other health workers, the care of patients, and the research itself.

That the President's Task Force on Science Policy is commendable for its emphasis on the importance of scientific leadership to the achievement of national goals (2).

4. That the President, in the spirit of his Task Force's recommendations in support of science, endorse an unequivocal statement of the federal commitment to biomedical research.

That the environments in which productive research can be conducted vary greatly and that the deployment of efforts should be guided by the principle of maximum yield for funds invested.

5. That maximum productivity be sought through encouragement of the creative mind and of creative interaction, to be achieved through freedom of choice in careers and residence.

That the President's Task Force, in extolling the free-enterprise system as a science resource, failed to give due credit to nonprofit institutions for the conduct and support of live-saving discoveries.

6. That national science policy take full cognizance of the productive relationship of the federal government and academia and that ways to improve this relationship be explored. Consideration should be given to the potentialities of the university consortium—of voluntary cooperative efforts to solve a given problem in multiple settings through shared awards.

That the National Institutes of Health is the main federal supporter of research and development at educational institutions and that its parent agency, the Department of Health, Education, and Welfare, accounts for over half of all federal aid to academic science.

7. That the Association of American Medical Colleges engage actively in shaping

national biomedical research policy, particularly in respect to the important role of NIH in science support.

That the federal government has become the main source of funds for biomedical research, providing nearly two dollars for each one from the nonfederal sector. In addition, its programs support research training, facilities, special resources, and the institutions themselves.

8. That the bodies of the executive and legislative branches of the government concerned with the making of science policy be urged to continue federal appropriations for biomedical research as vital to the national health effort and in the public interest.

That the rate of increase in biomedical research support has not kept pace with that of the gross national product, the federal budget, or national health care. Recent increases have been more than offset by rising costs so that the trend in constant dollars is level or downward. Meanwhile, the phasing out of research construction and the reduction of training programs bode ill for the future.

9. That the national policy for biomedical research assure support at levels sufficient to engage all well-qualified brainpower and that consideration be given to expansion at a rate determined by widening research opportunities.

That a high proportion of graduate trainees in medical schools (about 60 percent) would be unable to continue their extra training, vital to research and teaching, if their stipends were changed to loans, as contemplated by the Office of Management and Budget.

10. That the Administration and the Congress be urged to continue federal programs providing fellowships and other stipends for advance training in the health sciences and clinical specialties.

That various means of support for biomedical research, ranging from the individual project grant or contract to the program-project and institutional grant, have their place in meeting program objectives of both supporting agencies and performing institutions.

11. That the individual project grant, awarded through peer review, continue to be the primary instrument of biomedical research support. An expanded system of program-project support should be addressed to problems of high relevance.

That the biomedical research to be supported is of two main types—basic and applied. No fixed ratios can be stipulated, but allocations should be based on research opportunity and on national priorities among health problems.

12. That new ways be sought to meet the various needs of biomedical research and training, including consideration of a department of health or a department of science and education. Peer review is strongly endorsed, but the review mechanism should be streamlined.

That important tasks and questions face the AAMC and the CAS. These include determination of support levels for the next decade according to the recommended principle of full utilization of brainpower.

13. That the AAMC and the CAS undertake or sponsor studies to demonstrate the contributions of basic research, to delineate areas in which target research under contract would be productive, and to improve health-care delivery.

That the implementation of biomedical research policy requires effective communication at all levels. There is particular need for more public information on the nature, the goals, the implications, and the costs of medical science.

14. That a major effort be made to improve the general public's and their leaders' understanding of biomedical research through development of a communications system which would in turn be part of a broader network linking all persons and organizations concerned with matters of health.

Appendix A

Contributions of Basic Science to Medicine

Robert G. Petersdorf, M.D.

With a view to illustrating the process of medical advancement, the author asked a number of his colleagues to enumerate contributions of basic science to clinical medicine. Specifically, they were asked to provide examples demonstrating that basic science had explicitly contributed to the diagnosis, prevention, or treatment of disease. Their responses, summarized here, reinforce the conviction that there is no area of medicine that has not benefited from basic biomedical investigation.

The field of neonatology provides two important contributions:

1. Research in blood groups and immunology led to understanding of the pathophysiology of Rh hemolytic disease of the newborn. Understanding of the mechanisms of the disease resulted, in turn, in effective prophylaxis. More specifically, the injection of Rh antibodies after delivery eliminates Rh positive cells from the blood stream of the mother and thereby prevents immunization. It is significant that this discovery was made not by an obstetrician or a blood-group specialist but by a professor of medicine whose specialty was medical genetics and whose avocation was the breeding of butterflies.

2. Prenatal diagnosis is an emerging clinical reality of enormous potential. Basic research in biology led to the recognition that chromosomes are the carriers of the genetic material, and research in cytology and genetics led to simple methods for the demonstration and study of human chromosomes. The observation that many human diseases were caused by chromosomal malformations soon followed It is now possible to obtain fetal cells by amniocentesis (withdrawing specimens of fluid from the pregnant uterus). The diagnosis of a chromosomal malformation can be made early in fetal life, and, where indicated, therapeutic abortion can be performed.

Similarly, studies in metabolism and genetics, together with research in the biochemistry of enzymes, revealed that many diseases are due to inborn errors of metabolism, which in most cases are caused by enzymatic deficiencies. Research has made it possible to perform enzyme assays on amniotic cells and to diagnose many of these diseases while the fetus is still *in utero*.

Basic research has helped to identify, ameliorate, and prevent many inborn errors of metabolism, even when the diagnosis is not possible in the fetus. For example:

1. Studies on phenylalanine metabolism allowed the development of tests for identifying recessive carriers of the genes for phenylketonuria. Thus, guidance and counseling of parents who might transmit this recessive disease to their offspring became possible. Another outgrowth of improved understanding of the biochemical lesion was effective dietary therapy.

2. Wilson's disease, a recessive genetic aberration, involves an accumulation of copper in the brain and liver. The disease can now be diagnosed in affected individuals long before symptoms are apparent. Treatment aimed at getting rid of copper prevents a fatal outcome.

3. Research on purine metabolism has per-

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mitted elucidation of the genetic basis of a severe childhood neurologic disease, the Lesch-Nyhan syndrome. This is characterized by mental retardation, self-mutilation, and involuntary movements (choreoathetosis) The condition is associated with an excessive production of uric acid resulting from the sex-linked absence of an enzyme, hypoxanthine-guanine phosphoribosyl transferase Advances in tissue culture techniques now permit diagnosis of the disease *in utero* so that the pregnancy may be interrupted.

This is one of very few diseases in which mental retardation has been clearly associated with a biochemical lesion. The same enzyme that is absent in the Lesch-Nyhan children has been found to be deficient in a number of adults with gout, enhancing the understanding of this common disorder.

Through biomedical research, gigantic strides have been made in the diagnosis, treatment, and prevention of diseases of every organ system. For example, physicians interested in diseases of the nervous system might cite the following advances:

1. Studies of the membrane properties of skeletal muscle have led to the electromyogram, which is used diagnostically to differentiate neurogenic from myopathic processes. Muscle membrane physiology has also provided a rational approach to the management of patients with familial periodic paralysis.

2. Studies on the physiology of the neuromuscular junction have contributed a basis for the management of patients with myasthenia gravis who develop a tolerance or refractoriness to anticholinesterase drugs, the use of veratrum alkaloids, and like treatment.

3. The L-Dopa story is clearly an example of the value of basic research to medical practice. The discovery of abnormally low levels of breakdown products of norepinephrine in the spinal fluid of patients with Parkinson's disease raised the question whether administration of a precursor of norepinephrine would be beneficial. From this developed the experimental use of L-Dopa as an effective clinical agent.

4. Basic work on nerve cells has helped to explain the nature of excitability. From this has developed a better understanding of the mechanism of action of anticonvulsant drugs, and the selection of these drugs has been moved from an empirical to a somewhat rational basis.

5. Numerous physiologic studies on the reticular formation of the brainstem and descending autonomic pathways and on the neural control of respiration have resulted in a rational approach to the management of patients with coma.

Patients with pulmonary disease are benefitting from basic chemical and physiologic research. For example:

1. It was shown that carbon dioxide levels of the blood could be determined from changes in acidity (pH) detected by an electrode. This has resulted in widespread use of the carbon dioxide electrode, which permits critical management of acutely ill patients.

2. Studies of pulmonary surfactant, a natural substance lining the inside of the lung, have relied on basic disciplines—physical chemistry, lipid analytical chemistry, animal physiology—to demonstrate its importance and biological properties. This work is helping to clarify the respiratory distress syndrome and hyaline membrane disease. Several investigators have independently predicted that progressive collapse of the lungs (atelectasis) in seriously ill patients—a condition marked by deficient pulmonary surfactant—might respond to measures for increasing oxygen delivery to the pulmonary blood.

3 In bronchographic diagnosis, contrast media of the iodinated oil type can cause severe disturbances in pulmonary function. Thanks to previous work in basic radiation physics, several investigators were able to demonstrate that powdered metallic tantalum could provide far better bronchographs while interfering less with already compromised lung function. This procedure promises to be a major advance in diagnosis of pulmonary diseases.

4. The lung scan was developed from 1962 to 1964 by virtue of basic efforts to produce nontoxic, aggregated particles of human albumin with a suitable radioactive label. Now the lung scan is the most accepted initial

test in the diagnosis of pulmonary embolism. It has been instrumental in bringing that disease process to the foreground and has contributed significantly to its long-term management.

5. Penetrative biochemical studies on thrombolysis have shown the feasibility of treating pulmonary emboli with the enzyme urokinase.

Examples of the contributions of basic research can also be cited from the field of thyroid disease:

1. D-thyroxine. Extensive studies have been done to define structure-function relationships for thyroid hormones. It was shown in rats that D-thyroxine, the dextro-isomer of the naturally occurring hormone, has a greater effect on cholesterol levels than on oxygen consumption. This led to studies in man which again showed a disassociation between lowering of serum cholesterol and stimulation of metabolism. D-thyroxine is now marketed for the therapy of hypercholesterolemia. Its long-term benefits remain to be determined, but the hope is that it will prevent progression of atherosclerosis.

2. Anti-thyroid agents. Numerous basic studies in laboratory animals and *in vitro* systems have defined the ability of drugs such as propylthiuracil, methimazole, and perchlorate to block the synthesis of thyroid hormones. These agents are now used successfully to treat hyperthyroidism.

3. Iodized salt. Extensive research has shown that iodine deficiency is a major factor in producing endemic goiter. The use of iodized salt has markedly reduced the incidence of goiter in many parts of the world.

4. Calcitonin (thyrocalcitonin). The discovery of a calcium-lowering hormone in the thyroid gland is relatively recent. The hormone has now been synthesized and should become widely available. While the exact role of calcitonin in therapy has yet to be defined, it has already proved useful in treating Paget's disease and hypercalcemia of diverse etiologies. It has also been found that one type of thyroid cancer, medullary carcinoma, is accompanied by high levels of calcitonin in the blood. The assaying of blood for calcitonin may become the best way to detect this tumor early.

A gastroenterologist can point out that the field of physics has contributed fiberoptics for visualization of internal canals and crevices, that knowledge of physical chemistry has permitted the definition of micelles in fat absorption, and that phase solubility has provided the best explanation for gallstone formation Basic immunology had a hand in the development of the radioimmune assays of the hormones of the gastrointestinal tract—gastrin, secretin, and glucagon. The same discipline was responsible for guiding clinicians to the recognition of Australia antigen and antibody, which will facilitate the diagnosis and prevention of serum hepatitis.

No field has benefited more than cardiology from experimental studies in physics, electronics, electrophysiology, and bioengineering. For example, experimental studies on arrhythmias and the electrophysiology of the heart led to effective ventricular defibrillation in the control of sudden death. Defibrillators are now a part of every hospital's equipment. In a mobile heart unit in Seattle, 18 lives have been saved in a period of six months through the availability of ventricular defibrillation equipment.

The development of pacemakers that permit the treatment of complete heart block is another example in which basic research led to a technologic advance applicable to patients. Massive experimental work in physics and bioengineering laboratories led to the evolution of the pump oxygenator, which in turn resulted in monumental advances in cardiac surgery.

Much of this progress has depended upon maturation of the field of bioengineering, an area on which the National Institutes of Health is placing particular emphasis. The liaison between engineering and medicine has also produced artificial kidney equipment This is now used for extended dialysis, which has prevented deaths from chronic uremia and returned many patients to a useful life.

The entire field of nuclear medicine, comprising the application of radioisotopes and radioactive pharmaceuticals, has its home in physics. The initial photoscanning instrument was developed by a Ph.D. physicist working in

conjunction with physicians. Subsequent advances have included the lung scan (mentioned above), the brain scan, and bone and liver scanning. The Anger camera is a new instrument, developed by a physicist, which makes use of radioisotopes to permit rapid sequential and dynamic visualization of events within the body. It has opened up a vast new field of diagnostic procedures

The field of infectious diseases is, of course, replete with new vaccines and antibiotics. Poliomyelitis, measles, and rubella are three common viral illnesses that have been sharply reduced or eliminated within the past decade Underlying the development of all these vaccines was the discovery that viruses could be propagated in tissue culture, a fundamental advance of tremendous importance.

While the synthesis of new antimicrobials can be defined, by and large, as applied research aimed at finding effective new drugs, it should be recalled that the initial antimicrobial activity of penicillin was noted by Sir Alexander Fleming almost by accident during the course of experiments not specifically designed to find new antibiotics. Occasionally the discovery of a chemotherapeutic agent is based solely on observations made in the basic laboratory An example of the application of molecular biology to medicine is the use of "fraudulent molecules" in the treatment of herpetic keratitis. Here, the pathogenic virus is given material (IUDR) which prevents its multiplication and leads to abortion of the infection.

Occasionally the study of a rare disease may lead to understanding of basic defense mechanisms, with the possibility that these can be applied to man. Chronic granulomatous disease, or CGD, is a case in point. While uncommon, this is a very distressing infectious process resulting generally in early death. Research in the area, most of which can be classified as basic, has shown that:

1. The diagnosis can be made with certainty by a combination of tests (leukocyte microbicidal activity, NBT reduction, iodination, and others)

2 The carrier female can be detected, permitting genetic counseling. Approximately 50 percent of female offspring will be carriers; and among their children, approximately 50 percent of the females will also be carriers and 50 percent of the males will have CGD. Noncarriers will have normal families.

3. The leukocytes in CGD are deficient in the production of hydrogen peroxide, which in turn may diminish their microbicidal capacity Studies of the leukocytes have enhanced understanding of the body's defenses against other infections.

From the numerous possible examples in immunology, one might mention research on blood groups as having practical application of the utmost importance. The pioneer studies leading to discovery of the ABO and Rh blood-group systems have resulted in routine blood typing, which has made safe transfusions a commonplace of clinical medicine.

Similarly, the grafting of various tissues, such as bone marrow, kidneys, liver, and heart, is not possible unless there is genetic compatibility between the graft and the host. Developments of the last few years have led to the recognition of genetically controlled tissue types similar to blood types. As a result of this advance, the art and science of tissue matching has progressed to the point that successful tissue grafting is becoming a clinical reality

A field that has probably benefited as much as any from basic research is clinical pharmacology. The metabolism, distribution, and mechanism of action of drugs are now much better understood.

1. The study of drug metabolism, particularly in relation to the role of enzymes on the microsomes (microscopic intercellular particles), has clarified some causes of drug interactions which are both detrimental and helpful to the patient. For example, phenobarbital stimulates the microsomal enzymes and thereby decreases neonatal jaundice. The changes in microsomal enzymes can also explain some of the bleeding problems that have occurred with combinations of oral anticoagulants and various sedatives.

2. The study of protein binding of drugs has led to an understanding of toxicity of many drug combinations in which displacement from plasma binding is a major factor

In addition, plasma binding has helped to explain some of the relative effectiveness of antibiotics.

3. A study of the volume of distribution of lidocaine in patients with congestive heart failure and in normal persons has led to the concept that lipid-soluble drugs are distributed in a much smaller space in patients with decreased cardiac output or limited perfusion of the gut and skin. This concept may explain the increased toxicity of many drugs in such patients

4. Basic research has yielded some clues as to the types of enzymes that can be safely used in patients with cancer. In the future, the use of highly purified enzymes, possibly in an insoluble form attached to some matrix, may be useful in the treatment of specific genetic enzyme defects and as immunosuppressants.

5. The discovery that individuals react to drugs in different ways, a field called "pharmacogenetics," is another interesting outgrowth of basic research. It has been shown that the variety of drug reactions are caused by otherwise innocuous enzyme variants in the population. One example is glucose-6-phosphate dehydrogenase deficiency, which predisposes to hemolytic anemia from a variety of drugs. Affected individuals can be screened easily and hemolytic reactions prevented.

Abnormal pseudocholinesterase is not uncommon in many populations and predisposes to prolonged apnea on administration of suxamethonium, a muscle relaxant commonly used during surgery. Again, screening of affected individuals may forewarn the anesthesiologist that his patient has this difficulty, preventing fatal episodes.

Patients with porphyria are highly susceptible to certain drugs such as barbiturates. Identification of latent carriers for porphyria in patients' families may prevent the disease from becoming apparent if barbiturates are prohibited.

Pharmacology has benefited greatly from the application of biochemistry to the synthesis of drugs. An excellent example is provided by the several purine analogs. Many years of study in bacterial, yeast, avian, and rat models have established the basic sequence of purine synthesis and catabolism, and many of the enzymatic processes involved have been characterized. Without this foundation, none of the following clinical advances would have been possible:

1. The first effective agent to change the one-year survival in acute leukemia of childhood from less than 10 percent to greater than 50 percent was 6-mercaptopurine, a hypoxanthine analog. This antimetabolite remains one of the most effective agents against neoplastic disease.

2. Azathioprine, a substituted 6-mercaptopurine, has been widely used for suppression of the immune response. It is responsible, in large part, for the present success of transplantation of kidneys and other organs in man. Now under investigation, the agent appears very promising in the treatment of systemic lupus erythematosus and other conditions in which immune mechanisms are directly involved in the pathogenesis of disease.

3. Allopurinol, a hypoxanthine analog, is an effective inhibitor of uric acid synthesis, and has proved to be the drug of choice for managing the uric acid stones of severe hyperuricemia. It has been used to prevent the kidney damage involving uric acid which occurs after effective chemotherapy of malignant disease.

Masterful reviews of recent advances in biomedical research, with commentary on work in progress and needs for the future, are presented in two works entitled *Biology and the Future of Man* (15) and *The Life Sciences* (16) by the National Academy of Sciences' Committee on Research in the Life Sciences, under the chairmanship of Philip Handler.

Appendix B

TABLE 1

GROSS NATIONAL PRODUCT, NATIONAL BIOMEDICAL RESEARCH, AND FEDERAL BIOMEDICAL RESEARCH
(Dollars in Billions)

Years	GNP	NBR	NBR as % of GNP	Fed. Support of BR	Fed. Support as % of NBR	Fed. Support as % of GNP
1970	$—	$2.660	—	$1.652	62.1	—
1969	931.4	2.595	.2786	1.656	63 8	.1777
1968	865.0	2.440	.2820	1.571	64.4	.1816
1967	793 9	2 266	.2854	1.459	64.4	.1837
1966	749.9	2.053	2737	1.316	64 1	.1754
1965	684 9	1.837	.2682	1.174	63.9	.1714
1964	622.5	1.652	.2654	1.049	63.5	.1685
1963	583.9	1.486	.2545	.919	61.8	.1573
1962	556.2	1.290	.2319	.782	60 6	1405
1961	518.9	1.045	.2014	.574	54.9	.1106
1960	502.6	.845	.1681	.448	53.0	.0891
1959	482.7	.648	.1342	.351	54.2	.0727
1958	444.5	.543	.1222	.279	51.4	.0627
1957	442.8	.440	.0994	.229	52.0	.0517
1956	419.2	.312	.0744	.162	51.9	.0386
1955	397.5	.261	.0657	.139	53.3	.0349
1954	363.1	.237	.0653	119	50.2	.0327
1953	365.4	.214	.0586	.107	50.0	.0292
1952	347.0	.197	.0568	.103	52.3	.0296
1951	329.0	.175	.0532	085	48.6	.0258
1950	284 6	.161	.0566	.073	45 3	.0256

Source: NIH-OPPE (National Institutes of Health–Office of Program Planning and Evaluation), Office of Resources Analysis.

TABLE 2

FEDERAL BUDGET OBLIGATIONS AND FEDERAL SUPPORT OF BIOMEDICAL RESEARCH
(Dollars in Millions)

Years	Fed. Budget Obligations	Fed. Support of Biomedical Research	Fed Biomedical Research as % of Fed Budget
1970	$196,752	$1,652	0.8396
1969	184,556	1,656	0.8972
1968	178,833	1,571	0.8784
1967	158,254	1,459	0.9219
1966	134,652	1,316	0.9773
1965	118,430	1,174	0.9913
1964	118,584	1,049	0.8846
1963	111,311	919	0.8256
1962	106,813	782	0.7321
1961	97,795	574	0.5869
1960	92,223	448	0.4857
1959	92,104	351	0.3810
1958	82,575	279	0.3378
1957	76,741	229	0.2984
1956	70,460	162	0.2299

Source: U. S Office of Management and Budget, NIH-OPPE, Office of Resources Analysis

TABLE 3

SOURCES OF SUPPORT FOR NATIONAL BIOMEDICAL RESEARCH
(Dollars in Millions)

	1950	1955	1960	1965	1968	1969	1970
Total	$161	$261	$845	$1,837	$2,440	$2,595	$2,660
Federal government	73	139	448	1,174	1,571	1,656	1,652
State and local government	—	5	23	55	69	72	73
Industry	51	62	253	450	615	675	740
Private support	37	55	121	158	185	192	195

Source· NIH-OPPE, Office of Resources Analysis.

TABLE 4

EXPENDITURES FOR NATIONAL HEALTH CARE AND NATIONAL BIOMEDICAL RESEARCH
(Dollars in Millions)

Years	NHC Expenditures	NBR Expenditures	NBR as % of NHC
1970	$—	$2,660	—
1969	60,312	2,595	4 3
1968	53,869	2,440	4.5
1967	48,193	2,266	4.7
1966	42,286	2,053	4.9
1965	38,912	1,837	4.7
1964	35,648	1,652	4.6
1963	32,581	1,486	4.6
1962	30,187	1,290	4.3
1961	28,031	1,045	3.7
1960	26,367	845	3.2

Source· NIH-OPPE, Office of Resources Analysis

TABLE 5

NIH RESEARCH GRANTS BY KIND OF PROGRAM, FISCAL YEARS 1967–1970*
(Dollars in Thousands)

Kind of Program	FY 1967	FY 1968	FY 1969	FY 1970	
				Amount	Percent
Total	*$598,056*	*$626,018*	*$627,581*	*$602,153*	*100.0*
Research projects	*391,919*	*395,642*	*384,725*	*359,156*	*59 6*
Traditional	376,091	379,089	366,029	341,318	56.7
Chemotherapy and psychopharmacology	7,143	6,725	8,123	8,094	1.3
U.S.—Japan cooperative medical program	3,020	3,864	4,833	4,795	0.8
Internat. centers for medical research and training	2,360	2,264	2,294	2,070	0 3
Nursing	1,579	1,802	2,011	1,887	0.3
Conferences	1,042	1,203	1,059	752	0.1
Other	683	695	378	240	†
Program projects and centers	*154,438*	*170,702*	*182,155*	*185,320*	*30.8*
Research program projects	70,136	82,966	92,096	95,856	15.9
General clinical research centers	28,610	30,911	35,004	35,004	5 8
Categorical clinical research centers	24,899	21,217	19,255	19,072	3.2
Animal resources	11,902	15,042	14,537	13,791	2.3
Special research resources	10,758	10,529	10,494	9,867	1.6
Pharmacology-toxicology centers	2,608	3,253	3,969	4,374	0.7
Dental research institute program	2,996	3,000	3,000	3,400	0 6
Environmental health centers	2,529	3,000	2,993	2,850	0.5
Outpatient clinical research program	—	784	807	1,106	0.2
General support—research related	*51,700*	*59,674*	*60,700*	*57,677*	*9.6*
General research support	41,700	48,174	48,200	45,802	7.6
Biomedical sciences support	6,000	7,500	7,500	7,125	1 2
Health sciences advancement	4,000	4,000	5,000	4,750	0 8

* Includes BEMT and NLM for all years.

† Less than 0 05 percent.

Source NIH-DRG (National Institutes of Health–Division of Research Grants), Statistics and Analysis Branch, October 21, 1970.

TABLE 6

NIH RESEARCH GRANTS BY KIND OF RECIPIENT INSTITUTION, FISCAL YEARS 1968–1970*
(Dollars in Millions)

Kind of Recipient Institution	1968			1969			1970†
	Number of Institutions‡	Number of Grants	Amount	Number of Institutions‡	Number of Grants	Amount	Amount
Total	*1,044*	*13,121*	*$626 0*	*953*	*12,435*	*$627.6*	*$602 1*
Higher education	371	10,506	493.8	345	10,133	499.3	481.7
Medical schools		(6,291)	(317.3)		(6,019)	(322 4)	
Research institutes	120	685	51 5	128	664	51.1	46 1
Hospitals§	198	1,224	63.4	190	1,140	63 5	64.1
Graduate training centers	1	4	0.1	2	3	0.1	—
Patient centers	12	32	2.2	11	26	2.2	2 3
Associations, etc.	49	86	2 5	40	71	2.2	1 9
Government units	27	56	3.3	21	45	2.6	2.4
Other domestic	24	34	1.9	22	29	2 0	0.6
Foreign	242	494	7.1	194	324	4.6	3.0

* Includes general support grants that are research-related and research resources grants.

† Contains all comparable data available as of October 21, 1970

‡ The count of institutions considers each branch separately.

§ Independent hospitals and those owned by institutions not classified as "higher education" or "research institutes." Excludes foreign hospitals.

Source NIH DRG, Statistics and Analysis Branch.

TABLE 7

NIH RESEARCH TRAINING AND EDUCATION AWARDS,
FISCAL YEARS 1967–1969
(Dollars in Thousands)

	FY 1967	FY 1968	FY 1969
Research training	$159,342	$162,412	$171,700
Research training grants	133,129	133,766	140,799
Fellowships and traineeships	26,213	28,646	30,901
Education grants	77,183	103,711	137,548
Medical schools	23,260	32,546	50,177
All other	53,923	71,165	87,371

Source· NIH-DRG, Statistics and Analysis Branch

Appendix C

Members of the *Ad Hoc* Biomedical Research Policy Committee, Council of Academic Societies, AAMC

LOUIS G WELT, M D , *chairman of Committee.* Chairman, Department of Medicine, University of North Carolina School of Medicine

W GERALD AUSTEN, M D , chairman, Department of Surgery, Massachusetts General Hospital

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ASSOCIATION OF AMERICAN MEDICAL COLLEGES

POSITION

on the

CARNEGIE COMMISSION REPORT
"HIGHER EDUCATION AND THE NATION'S HEALTH"

Revised
June 1971

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

MEMORANDUM #71-25 June 23, 1971

TO: CAS, COD, COTH

FROM: John A. D. Cooper, M.D., President

SUBJECT: CARNEGIE COMMISSION REPORT - AAMC ANALYSIS

The Carnegie Commission Report, "Higher Education and the Nation's Health: Policies for Medical and Dental Education," was released to the public during the AAMC Annual Meeting. On behalf of the Association, I reviewed the report in detail and made a public statement acknowledging substantial agreement with the report and its major objectives, though identifying some areas of disagreement.

The report and our analysis have now been reviewed by the various constituent bodies of the AAMC. The attached document has been revised to incorporate recommendations received from the membership, and is forwarded to you to serve as a resource document as it identifies the Association's position on a number of issues relevant to your sphere of interest and activity.

INTRODUCTION

The Carnegie Commission Report, "Higher Education and the Nation's Health: Policies for Medical and Dental Education," has most cogently and consisely presented the evidence, paradox, and dilemma of a health care crisis in the most affluent country in the world! We are grateful for the insight demonstrated in the report by this independent group, and are in agreement with the roles assigned by the Commission to the various segments concerned with health care, education of health professionals, and biomedical research. As these are also the main areas of concern of the Association and its members, we would like to make additional comments on some of the issues and specific recommendations contained in the report; for this purpose we have organized our remarks under nine major headings and have included a comparative summary of goals.

I. HEALTH CARE CRISIS

The Commission lists five interrelated and overlapping factors characterizing the health care crisis (page 22)*: unmet needs for health care; rising expectations of the population for universal access to care; critical shortages in, and inefficient utilization of, health manpower; ineffective financing; and rapidly rising costs. They further state that: Americans deserve and can afford better health care (page 1); as the nation faces the 1970's, shortcomings in the system of delivery of health care in the world's most affluent society must have high priority among issues calling for attention and decisive action (page 13).

The AAMC concurs with these conclusions of the Commission and has made public statements on all of them. The Association has taken an official position supporting universal health insurance as a necessary component for eliminating arbitrary financial barriers to health care for those not now adequately served while pointing out that dollars alone will not guarantee access and availability of care. We further agree that better health care should rank high in the Nation's priorities and that given our affluence we "deserve and can afford better health care."

However, we question whether better health care has really yet reached the level of a high national priority (page 1). The lack of a genuine commitment by the Federal Government to better health care programs is evident. The failure to include better health or better health care as a national goal in the President's Staff Report on National Goals, and the level of support requested by the Administration, or appropriated by the Congress, for programs to improve health and provide better health care, for education of health professionals and to advance knowledge through biomedical research, suggests that the Federal Government has not given clear evidence of a high national priority for health care.

In our opinion, there is ample evidence that the benefits from our high level of medical competence and the fruits of biomedical research are not available in sufficient quantity and with equity to all citizens.

*Throughout this analysis, page numbers in parentheses will refer to page numbers in the Carnegie Commission report.

II. IMPROVING THE NATION'S HEALTH

We readily appreciate the Commission's decision to concern itself primarily with the education of health manpower (page 23), but nonetheless feel that all the principal factors involved in improving the health of a people must be brought out. The advancement of the nation's health requires more than better health care. The state of health depends upon:

The Environment and Quality of Life. Health is related to the quality of a man's life and the environment in which he lives and works. Optimum health cannot be achieved without adequate pure water and safe food and clean air to breathe. Further, the National Commission on Community Health Services observes:

> "It (also) means assuring hygienic housing to provide space for adequate privacy and family availability, for places of rest and quiet and places for activity and recreation. It means assuring an external milieu for man designed to stimulate his greatest growth potential."
>
> ("Health is a Community Affair," National Commission of Community Health Services, Harvard University Press, Cambridge, Massachusetts, 1967)

Attitudes, Understanding, and Behavior. Health also depends on the mores and habits of man; his dietary habits, exercise patterns, taboos, and superstitions can be influenced by education. Health education is an important change agent which deserves more serious attention in modifying man's health-related attitudes and behavior. Thus, health education is a crucial element of comprehensive health care.

Genetic Heritage. Health also depends on man's heritage and his genetic make-up. To achieve optimal health, we must develop more effective understanding of the genetic basis of health and disease.

Health Care. This is the principal topic considered in the report in terms of the relationships to and implications for academic institutions, and forms the basis for most of our following remarks.

Research. Though research is rightly a part of health care, we feel it is necessary to consider independently the important contributions of biomedical research to the improvement of the nation's health. Thus, in our later remarks we also deal with research under a separate heading. We believe that only through a better understanding of health and disease through research can we institute effective preventive measures and convert empirical and palliative medicine into definitive and effective intervention.

III. COMPONENTS OF BETTER HEALTH CARE

Expanded Health Manpower. The Association has long argued for the need of more health manpower. In the 1950's it was one of the few voices recommending an expansion of education for health professionals and undertook a vigorous campaign to establish new medical schools and expand existing schools. The substantial increase in entering class size since the middle 1960's in spite of inadequate financial support to the academic medical centers is largely the result of this effort.

The Association has formally adopted the recommendations of its Committee on Expansion of Medical Education for a substantial increase in the entering class size by the middle 1970's. The Bicentennial Program for the Expansion of Medical Education recommends an expansion of entering class size to 15,070 by 1976, a figure not significantly different from that proposed by the Commission (page 44). Both the AAMC Committee and the Carnegie Commission make the point that it is difficult under the present circumstances of health care to make a meaningful assessment of physician need but that an evident shortage exists and the increases proposed are both a necessary and feasible response.

As noted in the Commission report, some of our member institutions have already undertaken the establishment of programs to train physicians' assistants. Additionally, a task force of the Association has addressed itself to the responsibility of AAMC institutions for the training of such personnel. Presently the Liaison Committee on Medical Education, the joint accreditation body of the AAMC and the American Medical Association, has appointed another task force to clarify the issue sufficiently for presentation to the governing bodies of the two organizations for action and implementation. Thus, the Association agrees with the Commission that the university health science centers should take leading roles in the development of allied personnel (page 91). We also agree with the position outlined by the Commission relevant to the development of education programs for health professionals in comprehensive and community colleges (pages 91 & 96), but stress the need for consideration of financial support for such endeavors.

With regard to "better manpower," the Association and its members have been major factors in improving the quality of health professionals. They concurred in and implemented the recommendations in the Flexner report that brought the medical schools into the university and introduced biomedical science into the educational program. They believe that the basic Flexner concept of rooting medical education in science is still valid, even though the scope of medical education must encompass health care delivery as stated in the Commission's report (page 5). Adequate scientific knowledge is still the hallmark of a properly trained physician. The Association is committed to the maintenance of quality in the face of pressures to increase rapidly the output of their schools. It is convinced that any other approach would derogate the intellectual integrity of medicine as a science-based profession and would thus be inimical to the best interests of society. We are, therefore, pleased to note that the Commission's recommendation that there be a diversity of school models specifically included preserving the Flexner model (page 5).

Expanded Health Care Facilities. The creation of nine additional academic health science centers is essentially in agreement with the recommendation of the Association's Bicentennial Program for the Expansion of Medical Education, which calls for twelve new schools. The new institutions would be located in areas not served by medical schools to provide the benefits derived from the presence of a school. The Association recommends, but does not insist, that medical schools be a part of a university, as does the Carnegie Commission by implication (page 47).

The relation of the area health centers to the academic health science centers furnishes a means to begin the regionalization of health care services. Many university health science centers have already entered into cooperative programs with surrounding communities. The Commission recommends an extension of this approach (page 58) which the Association agrees could provide an important way to improve health care, provide additional clinical training facilities, and avoid overlap and unnecessary duplication of resources.

Better Financing. We are in agreement with the Commission that better financing arrangements for the health care of the population is of paramount importance (page 22). Indeed, the Association adopted an official position recommended by our Committee on Health Insurance that better financing arrangements are critical to the improvement of health care delivery. The Commission did not, however, point out clearly enough that any financing system must accommodate the special aspects of patient care in the teaching setting, support and sustain the particular role of teaching hospitals in educating health manpower, and recognize their critical function in the process of health care.

Planning. It is gratifying that even though the Commission's report is concerned largely with health manpower, it recognized that just producing more manpower will not in itself correct all of the shortcomings of present health care. In fact, that action, taken alone, would improve least the care for the urban and rural poor, who have the greatest need. It would, therefore, serve to increase the disparity in health care between the "haves" and the "have nots." The Association has repeatedly gone on public record to point out the errors of the many proposed simplistic 'solutions' to the health care problem.

The Commission recommends the expansion of health manpower research programs (page 77) and the appointment of a National Health Manpower Commission (page 78). The Association agrees completely with the need to expand studies in health manpower. It believes that equally important are studies, innovation, and demonstration in health care systems. We would have preferred, therefore, that the Carnegie Commission was more explicit in proposing a rational and effective mechanism for planning in the health field on a continuing basis.

The Association is convinced that the market place cannot provide the necessary control for the number of health professionals with sufficient speed. The lag time in the feedback and the complexities and span of education for health professionals makes this an ineffective and costly method. Some responsible and authoritative body must access and project the need for the number of types of health professionals on a rational basis, including the number of the various specialists. There must be an effective way in which the recommendations of this body can influence the educational programs. It is obvious that assessment and projection of need will be heavily influenced by the nature of the system in which health care is to be delivered.

The proposed expansion of the AAMC/AMA Liaison Committee on Medical Education with the ultimate creation of a Commission on Health Professional Education could serve in this role. Through involvement of appropriate organizations and government representatives, a mechanism might be provided for implementation of the Carnegie Commission's recommendations. The newly created Institute of Medicine of the National Academy of Sciences might also plan an important role.

Although the Federal Government has not really developed a national planning role, with its greater involvement in the financing of health care delivery and the education of health professionals this may change.

The Association is on record in favor of the establishment of a Council of Health Advisors to the President that could increase the effectiveness of growing Federal expenditures in health in the Department of Health, Education, and Welfare, the Department of Labor, the Department of Defense, and the Veterans' Administration. We do not believe that the Council should be the single national planning body, but it could work with a non-governmental organization to relate Federal programs better to the civilian needs. In the longer run, it seems both desirable and necessary to consider a complete restructuring of our policy development framework for health in the Executive branch. The national importance of these issues is increasingly incompatible with the present subordinate location of health within the Department of Health, Education, and Welfare.

The Carnegie Commission also recommends the strengthening of existing Federal legislation for regional, state, and local health planning to encompass regional planning of all health manpower education and health care facilities (page 76). The Association sees highly trained health professionals as national rather than regional, state, or local resources. Migration patterns, especially for physicians, substantiate this view. For this reason the Association believes that planning in relation to the educational programs in academic medical centers must be related to national as well as state and local purposes, though allied professional training might fit logically in regional planning. Since the health care activities of the academic medical centers are more related to the geographical area, closer coordination with regional,

state, and local planning groups is more appropriate in this area. However, due consideration must be given in extending university health care activities to the particular needs of clinical training and educational programs of the centers.

The Association believes that reorganization aimed toward a program with the academic health science center as an integral part of interrelated facilities is essential to effective and efficient use of scarce resources. The Comprehensive Health Planning program can serve to provide consumer and provider input for identifying gaps in service and avoiding duplication and overlap of services. The Regional Medical Programs can serve as the mechanism for accomplishing the regionalization and integration required to meet the needs identified. However, to accomplish this, the mission of the RMP and the operation of its programs must be redirected.

The ultimate institutional framework in which health care will be delivered has not yet been designed. It will have to encompass all of the health care services within an appropriate geographical boundary and provide the means by which the accessibility, quantity, quality, and cost of cure can be determined by an appropriate interaction of providers and consumers.

IV. UNDERGRADUATE MEDICAL EDUCATION

Program Acceleration. It should be emphasized that the modifications in undergraduate education proposed must not involve a sacrifice in the adequacy and thoroughness of the educational preparation for the M.D. degree. Additionally, the Association feels that emphasis should be on flexibility in regard to the educational programs instead of the arbitrary assignment of a specific time span for the educational process; we must not move from one inflexible model to another equally inflexible. Actually, it would seem more appropriate to consider the time span from high school graduation to 'practicing M.D.' in our planning rather than the present system of concentration on three or four years of undergraduate medical education. This would also allow for greater flexibility in adapting the educational program to the individual's knowledge, goals, and abilities.

Tha assumption that sizeable monetary savings will be recognized by shifting from a four-year to a three-year program (pages 10 & 43) does not take into consideration the increased facilties required for increased class sizes - both in the school and clinical settings.

Curriculum Integration. Another area of concern relates to the recommendation that basic sciences be shifted to main university campuses (page 52). While we recognize that experiments of this kind are already in progress and that strong arguments can be made for a greater integration of premedical and medical education - a point we ourselves make - there is real question as to what liabilities will be incurred in separating basic science departments from their clinical colleagues. In the past, close collaboration and interaction between basic scientists and clinicians

have produced significant advances in teaching, research, and therapy. Though we are not opposed to such a shift for some schools, we do not feel that the case in favor of this shift is strong enough to warrant broad recommendation. The experiment under way should provide additional insight.

We are in agreement with the Commission's recommendation that the establishment of free-standing or autonomous two year schools not leading to the M.D. degree within the same university system be discouraged (page 53). In developing an earlier position statement in this matter, which urges institutions contemplating the development of an undergraduate medical education program to consider the totality of the program including the M.D. degree and entrance into residency programs, the Association felt that the difficulties involved in students transferring for the last two years were too formidable for the practice to be encouraged.

V. GRADUATE MEDICAL EDUCATION

Though the Association is in general agreement with the recommendations of the Carnegie Commission relevant to graduate education, here again we would like to see program flexibility stressed rather than a specific time frame. Additionally, we feel that a thorough study to assess the schools' fiscal requirements in this matter is necessary. A better mechanism for financing graduate medical education than is now available could then be proposed.

The Association is presently considering the report of its task force on graduate medical education which discusses the implications of corporate responsibility for graduate education. The Assembly of the Association is expected to make a policy statement on the issue later this year.

VI. CONTINUING EDUCATION AND RECERTIFICATION

The academic health science centers are the logical institutions to direct continuing education of health professionals. If they have not assumed their proper role, it is probably due to lack of support for the activity and the ineffectiveness of present approaches to this difficult area of education.

Meaningful continuing education remains a problem of concern to the academic health science centers, the profession, and the consumer. Present programs are for the most part episodic rather than continuing. They do not provide education in the context of the physician's patients in the way that medical students learn in the health care setting.

Continuing education will probably not be effective until there can be an ongoing assessment of the care provided by a physician and an identification of the areas in which his behavior must be changed. The

problem-oriented record may provide such an opportunity. If this kind of approach can be instituted for the practicing community in an effective organization framework for health care, the centers might be stimulated to become more involved in continuing education.

The Assocation agrees that some method must be found to assure that physicians are capable of providing adequate care using current medical knowledge. However, re-examination may not be the best way in which to accomplish this goal. A properly organized health care system which used an auditable record, such as the problem-oriented record, would make it possible to carry out a continuing assessment of the physicians' performance in a more logical and accurate way than by a periodic examination. Furthermore, the areas in which physicians had deficiencies could be identified and incorporated into the continuing education program in the setting in which he provides health care.

VII. BIOMEDICAL RESEARCH

The Association is in agreement with the Committee on Research in the Life Sciences of the Committee on Science and Public Policy of the National Academy of Sciences that the current biomedical research level is below optimum:

> "From the best estimate we can make, in the current year (fiscal year 1970) appropriations for research, per se, are approximately 20 percent less than required to ensure that the Nation's truly qualified academic life scientists are fully and usefully engaged."

Additionally, we believe that the level and growth of biomedical research should be determined by more substantive considerations that bear upon the relationship of research to important national objectives. Federal support to biomedical research should be derived from three basic factors:

--the level of research support necessary to sustain the integral relationship of research to undergraduate and graduate education in the health professions;

--the additional level of scientific effort required to maintain a full and vigorous research engagement at the frontier of the biomedical sciences;

--the further scientifc effort required to exploit fully specific scientific opportunities to control disease and to solve the problems surrounding the organization and delivery of health services and medical care.

We agree with the Commission on the need for research in medical education and the delivery of health care and, indeed, the university health science centers have already increased their efforts in this field by ten-fold in the past two years. However, these programs should be funded in their own right, and not by transfer of funds from the support of biomedical research.

The appropriate level of institutional grants for research depends upon the amount of support for the other activities of the university health science centers. If adequate allocations are made under other institutional grants, it is possible that the basic level of research required to meet the needs of the educational programs could be provided by this mechanism.

VIII. STUDENT ASSISTANCE

The Association strongly supports the concept of non-refundable grants for students whose financial need can be established. It concurs in the view that the national interest is best served if all students have available adequate financial resources to permit them to achieve the highest level of education to which they aspire and can achieve. Grants are essential to the meeting of this objective. We feel that the views held by some, including highly placed officials in the Administration, that every student should pay for the entire costs of education because of the higher income it permits is not the way to develop the most precious national resource of the nation - an educated citizenry.

We agree on the importance of developing a more rational basis for establishing need and the Association is expanding its efforts in this direction. We do not believe that need can be determined from a simple assessment of gross family income and we object to the regulations instituted by the National Institutes of Health restricting grants to students from families with less than $10,000 annual income.

Loans. The Association believes there should be alternatives in addition to the Educational Opportunity Bank for providing loans to medical students recommended by the Commission (page 66). The present method of providing loan funds through the academic institution under the Health Professions Educational Assistance program should be continued. Loan funds should be available at a level consistent with the requests from the institutions and the attempts being made to broaden the socio-economic base of medical school classes. The Association views sole dependence upon a guaranteed loan program as inappropriate to, and ineffective for, medical students and contrary to the national interest in increasing the number of physicians.

National Health Service Corps. The Commission has recommended the development of a voluntary National Health Service Corps and has included certain financial considerations as incentive for participation in the Corps (page 66). The Association supports the concept of a National Health Service Corps and has testified

favorably in the Congress on bills to establish such a Corps. However, we are concerned about the form and structure of the Corps and believe that it should not be restricted to physicians and dentists, but should incorporate all health professionals. Further, all members of the Corps should receive equal benefits from service in the Corps, including draft exemption and excuse from loan repayment. The Association believes that the Secretary of Health, Education, and Welfare, with appropriate advice, should be able to designate directly areas and locations in which members of the Corps are needed.

Tuition Changes. The Association does not believe that the Commission's recommendation regarding a uniform national tuition policy (page 68) can be implemented and is unnecessary if the Educational Opportunity Bank is not established. The ability of students to pay for their total educational costs will exert a control over tuition costs, particularly if there are larger numbers of students from low-income families. It is not anticipated that grants and loans will ever be provided in sufficient amounts to permit tuition to be raised without regard to the student's ability to pay.

IX. FINANCIAL SUPPORT - INSTITUTIONS

Cost of Instruction Supplements. The Association strongly supports the concept of a capitation grant to provide "first dollar in" over proposals to provide project grants which would furnish "last dollar in." The capitation route would be easier to administer and would preserve the freedom of action necessary for an educational institution. It would allay the financial stringencies under which most institutions are operating and drastically reduce the number seeking "disaster aid."

The Executive Council and the Assembly of the Association have adopted a Bicentennial Program for the Expansion of Medical Education which agrees in principle but differs in some detail from the Carnegie Commission recommendations (page 69). The Association's plan recommends an educational allowance of $5,000 per student with an annual increase to cover inflationary and other rising costs to $9,000 by 1980. For expansion of at least fifteen students, $9,000 a year per student is recommended with no escalation, under the assumption that after start-up costs are met, the regular subsidy is adequate.

The Association believes that its formulation is preferable to that made by the Carnegie Commission. It does not see the need for the other stipulations which are either difficult to enforce or covered by laws now in force. For example, the use of cost of education supplements only for instructional costs depends upon a definition of what constitutes instruction - an unresolved problem.

The Association also has warned that capitation support would accomplish little if research funds were not adequate and the institutions were not fully reimbursed for health care. Some provisions must also be provided

for the few schools whose financial base is now so inadequate that they cannot maintain educational programs of the required quality, even with a capitation grant.

Incentives for Curriculum Reform. The Association agrees with the concept of providing funds to stimulate and make possible curriculum innovations, but believes this can be better accomplished through project grants than through the capitation mechanism.

Construction. The Association concurs with the recommendation to provide the major support for new construction, remodeling and renovation through grants. It opposes plans to shift all construction support to loans, even with interest subsidy. Many public institutions are prevented by law from borrowing money. In addition, the financial status of academic health science centers make it difficult, if not impossible, to make the required payments for interest and principal. The loan plan only delays costs and not decrease but actually increase the total funds required.

The availability of loan funds for 25 percent of the cost would, however, be useful to those schools that can take advantage of the program. It would assist private institutions that are finding increasing difficulty in obtaining matching funds. The level of support involved would make it easier to pay interest and capital out of the annual budget.

The Association believes that the provision in its Bicentennial Program for the Expansion of Medical Education to provide a minimal level of construction support for schools undertaking expansion by a capitation formula is sound. This permits more rational planning and better assurance that the facilities required will be available when needed. However, other programs would be necessary to provide support for additional or other requirements on a project basis.

Start-up Grants. The availability of start-up funds has been an important consideration in the establishment of new academic health science centers, and this proposal by the Commission (page 73) would help solve this problem. Since start-up costs are always present, it would seem more logical to provide them to new schools on a capitation basis, as recommended by the Association in its Bicentennial Program for the Expansion of Medical Education. Since existing schools undertaking major expansion have similar initial costs, they should also receive "start-up" grants. The stipulations proposed by the Carnegie Commission on curriculum (page 73) might produce more rather than less regidity in devising new approaches.

Cost of Education for House Officers. The Commission recommends a cost-of-education allowance for house officers (page 70), and the Association agrees that institutions must have more funds to cover the costs of graduate education. Approximately half a billion dollars is currently involved in the support of educational programs for

house officers. A substantial portion of this money comes from patient fees, but the propriety of charging educational costs to patient care is being increasingly questioned. Universal health insurance would remove some of the objections, since the costs would be spread over the entire population and would not fall only upon those who were ill. This is a very complex matter and one that is very dependent on the method developed to pay for health care.

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SUMMARY GOALS

CARNEGIE COMMISSION	AAMC
Expansion of the functions of university health science centers so that they can play a central role in coordinating and guiding health manpower education and cooperating with other agencies in the development of improved health care delivery systems in their regions.	Studies, innovation, and demonstration in health care systems; mechanism for national health planning on a continuing basis.
Development and expansion of programs for physician's and dentist's associates and assistants.	Continued and expanded involvement of medical schools in development of allied health personnel.
Acceleration of medical and dental education, thereby achieving greater efficiency.	Greater flexibility of education programs to allow for individuals goals and abilities.
Integration of the curriculum, including such changes as consolidation of instruction in basic sciences on main university campuses, integration of preprofessional and professional education, and more carefully integrated coordinated programs of postgraduate training.	Curriculum innovations to better relate premedical, medical, and graduate medical education.
Changes in medical and dental education so that they are more responsive to the expressed needs of students and more concerned with problems of delivery of health care.	Expansion of teaching and clinical experiences to better incompass varied settings and systems of health care delivery.
A 50 percent increase in medical school entrant places (15,300 by '76).	15,070 medical school entrant places by 1976.
Initiation of nine new university health science centers.	Twelve new medical schools.
Positive policies to encourage the admission of women and members of minority groups to professional training in medicine and dentistry.	
A 20 percent increase in dental school entrant places.	N/A
Development of approximately 126 areas health education centers, affiliated with university health science centers.	Further extension of medical center programs into community settings.

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Statement on the Responsibility of Academic Medical Centers for Graduate Medical Education

A "Policy Statement on the Responsibility of Academic Medical Centers for Graduate Medical Education" was presented to the Assembly, having been approved by the Executive Council and considered by the three constituent Councils. Dr. Chapman presented two changes made by the Council of Deans as an amendment to the motion for approval. This amendment would insert the word "ultimately" in the first sentence and would delete the word "policy" from the title.

ACTION: On motion, seconded and carried, the Assembly approved the amendment proposed by the COD.

ACTION: On motion, seconded and carried, the Assembly approved the "Statement on the Responsibility of Academic Medical Centers for Graduate Medical Education." (copy of statement follows)

The Association of American Medical Colleges endorses the concept that graduate medical education ultimately should become a responsibility of academic medical centers. Through this endorsement the Association urges the faculties of academic medical centers to develop in conjunction with their parent universities and their teaching hospitals, programmatic plans for taking responsibility for graduate medical education in a manner analogous to presently established procedures for undergraduate medical education.

Assumption of this responsibility by academic medical center faculties means that the entire faculty will establish mechanisms to determine the general objectives and goals of its graduate programs and the nature of their teaching environment; review curricula and instructional plans for each specific program; arrange for evaluating graduate student progress periodically; and confirm student readiness to sit for examinations by appropriate specialty boards.

The Association encourages hospitals with extensive, multiple graduate education programs, which are not now affiliated with academic medical centers to develop their own internal procedures for student selection, specific program review and proficiency examinations. The accrediting agency is urged initially to accredit the entire graduate program of these hospitals. Ultimately, these institutions should either develop affiliations with degree-granting academic medical centers or seek academic recognition as free-standing graduate medical schools.

The Association urges that the Liaison Committee on Medical Education, the Residency Review Committees and the Specialty Boards establish procedures which will provide for adequate accreditation of an entire institution's graduate medical education program by one accrediting agency.

The Association further urges that the specialty boards continue to develop test instruments for measuring achievement of individual candidates that avoid superimposing rigid program requirements on the academic medical centers.

It is essential that all related components (including hospitals) of academic medical centers jointly develop appropriate financing for the program costs of graduate medical education.

Report of the Committee on the Financing of Medical Education

Dr. Sprague reported on the composition and activities of the Committee on the Financing of Medical Education. Charged with the responsibility for initiating and guiding AAMC studies in this area, the Committee hopes to eventually provide a body of data upon which future assessments of the various aspects of medical education can be based.

Structurally, the Committee has subdivided into three task forces. The Task Force on the Cost of Medical Education will consider the broad educational responsibilities of the school and its relationship to patient care. The Task Force on Biomedical Research will examine the financing of research, its fiscal relationship to other medical center functions, as well as the implication of national objectives. The Task Force on Construction will identify existing facility deficiencies as well as the needs of new, developing, and expanding schools.

Activities to date center around the NIH-sponsored cost allocation study. In addition to offering guidance to the AAMC super-

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Implications of Academic Medical Centers Taking Responsibility For Graduate Medical Education

Report of the Ad Hoc Committee on Graduate Medical Education
of the Association of American Medical Colleges
October 1971

Implications of Academic Medical Centers Taking Responsibility for Graduate Medical Education

Following is the text of the report by the AAMC Ad Hoc Committee on Graduate Medical Education. The Committee was chaired by Thomas D. Kinney, M.D., Duke University. The members of the Committee are listed at the end of this report. A policy statement based on the report was adopted by the Association of American Medical Colleges Assembly October 30, 1971, during the Annual Meeting at Washington, D.C.

During the years since the end of World War II, the responsibilities of the academic medical center for all forms of clinical education and training have grown. Particularly, education and training programs for postdoctoral clinical students have become a major activity of these centers. Yet the relation of such programs to regulatory agencies independent of academic medical centers remains unchanged. Simultaneously problems of financing these programs have become much more involved. The resulting fragmentation of authority and responsibility has been deplored repeatedly. In 1965 the Association of American Medical Colleges (AAMC), in its report, *Planning for Medical Progress Through Education*, called for broadened university responsibility for graduate medical education (1). The American Medical Association (AMA) has also been deeply concerned with these developments. The two organizations, working in conjunction through the Liaison Committee on Medical Education, have determined to become involved in graduate medical education, initially through careful reexamination of procedures for accreditation of these programs.

In 1969 the AAMC published a report on *The Role of the University in Graduate Medical Education*, advocating less fragmentation of authority in this area and the focusing of responsibility in the university (2). Because of the major responsibility they are taking in graduate medical education, the constituent academic medical centers of the AAMC authorized this study of the implications of their responsibility for graduate medical education.

Definition

The study is directed toward the implications of the assumption by the academic center and its faculty of the total responsibilities and authority of an academic institution for all its students and programs in medical education. This implies that the faculty would collectively assume the responsibility for the education of clinical graduate students (interns, residents, and clinical fellows) in all departments and that the education of these students would no longer be the sole responsibility of groups of faculty oriented to individual departments or single areas of specialty practice.

(The use of the word "student" in this document requires definition. The individuals discussed here have received

their doctorates and are engaged in an intensive postdoctoral program of training to become specialists in one of the areas of medical practice. They basically are students but usually have important commitments to medical care and teaching. They are, therefore, in some sense practicing physicians and faculty members. There is usually no degree goal, but certification by a specialty board or public acceptance of specialty status are the rewards of this training. In view of these considerations, no single word accurately describes persons in this role; with these reservations, the word "student" will be used in this discussion.)

Advantages

Among the advantages inherent in vesting responsibility for graduate medical education in the entire medical center faculty rather than continuing departmental fragmentation are the following:

1. Easier implementation of the continuum concept in medical education.
2. More effective adaptation of programs to individual student's rates of progress through the educational process.
3. Fostering multiple methods for conducting graduate education and thereby enhancing innovation.
4. Enrichment of graduate medical education by bringing to it more of the resources of the university and its faculties.
5. Promoting the introduction of greater efficiency and flexibility in the use of faculty and facilities.
6. Enhancing the principle of determination over educational programs by the individual academic centers.
7. Promotion of a comprehensive pattern of medical training and practice.

Fragmentation of Responsibility

A further significant fact is that, despite often repeated disclaimers, specialty board certification does represent a second degree and is the significant license for almost all American physicians. The evidence for this allegation is all around us but is found most importantly in the attitudes and behavior of the persons in practice and of those who make hospital appointments and decide on professional reward systems, both pecuniary and nonpecuniary.

This state of affairs is a significant departure from the historical precedents for licensure to practice. In the usual formulation, civil government, because of its obligation to protect the people, grants to agencies which it controls the authority and responsibility to decide who shall be admitted to the practice of a profession. Such agencies characteristically have as their primary charge protection of the best interests of the people. In one fashion or another, through either appointment or election, in the United States they are answerable to state governments. This is not true of specialty boards, if they are indeed *de facto* licensing agencies. In current practice they are primarily responsible to their respective colleagues in their specialties. This is far removed from usually accepted concepts of the nature of civil license.

Graduate clinical training or graduate medical education is now carried out in highly variable clinical settings; and since clinical graduate students are frequently licensed physicians who are primarily in a learning role, the status of these students is often ambiguous. Classically, interns and residents are considered employees of hospitals, although medical schools or other professional groups may contribute to their stipends. Their status as hospital employees versus members of the academic medical center student body or staff often leads to ambiguities.

In the majority of instances, house

officers are pursuing specialty board certification or publicly ascertainable qualification in one of the medical specialties. The duration, content, progress through training, and determination of eligibility for admission to the specialty board examinations are now determined largely by individual boards. Such boards are characteristically private, not-for-profit organizations with substantial autonomy. Academic institutions or hospitals have no direct influence on their policies or actions.

All internships are approved by the Internship Committee of the Council on Medical Education of the AMA. All residency programs are accredited by the residency review committees of the AMA, with the exception of pathology programs, which are examined and accredited by the American Board of Pathology. The residency review committees are made up of representatives appointed by the Council on Medical Education of the AMA from nominations submitted by the appropriate boards and colleges or academies. The residency review committees are autonomous except for matters of policy and do not have to report back to their parent organizations for ratification of their decisions. The graduate education section of the Council on Medical Education of the AMA provides secretarial assistance and administrative support for the operation of all residency review committees.

The concern of the Council on Medical Education for all facets of medical education is a matter of historical record. But in the area of graduate education, the Council has essentially no direct authority over either the boards or the residency review committees since both function independently and autonomously. In practice, however, its influence is significant. It should be noted that the AMA has its roots in the practice of medicine, and its policies will inevitably and properly always be strongly influenced by current conceptions of the interests of practicing physicians, whose direct contact with education has either ended or become a secondary part of their professional activity.

The individual to whom the resident is responsible is his service chief, program director, or departmental head. Such an individual always has a major hospital appointment, and his authority over a clinical service, and hence over its residents, relates to his role in the hospital. He may or may not have a university connection of significance, ranging from major to only ceremonial. This service chief has direct responsibility for the content of the program in accord with the requirements of the specialty boards and the residency review committees. Although service chiefs may work closely with members of their own departments, insofar as content and process of residency education, such chiefs have a considerable autonomy within broad policies.

The medical school or university, through its faculty members and affiliated hospitals, sponsors and influences a large segment of graduate medical education and accordingly should be considered for a more formal role in its design and operation. It has a very real authority, through its influence over hospital policies and the appointments of service chiefs, but it may or may not have real operational responsibility.

In summary, control of graduate medical education is fragmented among the following settings:

1. Hospitals, which employ trainees and provide the classrooms and laboratories for their education.

2. Specialty boards, which determine duration and a portion of the content of training and act as *de facto* licensing agencies.

3. Residency review committees, which accredit on a programmatic basis.

4. Service chiefs, who on a programmatic basis determine the balance of content and all of the process of graduate medical education.

5. Medical schools and universities, which exert considerable authority through the individuals whom they appoint but accept little direct operational responsibility as institutions.

Attributes of Current System

Today's system has consistently and reliably produced specialists well equipped to care for the disease-related problems of their areas of medical practice. In terms of its goals, the system has been an acceptably successful, pragmatic solution, adaptable to the variety of conditions found in so large and diverse a nation as the United States. These are the major strengths of this pluralistic system. If its goal, the replication of highly categorized specialists, were now acceptable in terms of public need, its ambiguities would be tolerable.

The degree of specialization which has been brought about by advancing knowledge has resulted in the evolution of an inordinately complex structure for graduate medical education. It is this complexity which has created demands for considering a more holistic approach to the total duration and content of medical education. Assumption of responsibility for graduate medical education by the entire faculty of the academic medical center could help provide this.

Unification of Responsibility

In many ways the situation in graduate medical education today is not unlike that of undergraduate medical education 70 years ago. It is widely recognized that the medical school and its parent university have assumed responsibility for the total program of undergraduate medical education. This was the significant reform of 1890 to 1925. The issues facing graduate medical education in the 1970s contain many striking parallels, and the solution being explored here has many features of that which worked so well for undergraduate medical education two generations ago.

In the 1960s, medical schools began major undergraduate curricular revisions. These efforts to make undergraduate education more responsive to perceived public needs are generally based on the assumption that the undergraduate educational process is preparing students to enter into a period of postdoctoral training. This combination of predoctoral and postdoctoral education finally produces the polished professional clinician. It now appears that the professional schools have as large a stake in the postdoctoral educational process as they have in the predoctoral.

Academic Center Responsibility

The responsibility which would be assigned to the academic medical center faculties may be enumerated as follows:

1. Determining educational objective and goals.

2. Establishing policies for the allocation of resources and facilities of the entire medical center to permit realization of these goals.

3. Appointment of faculty.

4. Selecting students.

5. Determining content, process, and length of educational program.

6. Evaluating each student's progress.

7. Designating completion of program.

These responsibilities for graduate medical education would be vested in the academic medical center and then would be delegated to its medical faculty and

teaching hospitals which in turn would create a program of educational advancement protecting the rights of students while responding to the requirements of society.

The medical faculty would have a concern for creating an appropriate environment for graduate medical education. Faculties would be responsible for selecting their fellow faculty members and for approving the design of programs in graduate medical education, including concern for the processes used, the duration and content of learning, and the coordination and interrelation between various units of the faculty. As a faculty, the members would have a voice in the selection of students and be concerned for their quality and number. They would also be expected to institute procedures which would allow them to determine their students' achievement of an appropriate educational level and their readiness to take examinations for certification by the appropriate specialty boards.

Implications of Responsibility

So many agencies and people would be affected by pulling today's fragmented responsibilities together and assigning to academic medical centers both the responsibility and authority for the graduate medical education now carried out in their spheres of influence that the only way to analyze implications of these changes is to look at the various forces involved one at a time.

THE UNIVERSITY

Administrative, financial, and organizational relations existing between parent universities and their academic medical centers would not be appreciably altered by this change. Long-range changes could be expected, and these will be touched upon in the following sections.

THE MEDICAL SCHOOL FACULTY

There would need to be relatively little immediate change in the day-to-day climate of the clinical faculties of medical schools. More significant would be the slow but predictable and desirable increase of interaction with other faculties in the medical center and the university at large. There would also be greater coordination of educational activity within the clinical faculty. Presumably, there would be more effective integration of various units of the medical center, both medical and nonmedical; and this integration could be expected to produce different educational and patient care alignments. Possibly, the medical faculty might develop course work, a credit system, and examinations similar to those now operated for undergraduate education.

These organizational patterns would likely precipitate decisions about which aspects of specialty training should precede and which should follow the M.D. degree. These questions must be faced in any event, and the recognition of medical education as a continuum—the responsibility of a single unified faculty—would be a great advantage.

THE GRADUATE SCHOOL

Assignment of responsibility to the academic medical center within a university would raise a consideration regarding the appropriateness of involvement of the graduate school. Although it is conceivable that the graduate school could be the assigned area of such programs, graduate clinical education is so eminently the business of physicians that it makes little sense to locate it in a general university graduate school rather than retaining it in the medical center setting.

DEGREES

The issue of advanced and intermediate degrees in medicine is not trivial. Residents now get unimportant pieces of paper from hospitals (certificates of service) and an important piece of paper from specialty boards (certification of specialty status). The advanced clinical degree has not caught on in this country despite its trial, especially in Minnesota, and despite practices abroad. The envisioned arrangement would probably result in some formal recognition of the end of the graduate educational sequence. A degree pattern of some sort might emerge in time, probably in an uncoordinated fashion from school to school. As an obstacle to a new plan or organization, the degree issue need not be settled early. Any move to imperil the strength of the M.D. degree would be very strenuously resisted. The public has a firm impression of the meaning of the M.D. degree, and any change that might alter its significance should be considered with circumspection.

HOSPITALS

Here truly significant problems may emerge. The major educational program of a hospital would become the responsibility of an agency that in some instances would be external to the hospital and governed by a different board. This is a significant shift, and it can be expected that hospitals everywhere will analyze this implication with their own interests in mind, as is only proper. The realities of getting a group of community hospitals or a community and university hospital to organize a single unified educational program will call for intensive bargaining. It can be predicted that there will be orders of difficulty, from least in a situation in which hospital and medical school are jointly owned and administered by a single board to most where hospital ownership, operation, financing, and location are all separate. As far as financing goes, there would be few differences from today's practices. Organizationally, there might be shifts in the influence of single departments. Operationally, this might emerge as another force toward more comprehensive medical care. In terms of accreditation or approval, the hospital educational program would be approved as a unit. This would mean the number, duration, type of training, and coordination of training offered would be returned to the local control of the joint medical school–hospital faculty.

NONAFFILIATED HOSPITALS

Although the academic medical center initially would assume responsibility for the graduate education of physicians in only its affiliated hospitals, ultimately the need for the center's influence on graduate programs in nonaffiliated hospitals would be necessary for several reasons:

1. A considerable segment of all graduate education is now conducted in nonaffiliated hospitals.

2. Academic medical centers and their affiliated hospitals cannot educate effectively the total number and type of physicians required.

The relationship created might vary from one institution to another depending upon the educational capability of the nonaffiliated hospital, the financial support required, and the desire of the nonaffiliated hospital to participate in an educational program designed and, in large measure, directed by a faculty not totally congruous with its existing medical staff. All such arrangements for cooperative or integrated efforts would be com-

pletely voluntary and obviously to the advantage of both institutions.

THE STUDENT

At first, there would be very few changes for the people in training. However, more ready access to other departments, readier availability of the resources of other units of the medical center and the university, and better coordination of training could be expected to lead to stronger, shorter, and more varied educational programs. These would all eventually work to the advantage of the students, and this must be seen as one of the major benefits expected from the change. Admission to, progress through, and certification of completion of training would become more formal, less casual, and more subject to regular academic procedures.

FINANCING

There is obviously a cost involved in graduate medical education. For years this cost has been absorbed by residents through deferral of earnings, by the clinical faculties through donation of their time, and by the patients through direct charges for hospital services. This system is now challenged by everyone: the residents in their demand for higher salaries, the faculties through the emergence of the full-time system, and the patients who through large third-party payers are challenging the inclusion of any educational costs in charges to patients.

The organization of graduate clinical faculties as a whole rather than solely as departments would have no direct effect on these issues, except for their probable clarification. Expenses should not increase except as academic functions increase. The emerging acceptance of the need to fund service functions by beneficiaries of these services will shortly bring to a head responsibility for funding of the educational component of clinical graduate training. The academic medical center will be unable to assume this burden unless it in turn is financed. The general trend to spread costs of higher education widely through society by any of a number of mechanisms is seen as the only way to handle this issue.

SPECIALTY BOARDS

The role of the specialty boards would change primarily toward their becoming certifying agencies not exercising direct control over duration or content of training. This again also seems to be a change which in one form or another is clearly on us. The boards would continue to have a major role in graduate medical education through the establishment of achievement criteria, the design and provision of examinations, and the certifying of candidates who complete them successfully.

EXTERNAL ACCREDITING AGENCIES

The Liaison Committee on Medical Education, the Council on Medical Education of the AMA, residency review committees, and the Joint Commission on Hospital Accreditation are examples of external accrediting agencies. This function must be carried out in order to protect the public. One of the fundamentals surrounding this proposed assumption of responsibility by academic medical centers is that the centers, in matters pertaining to accreditation, would relate to a single external agency and be accredited by it. The proposed Commission on Medical Education is an effort to create such an agency at this time. Its emergence remains in doubt; but if these changes come about, the academic medical centers would need and would indeed demand the organization of a single,

external accrediting and standard-maintaining body rather than being answerable to many as they are today. The Liaison Committee on Medical Education is already taking some steps to assure greater responsibility for accreditation in graduate medical education through expanding and broadening its membership.

PATIENTS AND CONSUMERS

No immediate effect on patients and consumers can be predicted at this time. However, since the *raison d'etre* of the whole health care and health education system is to serve the people, the vitality of all phases of medical education must eventually provide individuals and services for the people. Public input is desirable and has been proposed at a national level. The degree and the mechanisms for public input should be locally determined by each medical center.

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