

The Health of Clinical Investigation beyond Atlantic City

PRESIDENTIAL ADDRESS BEFORE THE 68TH ANNUAL MEETING
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The custom of presidential addresses before this society has been described by some of my predecessors as "barbaric," "expected," and "without constitutional basis." Despite these protestations, I have identified two distinct advantages that accrue to the speaker: It is an opportunity to speak formally on serious issues without the fear of immediate action being taken; and, perhaps of greater personal utility, this is a once-in-a-lifetime opportunity for an individual to publish exactly what he or she pleases in *The Journal of Clinical Investigation*.

With the initiation of this, the 68th Annual Meeting of The American Society for Clinical Investigation, we are bringing to an end the long-standing tradition of meeting regularly in these halls that abut the boardwalk of Atlantic City, New Jersey. The Society first met in this city in the spring of 1911, and by 1923 Atlantic City was established as the site of our annual meeting, in conjunction with that of The Association of American Physicians. Thus, for more than a half a century, this annual rite of clinical investigation, in recent years a multi-society function, has been known as the Atlantic City Meetings. Beginning in 1977 we will join our sister societies, The Association of American Physicians and The American Federation for Clinical Research, in an annual sojourn around the continent—perhaps in search of a new home that can provide not only formal meeting halls adequate for our combined expansive membership, but also replacements for the boardwalk and those other gathering spots which have served as extensions of our formal sessions and contributed so importantly to the

success and scientific quality of our annual meetings for the past three generations of clinical research.

This change in venue warrants some brief reflection of the past history of our society as it has evolved during our 54 consecutive meetings in this city. The scientific contributions of our members and the explosive development in both quantity and quality of academic medicine during the years since The American Society for Clinical Investigation was founded are matters of record and would gratify the founders of the Society beyond their expectations. It would be presumptuous indeed to attempt a review of these accomplishments in detail. As stated by J. H. Austin in a history of The American Society for Clinical Investigation compiled in 1949, "no one can compare the first presidential address with the record of the Society's achievements and not recognize the outstanding success with which our society has served the purposes for which it was founded" (1). Our scientific program this year continues to bear testimony to this success.

Instead, I have chosen to review briefly the issues the Society has faced during its history, as recorded in the minutes of our past meetings, in an attempt to focus on some major unsolved problems that we will continue to encounter in years ahead. The past topics of concern to the Society can be divided into two general categories: intrinsic issues that deal with the operation and policies of the Society, the conduct of clinical research, and the institutions in which clinical research takes place; and extrinsic issues that include economic, political, and

social forces arising outside the Society or academic institution but which directly or indirectly influence clinical research or the institutions in which it occurs. Most of the subject matter has been of an internal nature, issues intrinsic to our goals or our functions as a scientific society.

Intrinsic issues. These include the purpose of the Society; guidelines for clinical research; training the investigator; scope of clinical investigation; membership size and standards; structure of annual meeting; and the medical school and research.

There have been eloquent discussions of the purposes of our society and guidelines for clinical research and for training the clinical investigator. The presidential address has been used commonly to move the society to action on some issue. For example, nearly 40 years ago our president called for expanding the scope of clinical investigation to include new disciplines such as clinical epidemiology; such new directions for clinical investigation clearly have taken place. We have been called upon several times to increase our membership by electing a larger number of qualified individuals each year; this has occurred with some degree of regularity. In 1955 our president recommended extending the meeting for a second day to institute subspecialty sessions. This change occurred and continues with a high degree of success as our intersociety meetings on Sunday afternoon. In 1954 we were called upon to move the annual meeting, at least periodically, away from Atlantic City to another area of the country. Although there has been a 23-year lag time, the meeting will be moved in 1977.

These internal issues may seem trivial when compared to the external turbulence that biomedical research and academic medicine have encountered increasingly during the current decade. However, we should not dismiss lightly the important roles the Society, through its members, has played in shaping academic medicine and biomedical research as we know them today. Although we will continue to make errors of both omission and commission, on the whole, the very high standards maintained in the selection of our members, the publication of our journal, and the conduct and content of our annual meeting have been carried by our individual members into the research laboratory, into the leadership of our academic institutions, and into the committees, study sections, and councils of the National Institutes of Health. Unwittingly perhaps, The American Society for Clinical Investigation has been a major force in maintaining excellence in the medical research and educational systems of this country. When one considers the apocalyptic character of the many external problems academic medicine and biomedical research are confronting, it may seem unlikely that there are internal matters worthy of discussion in 1976. However, some of us on the brink of

emeritus status, or beyond, have concerns about preserving the best qualities of our annual meeting for future years. This topic is worthy of brief comment and lengthy thought.

There is no other conclave of which I am aware, where all who are active in clinical research, the awe-inspiring as well as the novice, independent of their special areas of interest, join together to discuss the most important clinical research of the past year. Many a career in academic medicine has been launched on the boardwalk and its environs and in the electrifying atmosphere of this annual gathering. This is the stuff that has been fed back into individual laboratories and the faculties of our medical schools. I believe that we can maintain both the programmed and unprogrammed attributes of our combined meetings if we are careful in the selection of future sites, keeping in mind the need to preserve the opportunity for close personal contact and the ability to move freely among our many simultaneous formal sessions. Hopefully we will develop some future pattern that will satisfy the desire for geographical equality as well as assure preservation of the qualities we have come to recognize in the Atlantic City meetings.

During the past year I have received suggestions from thoughtful members that we should reduce our plenary session to half a day or even eliminate it altogether, to provide more time for the subspecialty sessions. In my view such a change would lead to the eventual downgrading of the importance of this annual event and the risk that a major purpose of our Society would be lost. This joint meeting has provided a common ground for individuals concerned with the highest level of clinical research in every subspecialty. We have achieved a workable blend of subspecialty and general sessions, and the length of the combined meetings has already exceeded the tolerance of dutiful attendance. Adding more time to the meetings would risk de-emphasis of existing components, and shortening our general session to permit more simultaneous subspecialty presentations would weaken and possibly eventually destroy the bond that has held us together and served us so well.

Extrinsic issues. I would now like to turn my attention to those outside forces bearing so heavily on the present functions and future roles of academic medicine and biomedical research. The specifics of most of these issues have been eloquently discussed from this podium in recent years. In reviewing the history of the Society, I was surprised somewhat to find that these imposing extrinsic issues can be grouped into as few as three categories. What was even more surprising was to learn that these topics were addressed from this podium long before the problems as we now know them were evident. They are: funding for training and research; Society

responsibility in national policy; and medical schools and the health care system.

The first formal attention paid to extrinsic issues was in 1919, when Dr. Henry B. Christian warned that the young investigator should be free to pursue his own ideas and not become an instrument of the senior investigator, and that harm could come from large funds in the hands of few (2). Although his ideas of "large funds" would probably need revision by orders of magnitude by today's standards, Dr. Christian might be skeptical of the center-type funding that has evolved, and the tendency for the junior investigator's authorship to be remembered in the terms "et al." or "and co-workers."

Apparently the first full-fledged assault against extrinsic factors came in 1945 when Dr. Thomas Francis, Jr., devoted his entire presidential address to such issues as the possibility that federal funding of research might lead to political pressures that would influence the direction and quality of research. It was pointed out that the red tape of premature accounting and justification could be an evil that would consume time and energy and also might adversely influence the quality of research by the grantee eager to submit reports that showed progress. Quite remarkably, Dr. Francis called upon the scientific societies to play a role in influencing the philosophy and policy of federal support (3). I suspect that policies developed during the early days of the National Institutes of Health on broad support of basic and clinical research, peer review, and support of individual investigators satisfied most of these early concerns. Even so, we now find ourselves confronting the precise problems outlined at this meeting 30 years ago.

In more recent years it has become increasingly evident that our problems include much more than the uncertainty of federal support for biomedical research and training. In the minds of many, the medical school has become the focal point for some of the major problems in the medical systems of this country, and quite independently of the vagaries of funding, biomedical research is in jeopardy from an attack on other flanks. The country appears to be on the brink of major changes in national health policy, and these changes will undoubtedly involve the medical school. It no longer suffices to say that we have the best system of medical research and health care the world has known. As a matter of fact, some of the very things that we may consider good features of the system actually represent problems in the eyes of the public (4).

The various issues related to health care in this country are real and, if uncorrected, may reach proportions that justify drastic political and public intervention into the health system—justified, since in one form or another, public funds heavily support large segments of the educational system, the systems of hospitals, and the development of knowledge and technology.

Although problems related to training and distribution of physicians and the mechanics of health care delivery do not fall within our traditional definition of biomedical research, they are legitimate areas for study and experimentation by and within our institutions. Such new programs will require new means of support, and for long periods of time. As important as these problems are to the future of medicine, I do not believe our schools should tackle them at the expense of abandoning what we are now doing well. Nevertheless, if ignored, the potential of these issues eventually to damage the present environment of medical research is obvious.

All of this is familiar to us and, when examined carefully, these external pressures bearing on medical research and education appear so overwhelming that it is small wonder that the academic community has been able to do little more than react by conforming. Assuming that the current trend of social and political pressures continues, which I believe it will, what should we be doing as an organization of physician investigators to preserve the best features of medical research and the educational system? Biomedical research in general, and clinical investigation in particular, have been incorporated as major components of the academic structure, and the qualitative effects of research have been woven into the fabric of medical education. Neither can remain healthy if the other is allowed to atrophy. As a Society of medical investigators who also represent the faculties and leadership of our educational system, we are in perhaps the best position to examine this interrelationship in the interest of preserving the desirable features of the combined institution for future years.

If the history of the past 30 years of academic medicine is examined, few of us would disagree that providing support and protecting the time and independence of the promising young investigator have been essential to the development of our schools and the success of clinical investigation. Most of us here who began our academic careers during the 1950's or early 1960's received direct support for our own research in one form or another. During the past decade, independent funding for the young investigator has become more difficult to obtain and, moreover, the new demands on the faculties of medical schools are making it more and more difficult to assure protection of time and responsibility for the promising individual embarking on a career in medical research. I believe that we must begin to act now to reverse these trends if we hope to provide our expanding institutions with a next generation of leaders in clinical investigation. We must come to grips with some current aspects of the policies for funding research that may not favor optimal development of both new knowledge and new investigators for the future. In addition, we must examine our own house and see that our schools do their part to assure that this search for new

knowledge continues as a major component of the system of medical education throughout the country.

With respect to funding, it should be clear to everyone by now that the rate of growth during the 1950's and 1960's is a thing of the past. This by no means should be construed to mean that public support is finished, but we have reached a leveling-off period when growth will be slower; therefore, we must learn to plan ahead for optimal use of the resources entrusted to us. Recognizing this limitation, we must make collective efforts to defend rationally an approach to a stable level of funding based on the necessary size of the educational institution in this country. Long-range commitments to such funding should be sought on the basis that medical education and medical research are inseparable and necessary for continuing progress in health care.

It should be made perfectly clear to the public and to our legislators that we are engaged in an indefinite period of fact-finding and upgrading of the educational process. We are not poised to suddenly conquer mankind's major illnesses, lacking only money. That failing has been responsible in part for the public distrust we are now experiencing. We should not hedge on the fact that we cannot cure cancer just now—we don't know how. I believe we should be able to convince our constituents of the same things we so easily convince ourselves of: We are gathering knowledge that improves understanding of illness and in some cases leads to improved treatment; as we continue, unscheduled breakthroughs will occur, just as they have in the past, which may eliminate whole classes of diseases. We don't know the schedule and we should say so.

The present allocation of federal funds for biomedical research has become heavily weighted in the areas of categorical research and contracts for what are currently insoluble problems. The very notion of targeted, scheduled research is intellectually a contradiction in terms. The letting of federally funded research contracts should result from the same peer review mechanisms that apply to research grants; it should be the considered opinion of appropriate experts that basic information is sufficient to begin efforts toward a specific goal. When such directed efforts are undertaken, they should be supported through mechanisms that do not rob the ongoing program of basic research. Collectively, organizations representing biomedical research must take a stronger stand on funding of prematurely conceived, and in some instances hopeless, targeted research at the cost of diminished support for intellectual pursuit of basic questions born in the mind of the investigator.

The time has come to give serious consideration to the possibility that allocation of large sums of research money to the control of few individuals could become damaging overall to the progress we are after. Center grants,

specialized centers of research, and even program project grants may be of great significance to the development of an institution or to a research program within an institution. However, such funding can also result in the financial support of the ideas of one or at the most a few individuals, while many younger and fertile minds are occupied in directed research. In the future the dedicated young investigator may find himself forced into such team efforts in order to embark on an academic career.

All too often the principal investigator of such programs becomes more and more involved in institutional management, editorial commitments, national advisory roles, and air travel, and less and less involved in the day-to-day activities of the research projects. There is a real danger that allocation of large funds to the direction of few individuals could lead to a system of local research contracts. History is clear on the point that the truly major advances in science have not been the results of corporations of workers. Applied science and technological development, yes, but not the fundamental information necessary for advances.

What purposes would be served by this kind of meddling with the system of federal support for medical research? Our approach in the past has been simply to ask for more funds to add onto existing mechanisms of support, but that technique is no longer workable. If we hope to continue to secure intellectually unencumbered support for young and promising investigators in the expanding system of medical education, then we must be willing to accept, indeed support, elimination of inefficient funding policies, densely concentrated funds in limited areas, and research contracts that antedate basic information.

As medical investigators, we are not to be faulted for playing the game of funding by the rules that exist, and I do not expect individuals to rush home from this meeting to turn in their research contracts and SCOR grants so that more individual investigators may be supported. I do believe, however, that the biomedical research community as a group can be faulted for not playing a stronger role in the past in helping to formulate the rules of the game in which we are the players. As a society, we must continue to work toward a truly umbrella organization that can speak on behalf of academic medicine—research and education—in our relationships with the Administration, Congress, and the general public, an organization that can realistically plan for the future as well as ferret through the multitude of expedient and temporary measures that appear to place academic medicine in an adversary role at an alarming frequency.

What roles should the medical schools play in preserving biomedical research while at the same time meeting the increasing educational demands requiring either

larger faculties or new responsibilities for existing faculties? Funding for medical research during the 1950's and 1960's grew at a rate exceeding that of the educational institution. Now the situation is reversed and it will be necessary for our schools to continue to develop without the luxury of concordant growth of funding for research that existed in the past. Competition for funds will become even keener as new schools emerge and faculties increase in existing schools.

I do not believe that the expanding system of medical education that appears necessary will be able to afford faculties in which every member is recruited and supported on the basis of promise or productivity in traditional biological research. Moreover, the reasonable demands currently placed on our educational system are not consistent with such an approach. The future will not be able to afford repetitious and mediocre research, and our schools must accept that funding for research in every category of medicine in every institution is unlikely. Resources must be allocated to the most promising programs. Recruiting and support of some faculty in the future should be based on excellence in areas other than traditional biological research if we hope to meet overall institutional responsibilities and at the same time assure that sufficient funds will continue to be available to support meaningful clinical investigation as currently defined.

The years ahead offer many opportunities for creativity and innovation in medical education beyond the present scope of interest of most of us here, and the upcoming generation of faculty physicians must be convinced that there are alternate pathways to academic success. More importantly, our institutions must accept that excellence in academic achievement is measurable in terms other than grants funded and papers published. Every faculty member need not be engaged personally in laboratory research to remain alert, so long as such research is preserved as a fundamental component of the institution.

If our medical schools fail to grant academic equality to the high achiever in areas other than what we now define as medical investigation, we will surely find that increasing numbers of aspiring investigators will be unfunded and forced into career activities which they neither chose nor prepared for. Even if funding were possible, an all-research faculty such as we have been training in the past will find its time diluted more and more, as student bodies increase in size and as our schools accept more responsibility in such areas as continuing education and programs created from new technology or social demands. A compromise must be reached between the idea of the clinical investigator as a complete physician and faculty member, and sufficient protection to assure meaningful research.

But what lies ahead for the well-trained individual highly motivated toward a career in traditional biological research? Admittedly, as it now stands, things may appear somewhat bleak, but I believe there is reason for optimism. Hopefully, a reassessment of funding policies will make it possible to provide independent support for more young individuals with meritorious research proposals. The schools must provide a balance between faculty responsibilities and protection of time and independence necessary for the individual to embark on his or her career. At the same time it is mandatory that the investigator engage in sufficient educational and, if qualified, patient-related activities to maintain identity as a member of the faculty. If this is not done, then the major value of research as a component of the educational system will be lost.

In my view, initial support for meritorious research proposals should be for a minimum of 5 years. Shorter periods of time encourage pot-boiling projects that unnecessarily consume time of the investigator, editors, and reviewers, and clutter our journals with repetitious material, time that otherwise could be devoted to exploring multiple ideas in search of a lead to something new. If, after a reasonable trial at independent research, nothing of significance happens, then support should be terminated. The individual should be guided in directions more suitable for his or her talents, either within the institution or elsewhere. Neither our schools nor our funding agencies can afford to commit resources to unproductive or marginal research.

The young individual considering entering academic medicine today should be fully aware of the hazards of a career based largely in research. Every effort both within the institution and without should be made to support the truly dedicated investigator, but there will be little room for the tinkerer attempting to accumulate credits toward academic advancement.

All of this may have the appearance of an attack on biomedical research. Not so. In fact, the purpose of these comments is exactly the opposite. We must find means for protecting and supporting the dedicated independent investigator so that we do not find ourselves with a generation of retired principal investigators without successors. At the same time our educational institutions must meet other challenges that lie ahead. Our schools have developed for 30 years on both the practical and intellectual benefits of research, and we are rapidly outgrowing that blood supply. To maintain research as a major component of the educational institution, both the universities and the agencies that fund research must reassess goals and priorities.

The pattern for staffing our faculties in the future must include individuals concerned with educational, clinical, and administrative matters without the necessity for

personal achievement in biological research as traditionally defined. To insist otherwise will encourage wasteful and poor research, dilute the available resources, and discourage individuals, promising in other respects, from pursuing careers in academic medicine. With care we may be able to prevent wobble in the three-legged academic stool and at the same time preserve the strength of the leg called research.

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