A Policy for Investment in Biomedical Research

A case is made for directly relating biomedical research to national health service revenues.

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Man tends to do what he is able to do. The dramatic development of the biomedical research enterprise in the advanced countries during the last four decades is more a manifestation of man's capabilities than the result of a deliberately planned endeavor. This is one of the beauties of the achievement. True, men of great foresight such as Shannon, Fogarty, Hill, and the Laskers (*1*) helped the enterprise in the political arena, but it is hard to believe that the achievement would not have been the same in their absence, given two important factors. By the beginning of the 1940's, research in the physical and chemical sciences had reached a point where it could deal with the quantities and qualities of biologic phenomena; and the public was becoming aware that science could be a powerful tool for both war and welfare. In addition, the real rewards, in terms of the well-being of both the individual and of society, that could be obtained by adding science to shaman in the relationship of the patient and physician—the fact that the physician would now on occasion dramatically cure as well as loving care—spurred public support for a burgeoning biomedical scientific enterprise.

Costs were no factor in the 25 years that followed. The National Institutes of Health (NIH) struggled to spend, for the benefit of all, large quantities of money urged on it by the public's representatives (*2*). In some areas, the funds outran the available supply of scientists, if not ideas. There was no overt national policy tying goals to expenditures; such a policy would have implied upper limits of expenditure, and there was no ceiling stated. However, NIH did develop extremely fruitful policies for steering funds in the right directions; one such policy was peer review. But these were minor internal decisions as opposed to major decisions concerning the effects of overall investment. Biomedical research was exciting and productive during these 25 years.

A major factor behind these developments was that during this period health care delivery truly became a science-based industry. Prior to 1950, less than 1 percent of the gross revenues (*3*) of the health industry were spent on research and development, while planners and influential citizens knew that most science and technology-based industries spent from 8 to 15 percent on research and development (*4*). The public purse opened to expand support for medical research and development from $197,000,000 in 1952 to $3,320,000,000 in 1972, and to increase the proportion of R&D dollars from 1.2 percent to 4.8 percent of national health expenditures in 1966 (*5*). In the late 1960's, the political process began to feel the pressures of other social priorities for a limited number of dollars, and the proportion fell to just below 4 percent in 1972.

Now, while this science-based health industry is still in its early adolescence, the illogical arrangements that were made for its growth and management have become growing pains. The crux of the problem is that the new health industry has no central management or board of directors to make investment decisions based on the total revenue of the industry, estimates of "payoff," or other such criteria. Moreover, the funds available for R&D have almost no connection with the productive output of the industry itself—they are derived from tax funds and are thus completely subject to political control.

In this and the following arguments, it is recognized that there are other socially enriching values of research related to the esthetics of the academic enterprise, but it is important to emphasize that this is not what the public is buying, except in a limited sense. The country is still a long way from supporting symphonies directly. Scientists and academicians must acknowledge their direct economic value while quietly nurturing their art, as painful as this may be.

It should also be emphasized that research and development for the health industry properly include the relevant activities in economics, engineering, behavioral research, and systems analysis usually included under the term health services research (*6, 7*). Basic information in some of these disciplines, as far as it is related to health, is more rudimentary than that available in what might classically be called biomedical research. The study of man and his ills encompasses all levels of his organization, from the submicroscopic structure of the molecules that constitute his body to the gross characteristics of his social organization. The term biomedical research is used here to refer to the entire spectrum.

Research as a Social Good

Why must government instead of the private sector provide the source of funding for most research and development in health? "Private enterprise can realize gain only from those benefits which accrue *directly* [emphasis added] to individuals, since purchases of the services will be influenced solely by the direct benefits received as a result of the purchase. . . . Some activities . . . such as national defense, and protection of life and property . . . yield only social benefit, the goods or services not being divisible into measurable units which directly benefit individuals" (*8*). Research and, to some degree, development in the health industry are such "social goods." The hospital or the

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physician as economic units cannot be expected to capture the benefits of an individual investment in research, nor even may pharmaceutical houses be expected to gain more than minimal benefits from more basic research. Moreover, only certain economic monopolies that have developed as a result of specialization in a particular area of science, such as the Bell Telephone Laboratories in electronics and E. I. du Pont de Nemours in chemistry, might be expected to capture a significant enough proportion of the benefits of truly basic research to invest in it. There are additional problems. The time scale by which the benefits of basic research are measured is in decades. Moreover, of the major scientific discoveries that could be put to practical use, 70 percent were from research not classified as oriented to the final product or mission (*9*). Thus research and all but the most terminal development in the health industry must have their funding assured by government because of the elements of unpredictability, the time scale, and their nature as a social good. (The word "assured" and not "provided" is used deliberately here for reasons I shall discuss.)

Management Considerations

At this point, it would be valuable to consider the management structure in greater depth. The health industry is a loosely knit collection of individuals and organizations; it is comprised of health professionals practicing by themselves or in groups of various sizes, hospitals, pharmaceutical and electronic industries, and government at all levels. Its gross expenditures are now over $100 billion annually. The only other industry of comparable size is education and here, at least, the responsible arms of state and local government provide central management. Except for the individual subindustries of pharmaceuticals and electronics, everyone in health goes his "merry laissez-faire way" with only occasional constraints, such as licensing set by governmental regulation. The closest the country comes to having central direction, or a board of directors to develop coordinative planning and policy, is in its relationship with the U.S. Congress and the Executive in the political process.

When one considers the day-to-day delivery of personal services by the industry, there are advantages and disadvantages to having a lack of central direction, depending on one's political persuasions. However, one point is clear—there is no other substantial source of authority, direction, or dollars for investment in the *future* of the industry than that same political board of directors.

The health industry is an area where politics and sound management coincide only by luck, and it is dangerous for the well-being of our society to leave it so. The problem only became apparent when the political process and research tasks no longer were coincident. The fact of the matter is that the competition for public funds for biomedical research only occurs after the overall major allocation of funds has been made to the health-related activities of the Department of Health, Education, and Welfare, while an increasing proportion of this allocation to the health activities is being taken up by the uncontrollable item of paying for health care delivery programs. Thus, the relationship of research to delivery is, if anything, inverse. *The amount of research monies appropriated for health has no necessary quantitative or logical or administrative relationship to the level of expenditure by the agency in the enterprise of improving the health status of the public.*

Without some kind of guideline or link, it is impossible to plan ahead to devote resources, train manpower, or make any other investment decisions for the research base, especially given the 5- and 10-year time lag in the production of certain of these resources, such as manpower. For example, how can we possibly predict the need for research manpower, as both Representative Paul Rogers and Senator Edward M. Kennedy have requested in the current Research Training Legislation (*10*), if we are unable to predict the size of the research effort for that same future period in some reasonable and logical fashion. Whether Congress realizes it or not, it is asking that research investment somehow be isolated from the unpredictability of the political arena.

Approaches to Solutions

The problem seems threefold: Who shall set the level of the investment? On what should this level be based? And from where should the funds come? It may be worth elaborating on the last point first. If the sources of funds for investment in biomedical research are to come ultimately from the general tax revenues, it is pointless for us to argue that Congress and the Executive will have other than the predominant voice in the amount and dispensation of these funds. Their public accountability for these funds requires that it be so. Devices or guidelines or goals set by extrapolitical means may be inserted to stabilize and modulate the process, but the "who" and the "how much" will still be intimately political. To the degree that mechanisms can be devised to separate the source of funds from the general revenues, the instability could be mitigated.

Stability is of great importance for a vigorous and productive biomedical research enterprise, because the level of high-quality activity is not capable of rapid expansion. Downward adjustment can be made easily and rapidly by simply cutting funds if the inequity and waste resulting from displacement of valuable manpower is willingly disregarded. However, expansion or reexpansion are a different matter in such a highly labor-intense activity that utilizes personnel of extraordinary skills and prolonged training. It takes from 5 to 10 very expensive post-baccalaureate years to produce an independent biomedical scientist, and perhaps an additional 2 or 3 years to establish a well-working and productive team of investigators, assistants, and trainees. Thus stability and careful, advanced planning are required to make the enterprise most efficient. Recent history would suggest that the political process has not provided such stable support.

Within this framework, some of the alternative methods of estimating an appropriate overall level of support for biomedical research can be considered. The postulate that investment decisions should be related to an estimate of "payoff" for the health industry is an ideal to approach. In theory, such a payoff would be an improvement in the health status of the public. Rudimentary attempts have been made to estimate health status by the use of subjective questionnaires, by counting work days lost, and by evaluating the level of care provided to patients with certain diseases for which treatment is reasonably standard. None of these methods have been developed to the extent that the data they provide can be used as the denominator for overall investment decisions, though studies in these areas should be encouraged, espe-

cially to aid in the allocation decisions.

Should estimates of payoff be made subjectively by experts in the various disease categories using judgmental techniques, such as the Delphi method according to which the whole is the sum of its perceived parts? Such methods would seem to be without real substance for such significant decisions. The current attempt to use these methods in the cancer program may become a costly lesson in the imperfections of predictive techniques of success in biomedical sciences.

If payoff cannot be assessed in terms of health status, then might the "need" for health care be a more general criterion to use as a denominator? Here subjective techniques might be used to quantitate need. However, though imperfect, one objective measure does exist—the annual revenue expended in the delivery of health care in response to the "need." This is actually a measure of the amount of revenue consumed secondarily to the interplay of demand in the market, demand being the derivative of individually perceived need. This may not necessarily reflect true need for social goods as determined by experts. However, health care revenue is measurable and certainly has at least some direct relationship to health status, or lack thereof as perceived by the aggregate citizenry. Moreover, for investment purposes, it defines the gross revenues of the industry in which we are investing. It is a far more relevant measure of need or health status than total societal productivity, as measured by the Gross National Product, for instance. With the present state of the art, the annual health service revenues should be the keystone of our approach to the support of biomedical research.

This perspective allows some modification of the earlier discussion of biomedical research as a social good. Viewing the composite health services delivery enterprise and its revenues as a single industry allows one to consider it as an economic activity—an activity that is likely to capture most of the benefits of the investment in biomedical research and development from the most basic to the most applied. At the most basic levels, agricultural research, for example, would provide some cross benefits. Within this context, external benefits are restricted. Thus, the concept of biomedical research as a social good requiring direct governmental appropriations becomes limited, as long as there is a mechanism by which the revenues of the industry in support of its own research and development can be obtained directly.

For instance, if one established a means of directly relating a biomedical research trust fund to gross revenues of the health industry, by attaching the fund to a percentage of the insurance premiums or outlays, for example, one would obtain a device for investment in health research and development that would be separate from the general revenues. Accountability to the public for the expenditure of such funds would always have to be related to governmental process, but at least such accountability could be separate from the turmoil of yearly appropriations from the general revenue. The establishment of National Health Insurance would make this an even simpler device. In fact, the more the administration of such an insurance program were vested in the private sector, the greater could be the degree of separation of research management from government. It is important to reemphasize that the new role of biomedical research as the research and development arm of a huge social industry, and research's inherent need for stability, call for the special treatment provided by a trust fund. The federal highway and social security programs are other examples of trust funds established for similar, though not identical, social purposes.

Government and the political process could still be responsible for overall priorities and establishment of special investment in areas of national health problems, but a stable base would be established. The government would still be "assuring," but not directly "providing" the social good of research and development in the health industry. As revenues would increase in the health arena, so would research destined ultimately to bring the cost of health care down. If biomedical research were successful in improving health status, it would then become a lesser proportion of the national effort.

An Advisory Commission

Government will and should always have ultimate responsibility for expenditures of biomedical research funds, but the degree of its direct responsibility should vary depending on the source of the funds. Regardless of how this issue is settled, Congress and the Executive need expert advice from the concerned public, but such advice should be based on greater deliberations than those of the hurried hearings process from which undermanned staff now assemble what amounts to a national policy for a single year (*7*). Congress and the Executive would be better served by a considered recommendation, with alternatives spelled out, provided by a body with public prestige and credibility (*2*). A rigorous decision-making system should be developed to allocate resources according to judgments which balance scientific opportunities with social problems. Congress and the Executive should control or approve appointments to this body. This would give it enough breadth to ensure its scientific and economic prestige, credibility, and accountability. In fact, it would be through such an enlightened commission that the esthetic values of biomedical research could be given weight, and the time scale of the effects and the nature of the unpredictability of such research could be brought to public understanding.

Such a commission might be responsible primarily for the major decisions in biomedical research—that is, for decisions concerning the budget and gross target areas for research. Provided that the funding device were a trust derived as a percentage of national health insurance revenues, the commission might advise Congress as to the appropriate percentage and then set the gross investment priorities within the budget with, in this case, only congressional oversight or approval. The advantages of this form of organization would be that health research funds would no longer be discretionary. They would be logically and directly linked to the industry they supported.

At the very least, given a continuation of funding by yearly appropriations, such a body could establish targets for investment based on economic and management priorities (for instance, defined as a percentage of gross health revenues). The logic on which these positions would be based would be made public. If less money was appropriated by Congress than was recommended by the commission, or if there were an attempt to overspend, those in the political arena would have to explain why to the public.

There would have to be a device to separate clearly in the minds of those in public, political, and professional arenas the difference between investing for the future of the health industry

and trading off within the industry in the policy- and budget-making processes. Though health research funds would still be discretionary, the process by which they were appropriated would be clearer.

The Minor Decisions

The minor policy decisions in biomedical research are extremely important in spite of their designation. Among such policies are those which lead to training grants, general clinical research centers, general research support grants and, perhaps most important, the assessment of excellence and of degrees of priority by peer review. Only recently has the health services research end of the spectrum even begun to receive the attention it needs (*6*). The NIH has served with distinction in its efforts to support basic biomedical research and should continue to do so. The National Center for Health Services Research and Development has not yet had the opportunity to develop its traditions. The commission should work closely with both of these agencies and might, in fact, include on its staff members of both agencies, though compelling arguments could be made for the commission having a separate staff. Commission approval might be necessary, or at least recommendations might be made to Congress and the Executive, for implementation of the minor policy decisions made by the two agencies.

For ease of argument, I have suggested that the major and minor issues in biomedical research investment are separable. In fact, they are intimately related. For instance, the determination of the relationship between health revenues and research support—that is, the investment percentage, cannot help but require that some estimate of the summed minor assessments of payoff be made, and that some simplistic idea of what would be good for a science-based industry be formed. In the initial years such decisions might be based on recent historical experience (*7*). But once the percentage was established, minor adjustments in the budget should only be made to prevent damaging gyrations. My personal belief is that the biomedical science community would welcome stability and the capacity to plan even at the sacrifice of some of the rich years.

Conclusions

Given a continuation of the current approach toward the managing and funding of research across the spectrum of disciplines basic to health, the country is headed for stultification and possible social disaster. Health care delivery should be considered as a science-based social industry and managed accordingly. Stability and adequate relation of the research effort to the industry's output should be sought. The establishment of a trust fund, derived as a percentage of health revenues, and of a public commission or a board of directors to provide expert advice on its expenditures are suggested.

References and Notes

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