The Governance of Science at the National Cancer Institute: A Perspective on Misperceptions

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Abstract

The National Cancer Program, because of its size, has always been and remains controversial. Some of these controversies have their roots in insupportable myths attending the passage of the Cancer Act in 1971 and the Institute's management of a rapidly changing program, rather than the science it supported. The National Cancer Institute has changed its management systems to improve the governance of science allowing for continual scrutiny, adjustment, and/or phase out of programs that have served their purpose. This is necessary to husband scarce research dollars in support of the plethora of opportunities presented by the powerful new knowledge derived from the current biological revolution.

Introduction

The success of any complex, multifaceted scientific endeavor, such as the National Cancer Program, depends as much on the governance of science as on its conduct. This point is poorly appreciated by many investigators. How resources are allocated profoundly affects the stability of the scientific establishment. The decision to allocate resources to different areas of science, even in times of plentiful resources, must always be made by someone. This unavoidable truism is the very crux of the effective governance of science, but it sometimes appears to conflict with the treasured ideal of the spontaneity of investigator-initiated research. Because of diminishing fiscal reserves, changes in management of the National Cancer Program affecting the allocation of resources have been our highest priority since 1980. These changes have allowed the Institute to support important new programs even in times of tight budget, an essential component of the successful governance of science. The ability to alter course in response to changing conditions and to plan ahead for the next decade will allow NCI-supported scientists to continue to capitalize on the remarkable scientific advances of the 1970s.

Misperceptions and Myths

A recent communication to me from Dr. James D. Watson, Director of the Cold Spring Harbor Laboratory, with regard to an often controversial NCI scientific program helps to illustrate the importance to all of us of the proper governance of science. He wrote, "Given the still prevalent unfair public misconception that the NCI Tumor Virus Program was a failure, and the new strong possibility (fact?) that most if not all of viral oncogenes have their human counterparts, the time is more than ripe for NCI to point out how well the public purse has, in fact, been used." I would concur with Dr. Watson's views. Recent discoveries of retrovirus oncogenes and their human homologues make it reasonable to state that there are few areas of research which have been so fruitful. We are closer to understanding the underlying abnormality of growth that is cancer than the architects of the National Cancer Program could have imagined in 1971. In addition, the first credible human RNA tumor virus responsible for a T-cell leukemia-lymphoma was identified recently, fulfilling a primary goal of the special Virus Leukemia Program at its inception in 1964. Yet Dr. Watson mentions the "prevalent unfair public misconception . . . ." How did that perception about a program that has been so successful come to be? Can it be generalized to the whole National Cancer Program? I believe it can. It has its roots in the governance of science.

The controversy that has swirled around the Cancer Program centers around four major myths that remain difficult to dispel.

First, the Cancer Program was controversial because expectations for the immediate, practical application of the fruits of basic research were, in some cases, too high. Judging from the first public criticism, some critics naively expected control of cancer by 1976, a mere 4 years after funding to NCI was increased! The heightening of expectations of this kind was not generally fueled by knowledgeable laypersons, basic scientists, clinical investigators, or physicians who understood the long, drawn-out struggle necessary to unravel the complicated biology of cancer. Even so, the signs of success, now evident everywhere, indicate that many of the realistic scientific expectations have been met and exceeded.

The second controversy relates to the standard belief that money can't buy good ideas, and hence the resistance on the part of a large segment of the scientific community to sharply increased resources to the National Cancer Program in the early 1970s. This is the greatest myth of all. Money does, in fact, buy more good ideas because, if more gifted scientists are put to work, they originate good ideas and create momentum. The confusion is created by the lag between the availability of increased resources and the establishment of excellent productive research facilities that foster new ideas. The time lag makes the relationship between the availability of increased resources and the flow of new ideas and discoveries difficult to conceptualize. This is especially true for the public, who must also balance the...
and extramural, and away from the competitive pool and the criticism. It was viewed suspiciously, as a potential means the use of the contract instrument was the central issue in all normal marketplace of ideas. Although NCI’s budget grew rapidly between 1972 and 1976, the expense of other approaches to cancer prevention. Again, there were biases in the allocation of resources in favor of the viral oncology program, especially its intramural component, at the NIH. A quick review of the budgets of all NIH Institutes Cancer Program grew at the expense of the other Institutes of after 1971. Because the Virus Cancer Program had started before most other NCI programs, and because NCI’s top level was the recipient of a large portion of the increased resources was the Virus Cancer Program, shows that this is simply not so. While the NCI’s budget increased from approximately 200 million dollars to over three-quarters of a billion, NIH’s budget increased from 1.2 to 2.3 billion dollars. In some cases, budgets of other Institutes increased at rates faster than they had before the passage of the National Cancer Act. Finally, it is not reasonable to assume that the increased cancer appropriations would otherwise have been divided among the other Institutes to add to their already increasing budgets.

The fourth controversy emanated from NCI’s use of contracts to fund research. This point is pivotal in the debate over the governance of science. During 1971 to 1976, the period of rapid growth, the NCI used the contract mechanism because of the speed which it afforded at that time in getting some kinds of programs started. In fact, between 1972 and 1975, the NCI disbursed more money through contracts than through the RO1 and PO1 grants, its main instruments for funding investigator-initiated research. Contracts were foreign to most basic researchers and the NIH community. In contrast to grants, regardless of the source of the idea, a request for contract proposal must be issued by the Institute’s staff while grant applications originate with the investigator. Contracts also implied (often incorrectly) NCI’s direction of research (which no one, then or now, likes), and finally contracts were awarded outside the traditional peer review system. Thus, the use of contracts brought intense scrutiny to and criticism of all of NCI that almost eclipsed the significant progress being made. The Virus Cancer Program, originally a targeted research program searching for human cancer viruses, was supported mainly by contracts and was the recipient of a large portion of the increased resources after 1971. Because the Virus Cancer Program had started before most other NCI programs, and because NCI’s top level management and intramural staff in the Division of Cancer Cause and Prevention were weighted heavily toward viral oncology, the notion prevailed that in the Institute’s etiology research efforts there were biases in the allocation of resources in favor of the viral oncology program, especially its intramural component, at the expense of other approaches to cancer prevention. Again, the use of the contract instrument was the central issue in all this criticism. It was viewed suspiciously, as a potential means for diverting monies to favored persons and programs, intramural and extramural, and away from the competitive pool and the normal marketplace of ideas.

Although NCI’s budget grew rapidly between 1972 and 1976, the rate of budget growth slowed between 1976 and 1980, to a rate not even sufficient to keep pace with inflation. As resources became less plentiful, competing interests within the cancer research community began to challenge how priorities were set and how systems for allocating scarce resources were functioning. Around 1976, for example, controversies over allocation of resources between prevention and treatment arose. Within the prevention program itself, arguments over allocation of resources between support for research on chemical carcinogenesis and viral carcinogenesis were particularly acrimonious in the scientific community. In both cases, the issues were also debated in the public press. Some critical scientists framed their desire for greater funding for their own area of research in terms of lack of success of a competing area during the time lag required for these areas to grow. The press found such internal discord unparalleled girt for the mill, and the misperceptions about progress in the National Cancer Program spilled out into the public arena.

The situations just described as they were debated in the scientific and public press are, in my view, the chief source of public misperceptions about the success of the National Cancer Program in general and the success of the Virus Cancer Program in particular. It should be noted, however, that none of the points have anything to do with the actual merit of science; they serve, however, to illustrate how failure to attend to the governance of science can affect science itself.

Management Practices and the Governance of Science

In 1980, we recognized two factors that contributed to the controversies. First, during the early years after passage of the National Cancer Act, the management system of the Cancer Institute had not kept pace with the allocation of resources and responsibilities to be managed. This was particularly true of details of contract financial management. It should not come as a surprise because the main goal of the early architects of the Program had been to establish new programs, with all possible speed. Secondly, a closed loop system had been used to allocate resources. Once funds had been committed to a program area, that commitment was maintained. A system to redistribute resources across program lines in response to the changing scientific opportunities had never evolved. New programs needed resources in order to get started and, between 1980 and 1982, new resources were scarce inasmuch as NCI’s budget actually decreased by 1.5%. Although the old system functioned reasonably well when monies increased at a rapid rate (as most systems do), it had become untenable in a time of shrinking budgets.

Management Changes at NCI since 1980

Between 1980 and 1982, major changes to correct these problems were instituted. The main elements of these changes are as follows. (a) The processes of decision making and priority setting for each NCI division were elevated to public view and conducted with expert advice from four divisional Boards of Scientific Counselors, constituted entirely of highly qualified non-government scientists, representing competing priorities within each research thrust. These Boards replaced the multitude of special interest advisory committees that had previously acted autonomously and advised in isolation, and their function is closely linked to the NCAB. (b) Decisions based on the advice...
that, when our intramural program was meticulously investigated facilities. This process has been completed for the entire NCI have been closed and relocated to the Bethesda campus or the extramural program while preserving its unique flavor and posi-
tions made in the site-visit reports, there have been major staff
recommendations made. As a result of the recommenda-
tions made in the site-visit reports, there have been major staff
changes and consolidation of our intramural program over 3
years which have enabled us to redistribute resources and therefore limit its growth to a rate comparable to that of the extramural program while preserving its unique flavor and position in the scientific community. Oft criticized off-site laboratories have been closed and relocated to the Bethesda campus or the FCRF to make better use of government-owned laboratory fa-
cilities. This process has been completed for the entire NCI intramural program.

The new intramural peer review system has worked so well that, when our intramural program was meticulously investigated by the Government Accounting Office at the behest of Senator Hawkins, with specific instructions to compare the quality of the peer review system for the intramural program to that for grant-
ees, the system now in use was recognized as comparable to that for the extramural program in its ability to judge the quality of the research and foster change. This review process and details of changes in NCI's management systems are described in two new publications prepared by NCI's Management Analysis Branch and will be included in a supplement of the Journal of the National Cancer Institute to be published soon.

All of these changes have contributed to improvements in NCI's governance of science and have enabled the NCI to survive the most intense Congressional scrutiny ever given a similar organization. As a result, NCI might now be characterized as "squeaky clean." The new corporate management system, functioning with detailed advice from the four deeply involved multi-
disciplinary Boards of Scientific Counselors, the NCAB, and the President's Cancer Panel, all in open forum, enabled the NCI Executive Committee to reprogram over $80 million in resources (the majority from contracts), to help absorb a loss of approximately $200 million in purchasing power between 1980 and 1982, and to maintain support for its highest priority basic research in the face of a declining budget. With greater confi-
dence in its review and management, NCI has salvaged the contract as a vehicle of support for research when its use is judged appropriate. In a sense, the contract mechanism itself had been maligned. It was not as though a contract could not be used to support research programs. Rather, appropriate use of contracts depended on whether and how they were initiated and reviewed and whether a mechanism existed to assure that contract programs could be phased out when the activities they supported were no longer of the highest priority or could be converted to grants or cooperative agreement mechanisms when these were judged more suitable.

Five other steps were taken to lend stability to NCI support of research.

1. The National Cancer Institute staff, with advice and support from the President's Cancer Panel and NCAB, proposed and arranged for the transfer of its chemical bioassay program, with all its resources ($45.6 million and 80 positions), to the National Institute of Environmental Health Sciences. This controversial step was taken for two reasons: (a) if the program were started today, it would need to address the multiple potential adverse effects of chemicals such as on the reproductive system, fetal development, and behavior, as well as the carcinogenic potential of chemicals, a broader testing mission more appropriately within the scope of the National Institute of Environmental Health Sciences; (b) it freed NCI staff from the task of managing and financing a routine testing program to devote its full energies and resources to the support of basic research and the applica-
tion of the results of basic research in cancer prevention. NCI wished to emphasize the interrelationship of its basic research programs, such as biological and chemical carcinogenesis and epidemiology aimed at giving a better understanding of the mechanisms of carcinogenesis.

2. As a result of this shift in emphasis, a major new initiative was begun in cancer prevention. In our newest Division, the Division of Resources, Centers and Community Activity, which administers the budget line item devoted to the Cancer Control Program, we have shifted resources to emphasize those appli-
cations of the results of basic research designed to interfere with the late stages of the carcinogenic process, presumably related to cancer promotion. Prospective clinical studies of materials known to interrupt or impede cancer causation in rodents are
now being launched; these substances often appear as positive variables in the numerous epidemiological studies supported by the increased resources made available to the program in the early 1970s.

3. In the early 1970s, the Organ Site Program was established as a means for assuring emphasis on research in neglected common tumors. Because of the rapid change in attitude of basic researchers in the past decade toward research related to a variety of common cancers and the need to complete the separation of program direction and its review, accomplished for all other grant and contract programs, the NCAB recommended that NCI convert the Organ Site Program to a new format referred to as the Organ Systems Program. The new format returns the review of organ site grants to the regular NIH or, when appropriate, NCI review systems but should broaden its scientific base by allowing a new extramural organ system coordinating center to scan the entire scientific horizon for research advances ready for clinical application in the common tumors. The controversy generated by this organizational change, which has been debated at Board meetings and in the Congress, exemplifies the difficulty in allocating scarce resources. The proposal made by a subcommittee of the NCAB and accepted unanimously by the full Board and NCI staff after a thorough scientific review preserves the emphasis but increases the program's flexibility to respond to new advances in basic research that require rapid application.

4. A major change was made in the management of the Frederick facility. Established in 1971 with the passage of the Cancer Act to "convert swords into plowshares," it is a government-owned, contractor-operated facility. Since it is operated by a contractor, this contract must be recompeted periodically. In May 1980, 2 years before it was scheduled for recompetition, the NCI asked the NCAB to consider, in addition to other issues inherent in contract recompetition, whether the work at Frederick should be continued. After site visits and detailed analyses of the results of review of the scientific programs at FCRF, it was agreed that the program was of high quality scientifically and merited continued support. The NCI Executive Committee proposed and the NCAB agreed to proceed under the following guidelines: (a) the research portion of the contract was to be decreased by 20% because of the lean budgets anticipated for all of NCI (ultimately, it was decreased by 29%); (b) concurrent with the review of NCI's intramural program and decision to move off-site laboratories from rented space in the Bethesda area, NCI was urged to utilize the excellent laboratory facilities of FCRF to achieve a better balance between contractor and intramural scientists using space made available by the reduction in the research portion of the contract; (c) because of criticism during the previous investigation by the Government Accounting Office of the noncompetitive nature of a government-owned, contractor-operated facility this large, the NCAB agreed that NCI should take whatever steps are necessary to increase the competitive nature of the contract; (d) because of concern over the fragmented nature of the relationship between NCI and its FCRF contractor-supported science and its review and management, a consolidation of management and review under a single NCI Associate Director and scientific advisory committee was carried out.

The recompetition of the FCRF contract was a massive undertaking unique in the history of such facilities. It involved over 1000 NCI and contractor staff and took 2.5 years to complete. The contract was made more competitive by dividing it into five components. Proposals for each of the five components were subjected to rigorous peer review by panels of non-Federal expert consultants. The result of this enormous effort is that all initial goals have been met. Now a single FCRF advisory committee composed of distinguished extramural scientists oversees the consolidated contractor-supported research program and its review. Several of the committee members are chosen from the divisional Boards of Scientific Counselors because of their expertise in the comparative evaluation of contractor science relative to intramural science. The NCI program director is an NCI Associate Director (and member of NCI's Executive Committee) who works through an on-site manager to interact with the principal investigator of the research portion of the contract. Finally and most important, the overall combined cost of the NCI intramural program components moved to FCRF, and the FCRF contracts are 2% lower in 1983 than the same components as they existed in 1980.

5. Finally, the NCI Executive Committee, with the approval of the NCAB, established a series of funding plans aimed at stretching research dollars allocated to the grant pool to swell to a modest degree by the reprogramming efforts described above. Details of NCI's budget development and the rationale for these funding plans will be the subject of a subsequent publication.

**Consequences for the NCI Tumor Virus Program**

In spite of some initial concern, the Viral Oncology Program has fared well in this shift and reallocation of resources. In 1970, its total program resources were $21 million. These peaked in 1979 at $110 million, and in 1983 its budget is $90 million. This decrease of $20 million is mainly the result of a decrease of $30 million in contracts, much of which came from intramural support contracts, concomitant with an increase of $10 million in grants. This shift from contracts to grants allowed NCI to maintain the health and balance in this program because the grants in the Viral Oncology Program are, in general, less costly than contracts. It also enhanced the diversity in research more easily achieved by investigator-initiated projects and maintained the impressive momentum of this important scientific area. It should not, however, be overlooked that the early success of the NCI's contract-supported Virus Cancer Program made it possible subsequently to use the grant as a vehicle of support. The recent identification of retroviral oncogenes in human tissue and the identification of the first credible human retrovirus was greatly facilitated by the initial use of the contract, an instrument usually regarded as more appropriate for the support of applied research.

**Conclusion**

There are two major challenges in the management of the National Cancer Program in the 1980s. The first is to support the momentum of the biological revolution in a time of scarce resources. This will require the kind of management system now in place and the continued willingness of everyone to share resources across program boundaries, and to change and/or phase out some programs to allow support for new research areas, even if resources dwindle. The second challenge is often
overlooked in the management of scientific resources. In the National Cancer Program, it is to keep the essence of the concept of the National Cancer Program intact as conceived originally, able not only to support basic research but also to apply, when appropriate, the results of this research. This is particularly important because, in addition to opportunities for the application of results of research in diagnosis and treatment, opportunities are now plentiful for applying results of basic research in prevention.

In a way then, the Cancer Program can be regarded as an unusual and fragile biological organism with a head at each end. One end is concerned with basic research and the other with the application of the results of basic research. The organism is unable to survive if either head is severed. The reason the second challenge assumes importance is that food for both ends of the organism flows, surprisingly enough, at a rate proportional to the Program’s willingness to apply the results of basic research. That is how the Cancer Program began in the first place. The delicate balance of sufficient support for basic research and the application of the results of basic research is the very essence of the governance of science and must be carried out in public view by individuals with a broad overview of the program. While support of basic research is and always will be our first priority, when the Program shows an unwillingness to apply research results, the public, the Congress, and many scientists as well get cranky. At this point, this organism seems to turn upon itself, the public hears only negative arguments, and resources for the support of the entire Program diminish. Then there is proportionally less to devote to basic research.

It is often asked if the National Cancer Program has been a success. While I acknowledge a bias, my answer is an unqualified “yes.” The success of the Virus Cancer Program which prompted this essay is a good example. Since its inception, this program has cost almost $1 billion. If I were asked what I would pay now for the information generated by that program, I would say that the extraordinarily powerful new knowledge available to us as a result of this investment would make the entire budget allocated to the National Cancer Program since the passage of the Cancer Act worthwhile. And there may well be practical applications of this work in the prevention, diagnosis, and treatment of cancer that constitute a significant paradigm change. The work in viral oncology has, indeed, yielded a trust fund of information, the dividend of which defies the imagination.

The misperception of the success of the Virus Cancer Program to which Dr. Watson referred relates to the approach to the allocation of resources in the early 1970s. The management problem in the Virus Cancer Program was in its switching mechanism; the decision about when, and under what circumstances to switch from contracts to grants (and back) when the work switched from the more applied to the basic (and back). Under the old system, these points were not reexamined periodically in the public arena, and contracts were continued for too long. With NCI’s present system, this point is reexamined for each contract-supported program by that program’s divisional Board of Scientific Counselors and the NCI Executive Committee on a continuing basis.

The public purse mentioned by Dr. Watson has been well used, but the reasons for the public misperception should also be clear. We have learned a valuable lesson: In order to have the public trust and support to continue the kinds of research we want and need, we cannot neglect the governance of science.
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