

THE

# CANCER LETTER

P.O. BOX 15189 WASHINGTON, D.C. 20003 TELEPHONE 202-543-7665

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## Review Of NCI Intramural Program Offers Over 60 Recommendations For Change

*The Working Group on the NCI Intramural Program last week completed its eight-month review of NCI's in-house research programs, releasing a report that includes more than 60 recommendations for change.*

*A summary of the report was accepted by the National Cancer Advisory Board in May (The Cancer Letter, May 19).*

*In its recommendations, the committee urged improvements in NCI's strategic planning, organization, quality assurance, and recruitment and retention of scientists.*

*The Cancer Letter will publish the text of the report over the next three weeks.*

*In this issue: Executive Summary, mission of the NCI intramural*  
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### In Brief

## Budget Resolution Calls For 1% Cut In NIH, Then Six Years At 3% Below Current Budget

Congress last week passed a seven-year budget plan that calls for a 1 percent cut in the NIH budget in 1996. Under the budget resolution, the initial cut would be followed by a six-year dry spell during which the NIH budget would be capped at 3 percent below this year's level.

Though the budget resolution is largely symbolic, many of its provisions are likely to be reflected in bills. If NIH funding provisions become law, the cuts would amount to \$2.1 billion over seven years.

The NIH funding provision resulted from a compromise between the House version of the measure that called for \$3.6 billion in cuts over seven years, and the Senate version that called for \$.8 billion in reductions.

The budget resolution also calls for reductions in virtually all major non-defense programs, including Medicaid and Medicare. Under the plan, the Office of Surgeon General would be eliminated.

The decreases in NIH funding could be offset by a tax on tobacco, Sen. Mark Hatfield (R-OR) said last week before the Senate Special Committee on Aging. Hatfield, chairman of the Senate Appropriations Committee, said he planned to introduce a bill that would raise an additional \$4 billion a year for NIH through a 25-cent increase in the tobacco tax.

Hatfield said that in recent weeks scientists have been effective in lobbying against cuts for NIH. "For too long, scientists and researchers have remained in their laboratories without entering the policy debate," Hatfield said. "Now that they have arrived, I have no doubt that their powerful message will take hold across Capitol Hill."

"With resources now constrained, the ability of NCI to be responsive to its constituencies has been compromised."

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"Too much [of NCI's] planning is reactive rather than proactive. As a consequence, vision suffers."

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"The Working Group urges NCI to reconsider its current budget to determine whether the 25 percent devoted to the IRP is appropriate."

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## Blueprint For NCI Requires "Will, Energy" To Implement

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*program, charge to the Working Group, and strategic planning in the intramural program.*

### Executive Summary

In the past few years, concerns expressed by the Congress and other bodies regarding the quality, appropriateness, size, and cost of the intramural research program of the NIH have led to a series of *programmatic and administrative reviews*. Most recently, in April 1994, an External Advisory Committee of the Advisory Committee to the NIH Director submitted a review of the intramural research program and its relationship to the extramural research program. One of the External Advisory Committee's recommendations was that each institute undergo a review of its intramural programs, taking into consideration the unique aspects of its mission and organization.

The NCI was the first institute to undergo the recommended review. A Working Group of extramural scientists was appointed by the Directors of NIH and NCI to determine the extent to which the recommendations of the External Advisory Committee applied to NCI, to assess NCI's implementation of the External Advisory Committee, and to identify and evaluate issues that might be distinctive for the NCI intramural program. The Working Group was advisory to the National Cancer Advisory Board, and its formation was a joint activity of NCI and NIH.

The broad issues considered by the Working Group were quality control; morale of the scientific

work force; nurturing of talent, especially that of younger scientists; the intellectual suitability and administrative efficiency of the organization within the intramural research program; and the effectiveness of strategic planning. More specific issues placed before the Working Group for consideration included:

—the size of the NCI intramural research program relative to its mission; the status of clinical research within the intramural program in terms of suitability, quality, cost-effectiveness, and prospects;

—the appropriateness, quality, and future of drug development activities; the status of AIDS research within the IRP, in terms of suitability, levels of funding, and effects on other programs in the intramural research program; and

—the quality and necessity of NCI programs at the Frederick Cancer Research and Development Center.

Recent attrition at the highest ranks of NCI management provides an opportunity to reconsider the current structure of NCI. In addition, the entire NIH is under a mandate to streamline its operations and reduce its full-time equivalent employees. The Working Group was asked to consider these events as an opportunity to reconfigure various components of the NCI intramural research program, and to provide advice on where resources are being used wisely and unwisely.

The Working Group met seven times over an eight-month period between October 1994 and May 1995. It requested and received detailed data on budgets, planning, quality review, personnel and administrative practices, operations of the Frederick Cancer Research and Development Center, AIDS programs, training, drug development activities, and the status of NCI Clinical Center programs; heard testimony from a variety of intramural personnel, including scientists, the NCI Director and Acting Director, division directors, Clinical Center staff, and administrative staff; solicited comments in writing from the entire professional staff of the NCI intramural research program; and made site visits to the clinical and drug development programs at the Frederick Cancer Research and Development Center.

More than 60 recommendations are offered to improve the quality and efficiency of NCI's intramural research program. They appear in their entirety in the full report. The spirit and intent of

### THE CANCER LETTER

Editors: **Kirsten Boyd Goldberg**  
**Paul Goldberg**

Founder & Contributing Editor: **Jerry D. Boyd**  
**P.O. Box 15189, Washington, D.C. 20003**  
**Tel. (202) 543-7665 Fax: (202) 543-6879**

E-Mail: [73322.2044@compuserve.com](mailto:73322.2044@compuserve.com)

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these recommendations are summarized below.

**Strategic Planning:** NCI's procedures for strategic planning could be improved. Efforts should be made to formally solicit input from leading clinical and laboratory investigators within the intramural and extramural research programs to provide regular and systematic advice to the director.

There seems to be a disproportionate investment in the intramural research program, and at least some of its individual programs appear to be poorly coordinated. NCI should reconsider its current budget to determine whether the 25 percent devoted to the intramural research program is appropriate.

**Organization:** The current organizational structure of the intramural research program is *unnecessarily complex and redundant*, and potentially disadvantageous to the extramural programs. In addition, burdensome administrative requirements appear to deter intramural scientists from their missions in basic and clinical research and technology transfer. There should be full separation of the intramural and extramural programs, consolidation of programs within the IRP, and measures taken to reduce administrative redundancies and inefficiencies.

**Quality Assurance:** The procedures used to evaluate the intramural research program and its scientists should be improved to encourage more objectivity and expertise on the part of reviewers, to reward excellence and initiative, and to improve the diversity and morale of intramural investigators. Oversight of budgets for investigators, laboratories, and branches should be strengthened.

**Sustaining and Renewing Talent:** The intramural research program has failed to recruit new talent vigorously, its policies for promotion of scientists have lacked rigor, and it has allowed the distribution of resources to become authoritarian. In order to fulfill its mission, the intramural research program must consistently seek to renew its intellectual capital. Its scientists should be provided the opportunity to work in a setting that encourages independence and rewards both creativity and excellence. Specific actions should be taken to sustain and renew talent in an open, equitable, and consistent manner. Leadership should be held accountable for failure to provide stewardship.

**Clinical Research:** Innovative clinical research, especially translational research, must be an essential part of the mission of the NCI intramural research program. In an effort to restore the clinical research

in the intramural research program to preeminence: all intramural clinical research should be gathered under one division; translational research should be made preeminent; the review and monitoring of protocols should be made more rigorous; coordination between basic and clinical investigators should be encouraged; consolidations and mergers should be considered between NCI and the National Naval Medical Center; clinical training should be enhanced; and review of clinical investigators should be subject to the same equitable and rigorous peer review for promotion as laboratory investigators.

**AIDS Research:** The intramural and contract program in AIDS research is a large enterprise with limited central direction or control. This makes the NCI intramural program particularly vulnerable to any reduction in AIDS funding. *Greater efforts must be made to coordinate AIDS research within the Institute and to undertake an expeditious and comprehensive review of all of its AIDS research for suitability and quality.* This review should be done in cooperation with the Office of AIDS Research.

**Drug Development Activities:** The development of effective therapeutic agents is one of the most challenging and important pursuits in cancer research and should continue in NCI's intramural program. However, drug development programs and the investigators in them should receive more rigorous and periodic review, as should the contracts supporting them. Serious consideration should be given to how NCI's drug development programs could become core facilities for the entire

**Members of the Working Group** were: Co-Chairmen: Michael Bishop, Univ. of California, San Francisco, and Paul Calabresi, Brown Univ. Karen Antman, David Baltimore, Judah Folkman, David Livingston, John Minna, Cecil Pickett, Leon Rosenberg, Louise Strong, Bert Vogelstein, and Samuel Wells.

**Comment** may be addressed to NCAB Chairman Barbara Rimer, Duke Univ. Medical Center, 2200 W. Main St. Ste B150, Durham, NC 27705, e-mail: rimer001@mc.duke.edu, or to Marvin Kalt, Director, NCI Div. of Extramural Activities, EPN Rm 600, Bethesda, MD 20892, e-mail: kaltm@dea.nci.nih.gov.

**The Cancer Letter** also invites comment in the form of Letters to the Editors. Letters may be sent to: PO Box 15189, Washington, DC 20003, or e-mail: 73322.2044@compuserve.com.



NIH. Collaborative opportunities related to the drug screening program should be increased and accelerated within NIH and beyond.

**Frederick Cancer Research and Development Center:** NCI activities at Frederick are not well integrated, either among themselves or with other aspects of the intramural research program. For programmatic and budgetary reasons, it would be wise to reorganize and consolidate the Frederick programs. The facility should be a core facility, or "cost-effective center," for the entire NIH. All clinical and laboratory components of the Biological Response Modifiers Program should be moved to the Clinical Center. Noncontract operations should be moved to Bethesda. When feasible, the operations of the Applied Biosciences Laboratory program should also be moved to the Bethesda campus.

**Implementation Plan:** NCI should submit an implementation plan to the National Cancer Advisory Board at the time of the Board's May 1996 meeting. After May 1996 the Board should review the progress of the implementation plan annually until it deems review to be no longer necessary.

These recommendations reflect a consensus of the Working Group. Some of the recommendations are *straightforward* and require only will and energy to implement. Many echo recommendations made in previous reports that have gone unheeded. They are offered in a spirit of adventure and urgency and in full recognition of the vitality and importance of the mission of NCI. The report is submitted to the National Cancer Advisory Board for its consideration and action.

### I. Introduction

Cancer is a challenge of immense dimensions. As a major cause of death and debility, it is a frightening prospect for the general public. As a disease with many causes and forms, it is a complex problem for research scientists. The National Cancer Institute represents our best hope for conquering cancer. No other institution combines the sense of national purpose, the diversity of instruments, and the magnitude of resources required to meet the challenge of cancer.

Over the past decade, the hope embodied in NCI has begun to reach fruition. Research has produced a unifying understanding of the cancer cell that promises new and more effective approaches to prevention, detection, and treatment of the disease. Despite this success and promise, however, there is

doubt that our nation will find the resolve to sustain the fight against cancer in the face of fiscal constraints that threaten to cripple all of the biomedical sciences. It seems a suitable time to review how well NCI has performed in the past and what might be done to improve its performance in the future. This report concerns an inquiry into one important arm of NCI, the intramural research program (IRP), based on the campus of the NIH in Bethesda, MD.

### Genesis and Structure of NCI

Cancer has been a focus of federally funded research since the first allocation of \$30,000 for that purpose was made in 1927. NCI was formally established in 1937 at the behest of President Franklin D. Roosevelt, and in 1947 was reorganized into its current configuration, with an intramural component geographically localized in Bethesda and a separately constituted extramural research program (ERP) that awards grants to scientists at universities and other research institutions. In 1972 NCI was elevated to bureau status within the Federal Government through the National Cancer Act (or the "War on Cancer," as it was styled by then President Richard Nixon). Today, with a budget of more than \$2 billion, NCI is by far the largest of the 24 institutes, centers, and divisions within NIH, with nearly 2,100 full-time-equivalent employees.

As a result of the National Cancer Act, NCI is like no other institute within NIH. The NCI Director is appointed by the President, as are the President's Cancer Panel and the National Cancer Advisory Board (NCAB). The President's Cancer Panel provides general oversight for the National Cancer Program and directly advises the President on the status of the program. The NCAB oversees the review of grant applications and provides advice on all aspects of program and planning for cancer research, reporting to both the Secretary of Health and Human Services and the NCI Director. This statutory organizational structure has created a distinctive working relationship between the NCI Director and his advisory bodies, and has created a sometimes difficult structural relationship between the NCI Director and the NIH Director, who must respond, sometimes in parallel, to both executive and legislative oversight.

After several decades of expanding resources, NCI and its sister institutes now face the prospect of abrupt and severe fiscal constraints. As a result,



the balance between the IRP and ERP of NCI has become uneasy. Now commanding nearly 25 percent of the total NCI budget (if contracts serving the IRP are included), the NCI IRP is the largest of its kind across NIH, in both absolute and relative size. The NCI intramural clinical program now expends \$100 million annually and is the largest program of the NIH Clinical Center, responsible for 40 percent of all its costs. NCI is further distinguished by its extensive contract program (\$200 million), much of it for support of IRP activities; its programs in drug development; and its organization into four research divisions (rather than one), each with responsibility for both extramural and intramural activities.

NCI must respond to legislative and executive mandates regarding the pursuit of its mission. The usual result has been a further expansion of that mission. Until recently the expansion was accommodated by steadily increasing resources. But with resources now increasingly constrained, the ability of NCI to be fully responsive to its various constituencies has been compromised, and this in turn has required that the mission and operation of NCI be examined. These are times for the scientific community to exert exceptional stewardship over the public funding of cancer research.

#### **Mission of the NCI Intramural Program**

The stated mission of NCI is to plan, conduct, and coordinate a national program involving (1) research on the detection, diagnosis, cause, prevention, treatment, and palliation of cancers and on rehabilitation of the cancer patient, and (2) demonstration of the effectiveness of cancer control methods and techniques. Specifically, NCI

- conducts and directs research performed in its intramural laboratories and through contracts;
- supports and coordinates research projects extramurally;
- supports training in fundamental and clinical science;
- supports construction of laboratories and related facilities;
- collaborates with voluntary organizations and other institutions engaged in cancer research, training, and control activities; collaborates with industry;
- collects and disseminates information on cancer incidence, outcome, and control; and
- consults with cancer research programs in other countries.

The NCI IRP has a multifaceted mission that reflects the diverse challenges posed by cancer. In general terms, the IRP should serve as a model cancer center, striving for integration of basic and clinical sciences. More particularly, the IRP serves the following purposes:

It is a flagship for all the efforts of NCI. Located close to the nation's capital, it is a visible representation of the cancer program to policy makers, and an intellectual resource for advice to the Federal Government as well as to the leadership of NCI and the entire cancer program.

It has relatively stable research funding, providing its scientists the opportunity, indeed the obligation, to take intellectual risks and "push the frontier" of feasible experimentation.

It should conduct fundamental research of the highest quality, to produce an example to the entire community of cancer researchers, as well as an intellectual infrastructure for the other activities of the IRP.

It should set an example in pioneering clinical research on cancer.

It provides an exceptional setting in which to link fundamental research to the bedside, to conceive and test novel therapies, and to lead the way in what is now called translational research.

It must often devote a small but critical portion of its budget to "strike forces" that can react quickly to newly emerging challenges in the fight against cancer, particularly through epidemiologic studies.

Some aspects of the intramural mission, however, pose special problems. For example, the prominence of the IRP as the flagship of NCI can be a double-edged sword by detracting from the larger mission of NCI. Research mandated in response to political expediency diverts funds from other programs and monopolizes resources on behalf of legislative and executive mandates. The basic research in the IRP needs to be sufficiently catholic, yet it is sometimes faulted for being unduly duplicative of efforts in the ERP. The stability of funding, while intended to encourage risk taking, can result in complacency, inbreeding, intellectual isolation, and lack of vision.

The challenges faced by the IRP justify investment of ample resources. The questions before the Working Group were, How well have the resources been utilized, and how well has the mission been pursued? The answers become especially critical in light of the rapidly changing environment for extramural biomedical research, where resources



are increasingly scarce and pressure is mounting to hold down medical costs, sometimes at the expense of research and training. In this context, the IRP becomes an even more precious resource.

#### Previous Renewals of the NIH IRP and NCI

The performance of the IRP has been evaluated several times and in several different ways in the recent past. Some of the challenges facing NCI are universal among institutes, such as downsizing, streamlining, and calls for aggressive performance review at all levels.

Previous advisory groups have addressed these issues in response to administrative and legislative mandates over the past 25 years. These included:

—A 1976 review of NIH by the President's Biomedical Research Panel, [Report of the President's Biomedical Research Panel, submitted to the President and Congress (US Department of Health, Education, and Welfare, Public Health Service, DHEW Publication No. (OS) 76-500), April 30, 1976];

—A 1988 report of the Institute of Medicine regarding the NIH intramural program, [Institute of Medicine, Report of a Study: A Healthy NIH Intramural Program: Structural Change or Administrative Remedies? (Washington, DC: National Academy Press, 1988)]

—A 1992 report of the Task Force on the Intramural Research Program of the National Institutes of Health, [Report of the Task Force on the Intramural Research Program of the National Institutes of Health, transmitted April 13, 1992, to Bernadine Healy, NIH Director, from Richard Klausner, Chief, Cell Biology and Metabolism Branch, National Institute of Child Health and Human Development, NIH];

—A 1994 report of the Committee to Examine How the NCI Can Best Manage Hard Times, [Report of the Committee to Examine How the NCI Can Best Manage Hard Times, NCI, Jan. 31, 1994];

—The 1994 report of the External Advisory Committee on the Intramural Research Program [Report of the External Advisory Committee of the Director's Advisory Committee, NIH, The Intramural Research Program, April 11, 1994.].

At first glance, this might seem an excess of scrutiny. But a neutral observer might equally wonder whether the repeated calls for review reflect a continuing concern about performance and a lack of response to criticism and recommendations.

A number of the issues identified by the more recent deliberative bodies deserve mention, in particular because they prefigured many of the problems encountered by the present Working Group. The 1992 Task Force on the Intramural Research Program of the NIH was appointed by then NIH Director Bernadine Healy to prepare a report concerning the scientific vitality, excellence, and eminence of the NIH IRP.

The Task Force in its deliberations relied on the views of working intramural scientists and developed recommendations for improving the NIH IRP. Specifically, it recommended:

—the creation of permanent-faculty trans-NIH organizations that would participate in the decisionmaking of the institutes;

—the establishment of discipline-based postdoctoral fellowships administered through the faculties, a clearly defined tenure track policy, and funding for recruitment of tenure-track scientists from outside the IRP;

—the development of a uniform process for the review of research scientists and administrators; and

—the establishment of a central Administrative Policy Board to evaluate the impact of administrative decisions on the conduct of research.

In January 1994 an internal NCI committee, composed of representatives of each scientific division and the NCI Director, examined selected aspects of the NCI structure, staffing, and functioning. This committee's report, *The NCI in Hard Times*, identified issues NCI leadership should address, including:

—redundancy and overlap among divisions and between the intramural and extramural programs,

—ineffective use of staff,

—insufficient vision and planning,

—lack of effective linkages among programs,

—the adverse influence of operational styles on the conduct of research.

Concern expressed by Congress and others regarding the quality, appropriateness, size, and cost of the NIH IRP led to the establishment of the External Advisory Committee (EAC) of the Advisory Committee to the Director, NIH. In particular, the fiscal year 1994 House Appropriations Committee Report mandated the Director of NIH "to review carefully the role, size, and cost of the intramural program and its relationship to the extramural research program," and indicated that NIH must put together a process



“for allocating resources to and among its intramural programs based on a thoughtful analysis of these issues.” To review the IRP, the NIH Director appointed the EAC, which completed its work in the spring of 1994.

In its many recommendations to the NIH Director, the EAC concluded that the problems plaguing the IRP, unless addressed, may destine it to a mediocre future. The EAC identified seven areas of concern:

- the review process for tenured scientists and scientific directors,
- the review process for appointment to tenure,
- postdoctoral training,
- administrative issues affecting recruitment and retention,
- NIH-private sector collaborations,
- the process for allocating funds between the extramural and intramural programs, and
- renewal of the Clinical Center.

In addition to its evaluation of the IRP throughout NIH, the EAC recommended that each institute be subjected to an individual review along the lines established by the EAC. The present Working Group was formed in response to that recommendation. NCI was chosen as the first institute to receive individual attention because it is the largest, and because a substantial turnover in leadership has been in process, providing an opportunity for revision and renewal.

In response to the EAC report, NIH has prepared an implementation plan addressing the review process for tenured scientists, a tenure track program, and changes in postdoctoral recruitment and training. In addition, progress has been made in removing some of the administrative impediments to research and enhancing the attractiveness of employment in the IRP through changes in the payscale and retirement options for senior investigators. The Working Group considered the implementation plan and used it as one point of departure for its deliberations. However, there are aspects of the NCI mission and organization that are unique and were not reviewed by the EAC. The Working Group has taken pains to identify and evaluate these distinctive issues.

#### **Charge to the Working Group**

The charge to the Working Group was to perform a review of the NCI IRP similar to that conducted by the EAC for the entire IRP of NIH. The Group

was asked to determine the extent to which the recommendations of the EAC applied to NCI, to assess NCI's implementation of the EAC recommendations, and to identify and evaluate issues that might be distinctive for the NCI IRP. The Working Group was advisory to the National Cancer Advisory Board, and its formation was a joint activity of NCI and NIH.

The broad issues considered by the Working Group were quality control; morale of the scientific workforce; nurturing of *talent*, especially that of younger scientists; the intellectual suitability and administrative efficiency of the IRP as an organization; and the effectiveness of strategic planning. More specific issues placed before the Working Group for consideration included:

- the size of the NCI IRP relative to its mission;
- the organization and mission of the IRP versus NCI's extramural research program;
- the suitability of the current organization of the IRP into four divisions, each encompassing both intramural and extramural activities;
- the status of clinical research within the IRP in terms of suitability, quality, cost-effectiveness, and prospects;
- the appropriateness, quality, and future of drug development activities;
- the suitability, levels of funding, and effects of NCI AIDS research on other programs in the IRP;
- the quality and necessity of NCI programs at the Frederick facility; and
- the challenge of increasingly limited resources.

Recent attrition at the highest ranks of NCI management provides an opportunity to reconsider its current structure. In addition, the entire NIH is under a mandate to streamline its operations and reduce its number of full-time equivalent employees. The Working Group was asked to consider these events as an opportunity to reconfigure various components of the NCI IRP and to provide advice on where resources are being used wisely and unwisely.

#### **The Process of the Working Group**

The Working Group met seven times over an eight-month period between October 1994 and May 1995. It requested and received detailed data on budgets, planning, quality review, personnel and administrative practices, operations of the Frederick Cancer Research and Development Center (FCRDC),



AIDS programs, training, drug development activities, and the status of NCI Clinical Center programs; heard testimony from a variety of IRP personnel, including scientists, the NCI Director and Acting Director, division directors, Clinical Center staff, and administrative staff; solicited comments in writing from the entire professional staff of the NCI IRP; and made site visits to the clinical and drug development programs at FCRDC.

This report is organized around the issues addressed by the Working Group and reflects its consensus. Each section provides background information, describes the problems identified by the Working Group, and lists recommendations. The report is submitted to the NCAB for its consideration and action.

## **II. Strategic Planning At NCI**

Long-range planning of how to deploy resources and people is essential to meeting the goals of the NCI IRP. Such planning first requires crystallization of a vision for the future of NCI. Within that vision a role for the IRP must then be defined and continuously revitalized. Furthermore, knowledge of discovery in fundamental and clinical science relevant to cancer must be communicated regularly to the central planning process so that the vision reflects new discoveries and examines the presumed power of prior discoveries.

NCI faces special challenges in its planning process: much of its annual budget is committed for years into the future and, thus, is not available for new initiatives; and new mandates place unanticipated demands on the budget. These factors make it imperative that NCI have a resourceful and well-informed leadership, with well-articulated mechanisms for strategic and tactical planning.

Currently the strategic planning process at NCI is coordinated by the Executive Committee, a group of senior administrators from the Director's Office, the Budget Office, the Office of Operations and Planning, and Division Planning and Budget Offices. Each year NCI convenes planning meetings to initiate and review the Bypass Budget, review division activities, and identify new scientific opportunities. In addition to the regular planning process, the Institute must mount responses to public health crises, address the concerns of numerous health advocacy groups, and answer to congressional mandates. All of these require a more ad hoc approach to resource allocation.

In concept the Boards of Scientific Counselors (BSCs) are also involved in planning. They are charged to perform an annual review of division budgets, approve conceptually all contracts and requests for applications for grants before they are solicited, provide advice to the division directors and scientific staff, and provide peer review of intramural laboratories. Ostensibly, the BSCs serve as the principal source of scientific advice to the respective NCI divisions. The BSCs are appointed from the extramural community and report to the division directors, not to the NCI Director or the Executive Committee as a whole.

At yet another level, the President's Cancer Panel provides oversight over the development and execution of the National Cancer Program, and the National Cancer Advisory Board is charged with review and approval of grants, and program, policy, and budget guidance.

### **Strengths of Strategic Planning in the IRP**

Strategic planning as now conducted by NCI has its virtues. There is a formal and well-articulated planning process that relies on an active Executive Committee and regular retreats. In addition, the preparation of the Bypass Budget provides an annual opportunity for the review and revision of mission, tactics, strategy, and requirements for resources. Finally, NCI has indicated its willingness to improve planning by periodically initiating processes of self-inspection, the latest example of which is documented in the 1994 report *The NCI in Hard Times*.

### **Problems with Strategic Planning in the IRP**

Despite the strengths of the current planning process, the Working Group concludes that NCI's procedures for strategic planning could be improved. There is reason to believe that too much of the planning is reactive rather than proactive. As a consequence, vision suffers, in particular as it applies to the IRP. In addition, insufficient attention to strategic planning along substantive (rather than administrative) lines has resulted in the formation of a number of programs that seem poorly coordinated, either within themselves or with other NCI programs.

It is the impression of the Working Group that much of the involvement of the BSCs in planning is pro forma, the budget is presented as a fait accompli, and there is insufficient use of BSC scientific and



clinical expertise in major NCI decisionmaking. (See also Part IV, Quality Assurance in the IRP.) According to their own testimony, the BSCs have not been utilized consistently or effectively for planning purposes.

Many of the IRP scientists consulted by the Working Group expressed frustration and a sense of disenfranchisement, engendered by failure of the Institute to consult them sufficiently in its planning activities. Moreover, researchers in the extramural community, the largest scientific constituency of NCI, have almost no input into the NCI planning process (outside of membership on BSCs or the NCAB). The Working Group is concerned that lack of input from the extramural community impedes scientific advances and isolates intramural scientists from the broader community of scientists. Lack of input from the extramural community is particularly problematic, given that NCI division directors control both extramural and intramural budgets.

NCI planning efforts, therefore, lack direct and consistent participation by the leadership of NCI's major professional constituencies, (i.e. working laboratory scientists and clinical investigators). The Working Group believes that NCI must correct this deficiency to make the most effective use of resources, and to preserve the long term health of the intramural program.

Lack of a coordinated and rigorous planning process has allowed an imbalance to develop between the budgets of the IRP and the extramural research program. This imbalance, which has developed over time, has resulted in a maldistribution of resources between the two programs. In addition, the Working Group was concerned about the current practice of counting contracts that support intramural research as a separate budget item. Many of these funds are actually expended by the IRP and account for an additional 7 percent above the commonly used figure of 18 percent for the IRP budget. Because the funds are used in support of intramural research, they should be presented and reviewed as part of the IRP.

The IRP allocation for the entire NIH is 11.3 percent, an average of all 24 institutes, centers, and divisions across NIH (including NCI). This average was selected by the 1994 EAC as the level above which the IRP portion of the total NIH budget should not rise. In considering this EAC recommendation, the Working Group recognized that the clinical and epidemiologic responsibilities of the NCI IRP are costly and might warrant expenditures that would

bring the NCI IRP average legitimately above the 11.3-percent recommended ceiling. Other than the high outlays for these activities, however, the Working Group was unable to find any evidence of strategic planning by which the relatively high commitment of NCI to the IRP has been reached. This lack of justification was cause for concern, not because the IRP was found to be wasteful or deliberately over-funded, but because the Working Group believes that the funding of intramural research should be suitably proportioned in reference to the remainder of the National Cancer Program. To place nearly one quarter of the entire federal investment for cancer research in one site expects too much of a single research community and short changes the remainder of the scientific enterprise engaged in cancer research.

It should be noted that the Working Group reviewed the IRP in isolation and on its own merits, recognizing that any comparison to or prescription for advancing the cause of the ERP could be viewed as suspect. Nevertheless, the Working Group concluded that the current investment in the IRP might be excessive. Any savings achieved through better planning and streamlining in the IRP could be used by the NCI Director either to redress some of the inequities between the ERP and the IRP or to revitalize the IRP through innovative measures.

#### Summary and Recommendations

The Working Group found that the procedures used by NCI for strategic planning could be improved. In particular, there has been too little consultation with active scientists about goals and deployment of resources. One major issue in strategic planning for NCI is the allocation of funds within the IRP and between the IRP and the ERP. There seems to be a disproportionate investment in the IRP, and at least some of its individual programs appear to be poorly coordinated. To remedy these problems, the Working Group makes the following recommendations.

1. NCI should create a standing committee, composed of leading clinical and laboratory investigators within the IRP, to provide consistent and systematic advice to the Director as part of its long-range planning process. This standing committee should be included in planning retreats and should be represented directly on the Executive Committee of NCI.
2. The NCI Director should also consult regularly



on planning matters with a committee of leading basic scientists and clinical investigators from the extramural community. The Chairs of BSCs should be included in this group. Like the IRP advisory group, the extramural committee would contribute to planning, especially to the identification and prioritization of emerging areas of research.

3. In addition to meeting regularly with the NCI Director, these groups should meet annually with the appropriate basic and clinical research subcommittees of the NCAB. Both groups should prepare brief annual reports summarizing their recommendations. Such reports would provide useful documentation of the input received by the Executive Committee and establish benchmarks for judging the quality of the advice and its implementation.

4. The Working Group urges NCI to reconsider its current budget to determine whether the 25 percent devoted to the IRP is appropriate. The Working Group believes that the current investment is disproportionately high, considering the relative size of the effort in the IRP and the remainder of the National Cancer Program. The Working Group recognizes that the ceiling of 11.3 percent for the overall NIH intramural budget recommended by the EAC in 1994 need not strictly apply to NCI. Nevertheless, efforts to adjust the allocation for the NCI IRP from its current level seem advisable.

A report on efforts to adjust the allocation should be part of the formal agenda at the annual program review by the NCAB. The NCI Director and the division directors should provide the Board with projections of intramural compared with extramural funding, and with the rationales on which these are based. In addition, the cost of research and development contracts that support intramural research should be acknowledged as part of intramural expenses.

*Next week: In the second installment of the report, the working group addresses the organization of the IRP, quality assurance, stewardship and tenure.*

### Letter to the Editors

## **Plotkin Report To Be Released**

To the Editors:

As one who greatly admires the investigative work done by Suzanne Hadley on the Robert Gallo matter, I was concerned to read her ill-considered and inappropriate remarks regarding Dr. David Plotkin (*The Cancer Letter*, June 23).

Ms Hadley asks why ORI issued its press release exonerating Dr. Plotkin without releasing the full report. The answer is that Dr. Plotkin's reputation was unfairly damaged by erroneous press reports which led to a formal inquiry into whether he committed scientific misconduct. Once the ORI, after a thorough case by case investigation, determined that Dr. Plotkin had not been guilty of any falsification, fabrication or deliberate misrepresentation, it owed it to Dr. Plotkin to publicly clear his name at the earliest possible time.

Surely, Dr. Plotkin should not have had to wait to be exonerated until members of the media had a chance to see if they agreed with the result.

Ms Hadley also chastises Dr. Plotkin for not approving the release of the report. But as Ms Hadley knows, the report, *after* it has been redacted to protect the confidentiality of patients, will be released by ORI under the Freedom of Information Act.

It thus appears that Ms Hadley's real complaint is that ORI protected the confidentiality of patients or dared to publish its conclusions without consulting first with some members of the media. She should put her extraordinary talents to better use.

**James B. Swire**  
Attorney for Dr. Plotkin  
Townley & Updike  
New York, NY

## **RFA Available**

**RFA CA/DA-95-013**

**Title: Pharmacological Treatment Of Nicotine Dependence**

Letter of Intent Receipt Date: Aug. 11

Application Receipt Date: Sept. 21

NCI and the National Institute on Drug Abuse announce an RFA to develop controlled, randomized trials to determine the most effective, generalizable, cost-efficient, and durable adjuvant behavioral therapies to support the pharmacological treatment of nicotine dependence. About \$2 million in total costs per year for 4 years will be committed. Up to 9 awards will be made.

Inquiries: Thomas Glynn, NCI Div. of Cancer Prevention and Control, 6130 Executive Blvd, Rm 320, Bethesda, MD 20892, tel: 301/496-8520, fax: 301/496-8675, Email: glynnt@dcpcepn.nci.nih.gov. Debra Grossman, NIDA Div. of Clinical and Services Research, 5600 Fishers Ln, Rm 10A10, Rockville, MD 20857, tel: 301/443-0107, fax: 301/443-8674, Email: dgrossma@aoda.ssw.dhhs.gov