

National Cancer Advisory Board Ad Hoc Working Group

**To Create a Strategic Scientific Vision for the
National Cancer Program
and
To Review Progress of the National Cancer
Institute**

**Working Group of the NCAB
December 7, 2010**

Working Group Charge

To review NCI's current operating structure and strategic vision.

To assess the effectiveness of the scientific programs and business management structure of NCI, to determine the gaps and opportunities for delivering scientific progress in understanding, diagnosing, treating, and preventing cancer.

Report submitted to:

NCAB Subcommittee on Activities and Agenda

National Cancer Advisory Board

Membership of the Working Group

Chairs:

- Phil Sharp (MIT)
- Robert Ingram* (Pharma/Biotech)
- William Goodwin* (Banking, Philanthropy)
- Bruce Chabner* (Harvard/MGH)

**25 Members from Industry, Academia,
Lay Community**

*** NCAB Member**

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ES: Paulette S. Gray, Ph.D.

CMO: Ms. Claire L. Harris

Panel Meetings and Topics

The Working Group met on three occasions over six months and heard presentations from:

Current NCI leadership

Former and current NCI Directors

Leaders from various NCI divisions and programs

Basic, clinical, and population scientists

Cancer Center leaders

Leaders in academia, government, and industry

Authors of the Institute of Medicine report

Current National Institutes of Health Director

Panel Meetings and Topics

**May 5, 6 – NCI authorities, 1971 Cancer Act, NCI
Co-operative Groups**

**July 7,8 – Frederick Contract, Cancer Prevention and
Control Programs**

**August 25, 26 – Medical Oncology Branch, Cancer
Centers and SPOREs**

Background / Context of Review: Transformative Forces at Play

NCI is facing a period of severe fiscal restraint:

- **Flat budget for the past eight years, 2003-2010**
- **Erosion in real dollars over that period**
- **Limited prospects for budget growth in the next few years**

Expanding opportunities for advances in diagnosis and treatment:

- **Growth of knowledge base regarding the molecular origins of cancer**
- **Major contributions of the biotechnology industry, and expanding investments by Pharma**

Transformative Force: Global Interest in Cancer (cont'd)

- **Aging of populations and control of infectious and cardiovascular disease – increased incidence of cancer worldwide**
- **Cancer research and biotechnology now a world-wide priority**

Review of Programmatic Areas

Findings and Recommendations

Industry-NCI Relations

Findings: Industry is now the major source of new cancer drugs. Industry-NCI relationships are seriously hampered by COI rules and by overlapping and at times competing activities in drug evaluation and clinical development.

Recommendations:

- NCI should avoid competition and overlap with industry in areas of drug discovery and evaluation where industry has a clear responsibility and financial interest.
- NCI/NIH should revise COI regulations that unnecessarily hamper interaction of its intramural scientists with industry.

Clinical Trials Programs

The Cooperative Groups

Findings: The Cooperative Groups continue to be vital to mission of defining treatment strategies. The Working Group endorsed the 2009 IOM Report, which called for efforts to address delays in protocol development and review, unnecessary duplication in group functions, underfunding of trials, and failure to complete trials.

Recommendation: NCI should rapidly implement IOM recommendations for streamlining review, improving funding, consolidating functions, and should report progress to NCAB.

Intramural Research: The Medical Oncology Branch (MOB)

Findings: MOB has been the focal point of translational research in Intramural NCI, but has had recent difficulty in attracting top researchers and fellows, and has lost its leadership role nationally.

Recommendations:

- **Consolidate medical oncology faculty within MOB**
- **Develop new mechanisms to recruit and retain talented investigators**
- **Encourage collaborations with industry in new drug evaluation and development**
- **Resolve the growing financial predicament (rising budget, fewer users, increased costs to NCI) of the Clinical Center.**

Cancer Prevention Programs

Findings: The Division of Cancer Prevention supports clinical trials in cancer prevention and a screening program for chemoprevention that do not connect effectively with either basic science, cancer drug development, or clinical trials activities in other divisions of NCI.

Recommendation: Evaluate alternative organizational structures to encourage closer ties of prevention research with related programs in other NCI divisions and with basic science.

Cancer Prevention Programs (cont.)

Findings: The Division of Cancer Control and Population Sciences (DCCPS) has forged important collaborative relationships within and outside NCI. These efforts are essential to an effective cancer control program and should continue.

Recommendation: DCCPS should pursue further synergies and efficiencies in resource utilization with the Division of Cancer Prevention and the Division of Cancer Treatment and Diagnosis.

NCI Frederick Operations

Findings: FCRF a critical rapid response mechanism for NCI and NIH for drug development, AIDS support, research resources. However, numerous research initiatives in past decade have been initiated/expanded without fully transparent external review.

NCI – Frederick (cont.)

Recommendations:

- Major initiatives such as the cancer Biomedical Information Grid (caBIG) and Cancer Human Biobank (caHUB) may require periodic assessment, reconsideration and review.
- NCI should consider establishing a chartered committee to provide advice about and evaluate ongoing activities at the Frederick facility.
- NCI should consolidate review of its community oncology programs into one competitive process.

NCI Training Programs

Findings: The NCI T32 program eligibility policy has been skewed strongly toward mentors holding NCI R01 funding and toward postdoctoral trainees pursuing projects that are explicitly cancer related. Simultaneously, predoctoral training has been de-emphasized, and the important goal of promoting team research during training is not being pursued effectively.

NCI Training Programs (cont.)

Recommendations:

- **Recognizing that cancer can arise from defects in a broad range of cellular processes, most of which remain poorly understood, NCI should consider rebalancing its training mechanisms to support a more equal blend of cancer-directed and basic, clinical, and population-based science.**
- **Increase overall expenditure for training programs, especially funding for early training—that is, funding for medical student research programs (e.g., matching or supplementing institutional or private sources) and particularly for broad-based T32 support of pre-doctoral trainees.**

NCI Training Programs (cont.)

- **Create an Integrative Cancer Research Training Award, which would bring together two or more trainees (at any training level) with different disciplinary foci, especially those linking basic and clinical approaches, to establish a collaborative research and training plan.**

This new training mechanism would present basic research in a direct cancer context, making explicit the cancer relevance of the basic studies.

Importantly, this mechanism also would help to establish, at the level of training, a culture of collaboration and teamwork that would then extend into the independent careers of the trainees.

Cancer Centers

Findings: Cancer Centers (and their investigator initiated grants) have led the revolution in cancer biology and the application of this new knowledge to treatment and diagnosis.

Recommendations:

- **NCI should streamline the process of applications and review of cancer centers, focusing on scientific accomplishments and translational applications.**
- **NCI should encourage and reward partnerships among cancer centers, and team science.**

SPOREs

Findings: SPORE grants have become a major instrument for supporting disease specific research, primarily in cancer centers. They have encouraged team science and early translational research not easily funded in the R01 pool.

Recommendations:

- **Consider establishing SPOREs directed at specific pathways or molecular mechanisms common to multiple cancers.**
- **Consider alternatives for integrating SPORE and Cancer Center reviews.**

NCI & Comparative Effectiveness Research

Findings: NCI has invested substantially in CER to date and involvement in the following types of efforts should continue:

- **Developing data infrastructure for CER.**
- **Facilitating the development and refinement of methods for CER.**
- **Ensuring that priority populations are not left behind in cancer CER.**
- **Training future generations of researchers to carry out cancer-related CER.**

Working Group Thanks

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- **To the NCI Directors, Drs. John Niederhuber and Harold Varmus, for their encouragement, candid discussions, and support**
- **To NCI program staff, for their very helpful presentations**
- **To the cancer research community at large for their discussions and insights**