THE CANCER LETTER

Vol. 21 No. 32
Aug. 11, 1995

Price $255 Per Year US
$280 Per Year Elsewhere

P.O. Box 15189 Washington, D.C. 20003 Telephone 202-543-7665

Klausner Unveils New NCI Structure, Aims To Change Institute's "Ethos"

In his first week as NCI director, Richard Klausner met with the Institute's staff to outline his vision of what he calls "the new NCI."

Klausner was sworn in by HHS Secretary Donna Shalala on Aug. 1. The following day, at a meeting with NCI extramural program staff, he

(Continued to page 2)

In Brief

ACS Awards Professorship To Bernstein; HCFA Clears Dana-Farber For Medicare

IRWIN BERNSTEIN, of Fred Hutchinson Cancer Research Center, has been awarded an clinical research professorship by the American Cancer Society. Bernstein received the award for his work on the treatment of leukemia and lymphoma. He is professor of pediatrics and director of the pediatric hematology/oncology division. He becomes one of six ACS clinical research professors. The awards free the recipients from academic tasks to allow them to concentrate solely on research and clinical activities. Bernstein will receive support from ACS for the duration of his career, subject to scientific review every five years. He received an initial award of $250,000 for the next five years. . . . **DANA-FARBER** Cancer Institute has been cleared to continue receiving Medicare reimbursements that had been jeopardized by a chemotherapy overdose that killed Boston Globe health columnist Betsy Lehman. The Health Care Financing Administration wrote the hospital July 21 that Dana-Farber will continue receiving payment for caring for Medicare recipients. "We're pleased to have the state and HCFA confirm what we already believed: that we had corrected all the deficiencies cited by the state and have greatly improved all our systems for ensuring patient safety and care," a hospital spokesman said last week. A panel of doctors selected by the hospital is reviewing Lehman's death, and the Joint Commission on Accreditation of Healthcare Organizations is scheduled to return to Dana-Farber in September to decide whether to restore full accreditation. . . . **MORESHWAR NADKARNI**, who retired in 1986 from the NCI Developmental Therapeutics Program, died Aug. 2 in Bethesda, MD, after a stroke. He was 78. Nadkarni worked at NIH for 30 years, where he spent most of his career in grants administration. When he retired, he was chief of DTP's Extramural Research and Resources Branch, since renamed the Grants and Contracts Operations Branch. . . . **DANIEL VON HOFF**, director and CEO of the Cancer Therapy and Research Center's Institute for Drug Development, San Antonio, TX, has been named national director for research for the Physician Reliance Network, an oncology practice management company.

New NCI Structure In Place By Oct. 1, Klausner Says

(Continued from page 1)

revealed his proposed organizational chart and named several officials to top positions.

Klausner said his swift action to revitalize the Institute was the result of the months he spent studying NCI prior to his appointment.

"I've thought about this for a long time, and I think the Institute is hungry for change," Klausner said to **The Cancer Letter**. "We have put together a really spectacular leadership team. We are active individuals and we are ready to move."

Seven Divisions Planned

In one of his first actions, Klausner named Alan Rabson acting deputy director of the Institute. Rabson, a 39-year veteran of NCI, has been director of the Div. of Cancer Biology, Diagnosis & Centers for 20 years.

A principal goal of the reorganization will be to separate most of the intramural and extramural programs, Klausner said.

This is consistent with the recommendations of the report by the National Cancer Advisory Board's Working Group on NCI Intramural Programs (known as the "Bishop-Calabresi report"), he said.

The new divisional structure should be finalized by Oct. 1, Klausner said.

The two intramural divisions will be:

●**Div. of Basic Sciences**, to be directed by George Vande Woude, currently principal investigator of the Basic Research Program at the Frederick Cancer Research and Development Center.

●**Div. of Clinical Sciences**, to be directed by Philip Pizzo, currently chief of the NCI Pediatric Branch.

A new division will include extramural and intramural components:

●**Div. of Cancer Epidemiology and Genetics**. Joseph Fraumeni, currently director of the Epidemiology and Biostatistics Program in DCBDC, will be the acting director. Alfred Knudson, of Fox Chase Cancer Center, will join NCI as special advisor for the division for at least the next year. The division will have both intramural and extramural components.

The new division "reflects the growing importance and priority that this Institute will have in fully capitalizing on the revolutions in simple and complex genetics and its role in cancer," Klausner said.

There will be four entirely extramural divisions:

●**Div. of Cancer Prevention and Control**. Peter Greenwald will continue as director. The structure of the division appears to stand as it was prior to Klausner's appointment.

●**Div. of Cancer Diagnosis and Treatment**. Robert Wittes, acting director of the Div. of Cancer Treatment, will be acting director of the newly organized division.

●**Div. of Cancer Biology**, which will also have responsibility for the Frederick Cancer Research and Development Center. Klausner said he is negotiating with "someone outside of NCI" to direct the division.

●**Div. of Extramural Activities**. Marvin Kalt will continue as director of this division, which oversees grants and contracts review.

"Beyond this divisional structure, exactly what happens with all of the branches and structures will be answered with a process that has been ongoing at the Institute and it will be a process that we will involve all of you in," Klausner said at a meeting with NCI extramural program staff. "I hope this doesn't create too much anxiety, but I promise it will be done with your consultation, to achieve an institute that functions well."

A "Flat" Administrative Structure

The administrative structure of the extramural and intramural programs will be completely redesigned to push decision-making down to the lowest level possible, and to eliminate duplication across the Institute, Klausner said.

An extramural administrative office will be

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

Subscription $255 per year US, $280 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

headed by Philip Amoruso, currently director of the Office of Administrative Management.

Maryann Guerra, associate director for administrative management of the National Heart, Lung and Blood Institute, will move to NCI to direct the intramural administrative office, Klausner said.

"We are going to develop a flat structure, where people with administrative expertise are allowed to fulfill their functions to making things work for the science," Klausner said to **The Cancer Letter**. "As much as legally possible, we will delegate to scientists how to use their budget.

"Administrative staff will report to, in part, the scientific staff and their performance will be reviewed by the scientific staff," he said. "This is absolutely new."

NCI also will develop a program to improve its information management system, he said.

"These represent an enormous structural change," Klausner said. "We want to do it carefully, and we want to make sure things keep working in the meantime and everyone buys into it."

New Internal, External Advisory Boards

Two new boards made up of NCI staff members will be formed to advise the Institute's leadership on scientific and administrative matters, and will enhance communication between the staff and officials, Klausner said.

An extramural programs advisory board will be comprised of staff members in the Institute's extramural programs. A chairman has not yet been named.

An intramural advisory board, comprised of staff from NCI intramural programs, will be chaired by Claude Klee, chief of the Laboratory of Biochemistry, currently in DCBDC. The IAB's first task will be to examine all internal rules and regulations to begin to eliminate unnecessary bureaucracy, Klausner said.

Each chairman will choose approximately 15 board members. The chairmen also will sit on the NCI Executive Committee.

"These boards are going to be very important in the governance of the program," Klausner said to **The Cancer Letter**. The boards will report to Klausner, Rabson and the division directors.

The Boards of Scientific Counselors, made up of scientists outside of the Institute, will be restructured, Klausner said. Currently, four BSCs advise each of the four program divisions.

Under the new structure, there will be three BSCs: One for the intramural basic science division, one for the intramural clinical division, and one for the extramural divisions.

Members of the two intramural BSCs may serve on both boards, and the extramural BSC will make extensive use of ad hoc advisors to review the wide variety of extramural programs. Each of the boards may have 25 to 30 members.

"We expect these boards to be extremely active, absolutely outstanding parts of the program," Klausner said. "We will be making sure the review processes are very clearly articulated and what's expected by reviews is clear to everyone involved."

Reviews of the intramural and extramural programs will examine not only the quality of the science, but also the quality of the administration and use of resources, Klausner said.

The new BSCs will begin to function as soon as the necessary paperwork is completed, Klausner said. Prospective members have been contacted.

Eight Principles for "The New NCI"

At the staff meeting last week Klausner said he is trying to change the ethos of NCI, not just its structure. He listed eight "guiding principles" for this reform:

1. Leadership. "The leadership of the new NCI needs to function as leaders, not as micromanagers. Leadership means that we are able, through an open and scientifically based process, to make tough decisions about where we want to go.

"We need to be able to respond to needs and scientific opportunities, while having a clearly described and clearly anchored vision of what type of institution we are, what we do and what we do not do," Klausner said. "That is the only thing that is going to buffer us from all of the forces that are constantly pushing at and lapping at our doors.

"One of my major roles is to work with you to articulate those priorities and to make sure that I protect the Institute so we can accomplish those goals. It means we must learn as an institution to be proactive rather than reactive. It means we have to get away from lurching from crisis to crisis to crisis. It means we must not be motivated by fears about what might go wrong."

2. NCI is a part of the scientific community. "We need to create and support structures that allow us to communicate, to seek advice from the collective

community, and it means we must have the attitude that allows us to be open to discussion.

"Donna Shalala was very clear that she was not interested in my being NCI director because of my great political skills, but because I was a scientist and this is a scientific institution. It is time we return the National Cancer Program and NCI to the principles and the function and the culture of science."

3. NCI must be a meritocracy. "Excellence in all areas will be expected, and excellence will be what will be rewarded, in terms of resources, authority and responsibility."

4. No fiefdoms. "All institutions, NCI is not alone, tend to divide up into lines and over time those lines become walls and those walls define fiefdoms. We can little afford that and we cannot justify that in any way if we are engaged in a great scientific enterprise. We must replace fiefdoms and walls with interaction and communication."

5. Openness. "We are a community of peers. The expectation is that people are here because they are valued. People are professionals at every level. The leadership at every level has the responsibility of seeking advice from all of their peers, with the expectation that all of you have ideas. There must be openness of advice.

"There must not be attitude that to speak, to give your ideas, violates codes, ownership or control, or certainly that there ever would be retribution for speaking the truth. It means if we are a community of peers, that individuals are trusted and they are entrusted with authority to do their work. We need as an institution to delegate authority wherever possible, as closely as possible to people doing the work."

6. Responsibility. "With authority comes responsibility, not only to accomplish tasks but to contribute to the [Institute's] culture. One responsibility I take on as director of NCI is the responsibility to back you up."

7. Administration serves science. "The administrative functions of NCI must serve the science. I do not believe there is any budget but the NCI's budget. Resources will be distributed based on an open and defensible process of scientific discussion."

8. NCI is a scientific institution. "NCI must model in its culture the principles and ethics of science: Respect for ideas and individual creativity, openness of discourse and scientific disputation, and conclusions and decisions that appeal to evidence of validity, not to authority."

Porter: NCI Exceeded Mandate In Tobacco Lobbies Study

NCI exceeded its mandate when it funded a study of the voting records of state legislators who accept campaign money from tobacco lobbies, Rep. John Porter (R-IL) said in a statement.

"This is not clinical or behavioral research, and should not have been funded through NCI," said Porter, chairman of the House Labor, HHS & Education Appropriations Subcommittee.

The study in question was conducted by Stanton Glantz, professor of medicine at the Univ. of California at San Francisco (**The Cancer Letter**, Aug. 4).

A spokesman for Porter confirmed that the language critical of the NCI funding for the project was inserted in the subcommittee's report on Porter's initiative.

Since the language appears in the subcommittee report rather than in the actual bill that was passed by the House last week, the Institute is merely advised—as opposed to mandated—to refrain from funding such studies.

According to critics, Porter and the subcommittee were in effect politicizing the NCI grant process.

"For the US Congress to politicize the decision as to what specific research is or is not funded, thereby circumventing the NIH peer review system which has been used so successfully for so many decades, is reprehensible," George Lundberg, editor of the Journal of the American Medical Association, said to The Washington Post earlier this week.

JAMA has published several papers that resulted from the grant.

A Porter spokesman said the congressman is firm in his belief that NCI was the wrong agency to fund the study.

"When this grant was brought to Rep. Porter's attention, he made an attempt to determine whether that grant was within the boundaries of the NCI authority, and came to the reluctant conclusion that it was not," Dave Kohn, Porter's spokesman, said to **The Cancer Letter**. "This study was not appropriate for NCI because it did not represent behavioral or clinical research."

Kohn said Porter learned about the study after receiving an inquiry from The Washington Times, a conservative newspaper. The Congressman's initial concern was to limit the damage to the Institute.

"To read between the lines, Mr. Porter's inclination was to send a message that this was a lapse of judgment that could conceivably backfire on NCI by giving ammunition to the opponents of tobacco research," Kohn said.

The language of the report does just that, Kohn said. "Had Mr. Porter felt like taking a swipe at NCI's grant-making in this area, the committee could have cut funding for this project, or inserted legislative language, or something heavy-handed like that."

Kohn said Porter, being a long-term proponent of tobacco control measures and a strong advocate of biomedical research, has no objection to the government's funding of Glantz's study.

"He is making a narrow point here, but one that he thinks is important," Kohn said. "It is inappropriate to fund a study of a political system through NCI. It is a grant that could have been funded through other accounts available to the HHS Secretary."

The appropriations bill approved by the House includes a $642 million increase in funding for NIH.

Managed Care Threatens Clinical Research, Panel Says

Federal funding constraints and managed care threaten to limit access to clinical trials and slow progress in moving new cancer treatments into clinical practice, the President's Cancer Panel said in a recent statement.

The panel, mandated by law to report to the President any barriers in the progress against cancer, issued the statement following a meeting in Chicago last month.

As the panel met to consider progress in the treatment of leukemia, witnesses testified that clinical research has had a tremendous impact on leukemia in both children and adults, but, because of recent changes in reimbursement, new treatments may no longer be able to enter the clinic quickly.

"Federal funding constraints and the impact of managed care on drug development, translational research, and clinical research threaten to stymie the kind of medical progress Americans have enjoyed for decades," Panel Chairman Harold Freeman said in a separate news release.

"The President's Cancer panel believes that cancer treatment options that are suboptimal but less expensive will be reimbursable, while innovative and improved therapies will not be testable due to lack of funds," Freeman said. "This is one of the greatest threats to the mission of the National Cancer Program since its founding in 1971."

New Effort By Panel

By issuing its statement July 27, the panel appeared to be making a new effort to draw attention to problems in the progress of cancer research. In recent years, the panel has issued few statements beyond its required annual report to the White House.

"The panel is greatly concerned that the rush toward managed care is squeezing payers, providers, and ultimately the recipients of care whose increasingly limited access to investigative clinical trials will jeopardize the future of medical care in this country," the statement said. "We, as the cancer research community, need to redouble our efforts to educate the public, the patients, the insurers, the community physicians, and particularly our lawmakers about the real value of supporting clinical research."

Leukemia research has shown that patients who participate in clinical trials have higher rates of remission and longer responses to treatment that patients who do not, Freeman said. "Access to clinical trials must be maintained and expanded for those patients who desire that treatment option."

"The federal government has played and must continue to play a unique role in funding and review of high risk or long-term research," Freeman continued. "Otherwise, we face the demise of medical progress as we know it. Privatization will not address this need and managed care with its cost containment focus cannot accomplish it."

The panel recommended that:

- The cancer research community should "review how it communicates the results of clinical trial outcomes and with whom."
- The work of professional societies, academic organizations, and federal policy makers should be coordinated "to provide consistent, rigorously reviewed, medically and scientifically sound, minimum guidelines for insurance support of health care—including clinical trials."
- A public-private partnership should be established "to forge incentives for providers, payers, and recipients of clinical care to participate in clinical trials, the benefits of which can be assessed through health outcomes analysis."

Program Announcements

PAR-95-081

Title: **Clinical Research Scholar Supplements To M01 Grants**

The National Center for Research Resources announces the Clinical Research Scholar Program, a junior career development program for physicians and dentists who have the interest and aptitude for careers in patient-oriented clinical research, but who have had limited formal clinical research training or career development. The Program is intended to support the candidate for one year of course work and research to enhance the career development of the individual. The candidate should work closely with a mentor who is a clinical investigator supported by peer-reviewed grant(s). The mentor must work with the candidate in selecting course work to complement laboratory and patient-oriented clinical research. Applications to the CRS Program are to be submitted as competitive supplements to existing General Clinical Research Center (GCRC) grants (NIH Activity Code: M01).

Inquiries: Harriet Gordon, General Clinical Research Centers Program, National Center for Research Resources, 6705 Rockledge Drive, Rm 6030, MSC 7965, Bethesda, MD 20892-7965, Tel: 301/435-0790, Email: HarrietG@ep.ncrr.nih.gov

PAR-95-082

Title: **Developing and Improving Institutional Animal Resources**

Application Receipt Dates: October 1, June 1

The National Center for Research Resources encourages the submission of individual animal resource improvement grant applications from biomedical research institutions. A related objective is to assist institutions in complying with the USDA Animal Welfare Act and DHHS policies related to the care and use of laboratory animals. Support is limited to alterations and renovations (A&R) to improve laboratory animal facilities, and the purchase of major equipment items for animal resources, diagnostic laboratories, transgenic animal resources, or similar associated activities. The mechanism available is the Grant for Repair, Renovation, and Modernization of Existing Research Facilities (G20).

The total budget request for the improvement grant application and award is limited to $700,000 (direct costs), of which not more than $500,000 may be used for A&R and not more than $200,000 may be used for moveable equipment. Matching funds from non-Federal sources are required, equal to or exceeding one-half of the total allowable costs (equipment and A&R) of the requested project ($1 Federal to $1 non-Federal).

Inquiries: Charles Coulter, Research Facilities Improvement Program, NCRR, 6705 Rockledge Dr., Rm 6030 MSC 7965, Bethesda, MD 20892-7965, Tel: 301/435-0766, fax: 301/480-3770.

RFP Available

RFP NO1-CP-61000-21

Title: **Record Linkage Studies Utilizing Resources In Population-Based Tumor Registries**

Deadline: Approximately Oct. 2

The NCI Div. of Cancer Etiology is recompeting to replace their existing pool of qualified Master Agreement holders for record linkage studies. NCI wishes to contract with population-based tumor registries in the US and in other countries in order to collaborate in the conduct of record-linkage and subsequent analytical investigations.

The duties required in support of the record- linkage studies include: develop a study plan which includes the evaluation of existing records that are potentially valuable for record-linkage, develop or apply the appropriate record-linkage procedures to link a "population file" with the cancer registry files, and provide results of the record-linkage study to the Project Officer either on computer tape or in tabulated form as requested. After the record-linkage study has been completed, it may be desirable to consider additional analytical investigations that require data beyond that found on computer tapes. Offerors should have cancer incidence data for all patients diagnosed within a defined geographic locale for at least five years during the previous decade, 1980-1989, and have the ability to ascertain all cancer cases within the registries' catchment area of women of all age groups and U.S. minority populations, as appropriate. The offerors must have experience in the collection of cancer data from a variety of medical sources and multiple institutions, and must have legal authority to collect medical data within the given geographic area or be able to demonstrate the willingness of all medical facilities within that area to participate in data collection and patient follow-up activities. Master Agreements will be awarded to all respondents whose technical proposal is considered acceptable. The initial Master Agreement award is non-monetary, and is exclusively for the purpose of establishing a pool of contractors who are qualified to perform services for epidemiologic studies of cancer utilizing the resources of population-based tumor registries. Each Master Agreement holder will be eligible to compete for contract awards to carry out specific record-linkage and subsequent analytical studies. Master Agreement holders receiving a contract award will be selected from among those with a Master Agreement who choose to compete for the contract awards to be solicited through this pool, based on tecnical merit and on budgetary considerations for the specific tasks involved.

Contracting Officer: Barbara Shadrick, NCI, RCB, Cancer Etiology Contracts Section, Executive Plaza South Rm 620, 6120 Executive Blvd MSC 7224, Bethesda, MD 20892-7224, Tel: 301/496-8611.