THE CANCER LETTER

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Report Redefines Cancer Control Research, Sets The Agenda For Newest NCI Division

In a report presented to the National Cancer Advisory Board, the Cancer Control Program Review Group specified how NCI could build an aggressive cancer control research program and suggested a new definition of cancer control research.

The report also endorsed NCI's decision to form the new Division of Cancer Control and Population Science.

"If only half of what we know today were fully implemented at every nook and cranny of society, there would be 1 million fewer cancers

(Continued to page 2)

In Brief

Carnegie Mellon President Emeritus Honored By UPCI; Schiffer Leaves Maryland For Detroit

RICHARD CYERT, president emeritus of Carnegie Mellon University, has received the University of Pittsburgh Cancer Institute's Arthur McNulty Civic Leadership Award. The UPCI Cyert Chair in Molecular Oncology was established earlier this year, and the Richard Cyert Center for Molecular Oncology is currently under development. Cyert is a cancer patient at UPCI and serves on the technology transfer committee of the Institute's Council. UPCI awarded the Leo Criep Excellence in Patient Care Award to **Margarita Silverman**, former assistant professor of medicine in the Bone Marrow Transplant Program at the University of Pittsburgh Medical Center Health System, in recognition of her work with leukemia and lymphoma patients. **Dianne Fletcher,** a nurse clinician with the Joint Breast Program of UPCI and Magee-Women's Hospital, received the UPCI Excellence in Patient Care Award for her work with breast cancer patients. **Michael Lotze**, professor in the departments of surgery, molecular genetics, and biochemistry, and co-director of the UPCI Experimental Therapeutics Program, received the institute's Scientific Leadership Award for his work on the development of biological and gene-based cancer therapies. . . . **CHARLES SCHIFFER** was named director of clinical research at the Barbara Ann Karmanos Cancer Institute. Schiffer was also named chief of the Division of Hematology and Oncology, and professor of medicine at Wayne State University School of Medicine. He is the former head of the Division of Hematologic Malignancies at the University of Maryland

(Continued to page 8)

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NCI Needs "Vigorous Effort" In Cancer Control, Report Says

(Continued from page 1)

diagnosed every five years," David Abrams, chairman of the review group and professor and director of the Center for Behavioral and Preventive Medicine at Brown University School of Medicine, said to the NCAB at a meeting Sept. 25. "We have an enormous opportunity to reduce the cancer burden in our lifetime and for our children."

Barbara Rimer, director of the new division, said the report's recommendations are consistent with her goals (see story, page 5).

"The review group recommends that NCI pursue a vigorous effort to exploit existing and emerging opportunities in behavioral cancer prevention and cancer control," the report said.

"Given what is now known about the often decades-long natural course of cancer, NCI must make a long-term commitment to develop a more balanced partnership between the biomedical and behavioral/public health paradigms to continue to reverse the upward trend in cancer mortality observed over the past century," the report said. "Moreover, research should aim to reduce the burden and improve the quality of life of those who will get cancer despite our best efforts."

According to the report, NCI should:

- Create a unit focused on basic behavioral and social research within the new Division of Cancer Control and Population Science.
- Create a research focus in informatics and communication.
- Establish programs that recognize the role of behavioral prevention across the lifespan.
- Increase integration of and support for cancer screening research.
- Create a research focus on rehabilitation and survivorship.
- Establish research links to various health care delivery systems.
- Expand cancer surveillance and produce a "cancer report card."
- Maintain strong support of biometry and applied research within the new division.
- Focus research efforts on underserved populations and those with a disproportionate cancer burden.
- Expand training in cancer control research.

The report, "A New Agenda for Cancer Control Research," was presented in draft form to the NCAB. The report will be finalized after presentation to the NCI Board of Scientific Advisors next month, NCI sources said.

Defining Cancer Control

The review group, one of five panels of external advisors formed by NCI over the past year to study the Institute's major research programs, found that its first task was to define cancer control research, Abrams said to the NCAB.

The NCI Division of Cancer Prevention and Control, which was split apart in the reorganization creating the new cancer control division, has defined cancer control over the past 15 years as, "the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad systematic application of the research results," the report said.

This 1985 definition by DCPC Director Peter Greenwald and the late deputy director, Joseph Cullen, put cancer control on NCI's agenda and has withstood the test of time, Abrams said.

The review group found another definition of cancer control research in the NCI Bypass Budget (FY97-98): "Cancer control research bridges the gap between laboratory, clinical and population-based research, and health care by focusing on how to bring our discoveries to the practice of cancer prevention,

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detection, treatment, and rehabilitation."

Thus, the report said, "The review group identified a tension between alternative views of the scope of cancer control research, such as the view that cancer control research should focus on behavioral sciences to the exclusion of biomedical research, and the view that cancer prevention research should be directed at apparently healthy populations and cancer control research to those with clinically overt cancers."

The committee developed its own definition: "The review group defines cancer control research as the conduct of basic and applied research in the behavioral, social, and population sciences that, independently or in combination with biomedical approaches, reduces cancer risk, incidence, morbidity, and mortality."

According to the report, the new definition clarifies that, "cancer control research works best when it cuts across biomedical and behavioral/public health paradigms."

Specific recommendations of the cancer control review group's report follow:

Informatics and Communication

—Develop and fund research on multiple applications of communication and informatics for cancer control, including a) use of Web-based and other electronic-based systems to enhance current and future cancer control activities; b) creation of a cancer control expert system, including a knowledge base and expert rules that can be rapidly updated for a variety of users; and c) development of walk-up systems (e.g., kiosks) for cancer control communications and determination of optimal locations for placement in public spaces.

—Assess and analyze use of different information delivery systems for cancer control, including: a) user participation; b) user feedback; and c) system effectiveness in cancer control.

—Collaborate with the Cancer Information Service and other organizations in areas such as: a) evaluating mass media campaigns in terms of penetrance into a population; b) conducting "natural experiments," such as the impact of tobacco legislation on motivation and successful smoking cessation; c) reaching underserved populations; and d) linking the resources of CIS with extramural research at NCI-designated cancer centers, Community Clinical Oncology Programs, and programs involved in detection, treatment, rehabilitation, and survivorship.

—Extend the work of tailored communications beyond tobacco control and diet to other applications in cancer prevention and control.

Behavioral Prevention Across the Lifespan

—Create a Tobacco Control Program as a separate and distinct entity in the new Division of Cancer Control and Population Science, with a strong chief to assist in developing a research-based tobacco control plan for the nation.

—Create a Diet and Exercise Program with a new chief as a separate and distinct entity in the new division to assist in developing a research-based cancer control plan for the nation.

—Place high priority on interventions with children and youth, in order to establish preventive behaviors for the next generation.

—Establish formal mechanisms to: a) ensure the orderly transition of proven interventions, such as ASSIST and 5-a-Day, into public health policy and broad community dissemination; and b) track the fidelity and penetration of these model programs using enhanced monitoring and surveillance "report cards."

—Support the development and testing of interventions tailored to the specific needs of populations with high prevalence of behavioral risk factors, including those with lower income and lower education, and specific ethnic groups at known high risk for cancer.

—Evaluate the impact of policy and other system changes on risk-related behaviors and reduced exposures to carcinogens (e.g., tobacco policy and regulation). Research is needed to identify effective policy and systems changes that may influence both behavioral risk factors as well as potential environmental and occupational exposures to carcinogens.

—Establish specific criteria and oversight for making commitments to large-scale and long-term community trials.

—Include new tracking systems as part of the new "report card" within SEER and other surveillance systems to monitor organizational mediators and psychosocial factors that facilitate or impede behavioral lifestyle change in youth and adults.

Cancer Screening Research

—Provide a base for screening research in the

new DCCPS and assure access to clinical cooperative groups as well as to a critical mass of investigators with expertise in biometry, outcomes research, and basic and applied behavioral science.

—Ensure that the new deputy director for extramural science coordinates research on cancer screening throughout NCI.

—Develop mechanisms to assist decision-making regarding the initiation of randomized clinical trials of screening technologies.

Rehabilitation and Survivorship

—Conduct research on how to best quantify, prevent, and treat the immediate and long-term physical and psychological symptoms that result from cancer and its treatment.

—Examine the role of psychological factors, decision-making, and secondary prevention strategies, through lifestyle change and social support, in improving quality and quantity of life and slowing or arresting cancer recurrence.

—Develop a common indicator of cancer morbidity across cancer types to place morbidity data on par with incidence and mortality data.

Links To Health Care Delivery Systems

—Support research on large-scale interventions within health care systems to introduce or improve the delivery of cancer prevention in general, and cancer prevention and control services in particular, not only for those who seek medical care, but to the broader insured population.

—Strengthen the in-house research capability of NCI in applied cancer control research. This requires including health services and health policy research as part of the perspective of cancer control. Additional professional expertise in the area of health services, economics, and health policy research are needed.

—To facilitate the development of behavioral prevention and control research relevant to community-based activities: 1) explore with the Community Clinical Oncology Program the development of new organizational constructs, including a cancer control cooperative group; and 2) revise existing guidelines and incentives for behavioral prevention and control trials within existing cooperative groups.

Cancer Surveillance

—Expand the SEER program to include additional populations, more data from patients' medical records and patients themselves, and population data from the SEER regions to monitor individual and society mediators of cancer.

—Use the SEER expanded data and expertise to produce a timely report card on the cancer burden.

Biometry and Applied Research

—Maintain and strengthen the Biometry and Applied Research Branches within the new division.

—Add additional expertise in behavioral, social, genetic, economic, and related methodologies to the branches.

Underserved Populations

—Recruit a strong, visionary chief for the Special Populations Studies Branch.

—Provide the branch with the authority and resources to:

a) develop a program of extramural intervention research targeted to the needs of underserved and high-risk populations;

b) recruit social, behavioral, and population scientists capable of conducting fundamental and applied research to facilitate the research efforts of extramural investigators; and

c) expand the surveillance of risks, service utilization, barriers to cancer care, and measurement of incidence, morbidity, and mortality using SEER and other data sources in an effort to identify gaps in research and the cancer prevention and control needs of underserved and high-risk populations.

Training In Cancer Control Research

—Expand the extramural training/education programs with specific set-aside funds for cancer control research and institute systematic tracking mechanisms to follow trainees over time.

—Incorporate cancer control research in training programs for clinical and basic scientists, including areas such as basic behavioral science, epidemiology, health services and outcomes research, cost-effectiveness research, survivorship and quality of life research, screening and treatment, and adherence.

—Expand the T32 funding mechanism to including training in cancer prevention and control research.

—Investigate ways to promote the minority training programs to increase the number of applications.

Rimer: Cancer Control Report Consistent With Plans, Goals

CHAPEL HILL, NC—The report of the Cancer Control Program Review Group will serve as a blueprint for the new NCI Division of Cancer Control and Population Science as the division begins to build upon existing programs and develop new research initiatives, the director of the new division said last week.

Barbara Rimer, former chairman of the National Cancer Advisory Board, said the cancer control report is consistent with her goals as director of NCI's newest division. Rimer will work part-time at NCI for two months while phasing out of her position as director of cancer control research at Duke University Medical Center.

"There is a new appreciation of the importance of basic science as part of the cancer control mix," Rimer said to the annual meeting of the Association of American Cancer Institutes, held last week at the Lineberger Comprehensive Cancer Center at the University of North Carolina, Chapel Hill. "There is a continuum with many points for intervention along the way, and we are going to be looking for opportunities to develop interventions to increase our understanding of cancer control, among different populations, from relatively high-risk populations to cancer patients."

The new division will bring together the existing NCI extramural programs in epidemiology and genetics, behavioral research, surveillance research, and the Office of Cancer Survivorship. "This is a fundamental change in how cancer control is organized at NCI, and a very important change," Rimer said.

Rimer listed several goals for the division and areas of expansion of existing programs, but she warned the cancer center directors and administrators attending the meeting that the list is preliminary. "I wouldn't write any grants yet based on what I tell you," she said.

Rimer said the division's goals will be to:

—Reduce barriers to communication and collaboration between programs and branches.

—Emphasize evidence-based medicine and public health.

—Encourage a two-way street for sabbaticals to bring outsiders in to the division and take the division's staff out to other institutions.

—Encourage a full spectrum of research, from basic research to dissemination and policy research, and "broker" dissemination to other organizations such as the Centers for Disease Control.

—Minimize barriers between the division and the extramural community.

—Encourage cross-divisional planning and implementation.

—Recruit and retain active scientists.

—Encourage constructive self-criticism and strive for excellence.

In epidemiology and genetics, the division's greatest responsibility over the next year will be to launch the Cancer Genetics Network, Rimer said.

Rimer said other areas for expanded research, some of which are included in the cancer control review group report, include:

—Interactions between genetic and metabolic factors with lifestyles and social/behavioral factors.

—Genetic prevalence.

—Estimates of exposure.

—Basic biobehavioral research, studying, for example, the process by which teens become addicted to smoking, and developing basic tools for intervention.

—Expand the Surveillance, Epidemiology and End Results program.

—Strengthen tobacco research.

—Strengthen research on intervention and surveillance regarding underserved populations.

—Begin new programs in colorectal cancer screening and surveillance.

—Strengthen survivorship programs.

—Increase emphasis on research related to physical activity and dietary changes.

—Provide a "report card" to the nation on the status of cancer-related behaviors and cancer incidence and mortality.

—Increase attention to health communications, including risk communication.

—Expand initiatives related to informatics and use of "new media."

—Revise/expand training programs with emphasis on "cross-training," from basic biology of the disease to intervention.

"This is just the beginning of discussions with you, and I hope you will feel comfortable calling, e-mailing, writing—whatever your personal style of communication," Rimer said to the cancer center directors. "We really want this to be the program of the country, and not a program that stays only in Washington."

Patient Advocacy

Congress Delivers Symbolism, No Real Solutions, Visco Says

The 105th Congress has been generous with non-binding resolutions and other symbolic gestures involving breast cancer, but has not produced more meaningful legislative measures capable of reducing the burden of the disease, Fran Visco, president of the National Breast Cancer Coalition, said at a congressional luncheon last week.

"While we appreciate the resolutions, we also recognize that a resolution does not get health care for an individual woman, a resolution does not get quality standards for mammography out there to the public," Visco said, citing the examples of resolutions in support of breast cancer awareness month and the breast cancer research stamp.

"It is important to show your support, but we also recognize that the substantive issues are still out there and have not yet been enacted," Visco said at the Oct. 8 event, which was co-sponsored by Sens. Tom Harkin (D-IA) and John Warner (R-VA).

Visco said the coalition is aggressively lobbying for legislation that would guarantee coverage of breast cancer treatment for women diagnosed through the Centers for Disease Control Breast and Cervical Cancer Control Program. The CDC program screens for breast and cervical cancer, but will not treat the cancer once it is diagnosed. The absence of follow-up care has frightened many women away from the CDC program and cancer screening, Visco said.

NBCC lobbied to include in the Budget Reconciliation bill a provision that would expand the Medicaid program to include breast cancer treatment diagnosed by the CDC program. The Senate version of the bill included a provision that would allow each state with a CDC program to decide whether to use Medicaid to cover cancer treatment.

The provision was removed from the Budget Resolution bill during final negotiations between the House and Senate.

"There was such support articulated for the idea, but it didn't happen," said Visco. "The breast cancer research stamp happened, but this didn't happen."

"We think that's a real problem," Visco said.

The Stamp Out Breast Cancer Act requires the U.S. Postal Service to establish a first-class postage stamp with a higher rate than standard postage. Postal Service patrons would be able to purchase the more expensive stamp to contribute funds to breast cancer research.

The bill, which was not endorsed by NBCC but supported by several other breast cancer groups, passed the House by a vote of 422-3, and the Senate by unanimous consent. President Clinton signed the bill into law in August.

The NBCC agenda includes the following measures:

- The Breast Cancer Patient Protection Act (HR 135/S 143), a bill that requires health insurance to cover minimum hospital stays for mastectomies and lymph node dissection.
- The Reconstructive Breast Surgery Benefits Act (HR 164/S 609), a bill that requires health insurance to cover the cost of reconstructive breast surgery resulting from a mastectomy covered by the company.
- The Genetic Information Nondiscrimination in Health Insurance Act (HR 306/S 89), a bill that prevents health insurers from changing or denying coverage based on genetic information.
- The Breast Cancer Early Detection Act (HR 418), a bill that would provide Medicare coverage for annual mammography screening.
- The Mammogram Availability Act (HR 617), a bill that would ensure that no insurance plan can deny coverage for annual mammograms for women 40 and older.
- The Mammography Quality Standards Reauthorization Act (HR 1289/S 537), a bill that revises and extends the current program.
- The Medicare Cancer Clinical Trial Coverage Act (HR1628/S 381), a bill that establishes a demonstration project for Medicare to pay patient care costs for cancer patients enrolled in a clinical trial.
- The National Fund for Health Research Act (S 441), a bill that establishes a national fund to expand the nation's investment in medical research.

"I look at the list of bills that the National Breast Cancer Coalition, after much research and discussion, feels deserves your support, and I see that nothing has been enacted over the last year," Visco said. "That, as you can well imagine, is a fundamental disappointment."

NBCC is seeking $590 million for NIH breast cancer programs, which, according to the coalition's estimate, received $430 million in fiscal 1997. According to NIH estimates, breast cancer programs received $401 million last year. The 1998

appropriations bill, which is now in conference, is expected to contain an increase of 5.2 to 7.5 percent for NCI.

The Department of Defense peer-reviewed breast cancer research program received $135 million in the 1998 appropriations bill. NBCC requested $175 million for the program.

Last year, the program, which was founded as a result of lobbying by NBCC, received $100 million.

Cancer Policy

Health Care Cost Containment Impedes Research, Panel Says

Recent changes in the health care system have resulted in a loss of financial support for cancer research and training within clinical research centers, and limited care for the socioeconomically disadvantaged, the President's Cancer Panel said in a recent report.

The report details the panel's findings from four hearings during 1996 on the effects of managed care on cancer research, care, and training. The report was submitted to President Clinton last July, and publicly released last month.

"Recent and ongoing health system changes are demanding too high a price from the more than 1.3 million people diagnosed annually with cancer and the remainder of Americans at risk," the report said. "Short-term and short-sighted cost containment can and will impede the progress of the National Cancer Program in reducing the national cancer burden."

The panel's concerns about the impact of managed care on cancer research include: loss of patient care income to pay for cancer care for the indigent; limited patient access to cancer care due to complex approval processes and the exclusion of investigational therapies; and growing disincentives for physicians to conduct clinical research and to train future researchers.

"Managed care has made positive contributions to the health care landscape—breaking runaway health care costs, accentuating the need for evidence-based medical care, and addressing the need for certain preventive services," the report said. "It appears, however, that these positive influences are not without their costs."

The panel made the following recommendations to control managed care's negative impact on the quality of cancer care:

- "Measures must be taken to ensure that minorities, the poor, the elderly, the uninsured, and the under-insured are not excluded from access to appropriate cancer care as the health care system evolves.
- "Both the importance of and the ability to participate in all phases of clinical trials should be formally incorporated into the standards of care for cancer; appropriate trial participation should be an integral component of clinical guidelines for specific malignancies, and the ability to access such trials, when appropriate, should be independent of health care provider. Criteria are needed to define clearly the required review processes, objectives, and other characteristics of clinical trials acceptable for patient care cost reimbursement.
- "This coverage should be guaranteed through legislation and/or negotiated agreements at the Federal and state levels.
- "The costs of clinical research must be paid in order for the quality of health care to continue improving. These costs must be paid regardless of the structure and financing of the health care delivery system. All of the beneficiaries of clinical research—managed care and other payers; research sponsors including government, voluntary agencies, and the pharmaceutical and biotechnology industries; employer and employee participants; and other consumers—must bear their fair shares in its cost.
- "Given the evolving health care financing and delivery systems, mechanisms must be established to ensure support for the training of clinical cancer care givers and researchers. This crucial intellectual resource and our Nation's world leadership in cancer research and care must not be allowed to deteriorate in the interest of short-term cost savings.
- "Partnerships among the pharmaceutical and biotechnology industries and the public and other private (e.g., voluntary) research communities should be encouraged, but as a Nation, we must ensure that the questions with the most scientific potential, as well as those offering the greatest economic return, are addressed.
- "The process for appealing coverage decisions made by health plans must be simplified, standardized, and fully disclosed to participants in health plans of all types. Appeal decisions must be rendered expeditiously.
- "Consumer education at all levels—e.g., employers and the public—is needed to promote an understanding of the importance of clinical cancer

research and a realization that the need to access such care can become a reality for any person. This understanding is needed to create public demand for access to effective cancer care and to foster health system competition based on access and quality rather than on cost alone."

The report, "Fighting the War on Cancer in an Evolving Health Care System," is available from the NCI office of the executive secretary of the President's Cancer Panel, tel: 301/496-1148, fax: 301/402-1508, email: PRESCAN@nih.gov.

In Brief

(Continued from page 1)

Cancer Center. . . . **PETER GREENWALD**, acting director of the NCI Division of Cancer Prevention, received the Outstanding Research Award from the American Institute for Cancer Research last week. Later this month, Greenwald will receive the Cancer Treatment and Research Foundation Public Service Award, and in November will accept the American Cancer Society's Distinguished Service Award. . . **CORRECTION**: In a story in the Oct. 10 issue, **The Cancer Letter** incorrectly reported the status of historically black colleges and universities in relation to applying for federal grants and contracts. HBCUs do not qualify as disadvantaged small businesses, and are not eligible for Small Business Administration set-asides. These institutions compete for federal contracts the same way as other institutions of higher education. Participants at an NCI seminar were urged to stay in contact will federal small business managers to receive technical guidance.

Funding Opportunities

UICC Seeks Nominees For Athayde Cancer Prize

The International Union Against Cancer is accepting nominations for the 1998 Múcio Athayde Cancer Prize.

The $150,000 award will be given to a qualified candidate who has had a worldwide impact through a discovery or significant contribution in basic research, clinical investigation, or cancer control and epidemiology.

To qualify for the prize, candidates must have carried out the nominated work for the last 10 years. Earlier work will be accepted for contributions that were only recently recognized.

Candidates are nominated by a person qualified to appreciate the discovery. The nomination must be presented in a three-page memorandum describing the candidate's contribution and its relevence to the award.

Deadline for nominations is Dec. 31. The selection committee will meet in January to decide the winner, and the award will be presented at the UICC International Cancer Congress in Rio de Janeiro next year.

Nominations should be marked "confidential" and sent to Secretariat of the Selection Committee, c/o Executive Director, International Union Against Cancer, 3 rue du Conseil-General, 1205 Geneva, Switzerland.

The full text of the call for nominations is available on the UICC website at www.uicc.ch/congress/athayde.

Program Announcement

PA-97-109

Title: **Clinical Epidemiologic Studies in Hereditary Breast/Ovarian Cancer**

Deadline: R01 applications Feb.1, June 1, Oct.1, 1988; Competing Supplement applications March 1, July 1, Nov. 1, 1998.

The NCI Division of Cancer Epidemiology and Genetics invites investigator-initiated grant applications (R01s) and applications for competing supplements to existing NIH-funded research project grants (R01s, P01s) or cooperative agreements (U01s, U10s) for innovative epidemiologic studies to address clinical issues facing women with inherited predisposition for breast and/or ovarian cancer.

With increasing public awareness of genetic contributions to cancer risk and the commercial availability of testing for mutations predisposing to breast and ovarian cancer, women at inherited risk for these cancers must make decisions about preventive interventions--and often cancer-directed therapy--with only limited scientific information about the natural history of disease associated with predisposing mutations, the efficacy of prophylactic surgery and other preventive measures, and the appropriateness of standard oncologic care for cancers developing in mutation carriers. While prospective studies will eventually provide definitive answers to these questions, there is an immediate need to address these issues through retrospective studies based on existing resources such as tissue banks and high-risk clinic registries and through concurrent studies added to ongoing clinical or epidemiologic research projects.

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