

**University of California
Breast Cancer Research Council
Breast Cancer Research Program**

Meeting Minutes

March 28, 1994

300 Lakeside Drive, Oakland

Council Members Present: Lisa Bailey, Christopher Benz, Leah Cartabruno, Susan Claymon, William Comer, Adeline Johnson Hackett, Barry Hirschowitz, Deborah Johnson, Liana Lianov, John Link, Andrea Martin, Edith Perez, Carol Pulskamp, Susan Shinagawa Smith

Council Members Absent: Patricia Ganz, Mary Claire King

UC Staff: Adele Amodeo, Julie Chesnutt, Samuela Evans, Charles Gruder, Cornelius Hopper, Beverly Pachner

Invited Guest: John Young

Welcome and Introductions

Cornelius L. Hopper, M.D., the University of California (UC) Vice President-Health Affairs, welcomed members to the first meeting of the Breast Cancer Research Council (BCRC). Dr. Hopper expressed his enthusiasm for the upcoming partnership between the Council and the University. Nominations for the Council were solicited from 225 institutions and over 90 highly qualified individuals were nominated. The Council, as constituted, represents remarkable breast cancer expertise and commitment which, when paired with UC's experience as the research arm of the State, will be critical in shaping and implementing an effective Breast Cancer Research Program (BCRP) to pursue research into the cause, cure, treatment, earlier detection, and prevention of breast cancer.

The Legislature has high expectations for the Research Program. The mechanism for appropriating BCRP funds collected through the new tobacco tax in the current fiscal year (between 1/94 and 6/94) will be a "deficiency appropriation" to the University after the May budget revise. The Program will have no actual operating funds until this appropriation is made, historically in July. The Governor's FY 94-95 budget contains a BCRP appropriation to UC based on tobacco-tax revenue projections for next year.

Each BCRC member introduced him/herself, briefly describing his/her background and interest in breast cancer research. Members expressed enthusiasm for their service to the Council and its role in shaping the Breast Cancer Research Program.

Background Briefing on UC Management of Statewide Research Programs

In addition to research performed through UC's general budget, several special research and related programs are administered by the Office of the Vice President-Health Affairs. These programs include the Academic Geriatrics Research Program, the Northern and Southern California Centers on Occupational and Environmental Health, the Universitywide AIDS Research Program, and the Tobacco-Related Disease Research Program. They each have their own histories and differ slightly administratively, but they have a number of common features which include: broad-based statewide advisory committees; core policies and procedures on administration, conflict of interest, and confidentiality; evaluation of proposals using the NIH peer review model; awarding grants UC-wide or statewide; limits on administrative expenses; and substantial political sensitivity. The BCRP will also be housed in the Office of Health Affairs. Dr. Hopper encouraged the Council to build on this accumulated UC experience and systems resources in addressing BCRP's unique program elements.

Dr. Charles L. Gruder, appointed as the Interim Director of the BCRP, is the Director of UC's Tobacco-Related Disease Research Program (TRDRP). TRDRP's Annual Report was included in the background information packet sent to Council members. Dr. Gruder briefed the Council on TRDRP's history and walked the group through a handout, which included a flow chart of how research awards are made, as well as time-lines of TRDRP grant award and grant monitoring processes. TRDRP has evolved through four annual grant cycles, refining its priorities and operational mechanisms. Grants awarded in TRDRP's first grant cycle in 1989 expended the first 30 months of tobacco surtax revenues (\$70 million); since then, cycles have averaged about \$25 million a year.

There are many similarities between TRDRP and the BCRP, as outlined in the BCRP's authorizing legislation, AB 2055. The language of AB 2055 is very similar to TRDRP's authorizing legislation (SB 1613 of 1989). Both Programs are funded through tobacco taxes, a declining revenue source. Both have statutorily defined advisory committees. Both Programs are required to coordinate their research efforts with the cancer control activities of the Department of Health Services. The BCRP will also have to go through the processes of hiring a staff and creating mechanisms for establishing research priorities, notifying the research community of the program, recruiting peer reviewers and evaluating proposals, awarding grants, monitoring finances and research progress, and disseminating research findings. Members raised many issues that the Council will have to address in the coming months, including the timing and number of grant cycles it wishes to have, how it can encourage proposals from students and private sector organizations, how it will deal with patent rights in compliance with State and Federal law, and how it can monitor political developments that may impact the Program.

Review of the Breast Cancer Act of 1993

John Young, Legislative Director to Assembly Member Barbara Friedman, was invited to brief the Council on the legislative history of AB 478 and AB 2055, the Breast Cancer Act of 1993. A copy of AB 2055 was distributed to members. AB 478 established the Breast Cancer Fund by

raising the State tobacco tax by 2 cents per pack, and AB 2055 established guidelines for expenditure of the Fund. Fifty percent of the proceeds from this Fund is to be used for the Breast Cancer Control Program, established in the Department of Health Services (DHS) to provide early breast cancer detection services for uninsured and underinsured women. Five percent is to be used by DHS's Cancer Surveillance Section for collecting breast-cancer-related data and conducting epidemiological research by the State cancer registry. The remaining 45% is to be allocated to UC to establish the Breast Cancer Research Program, "for the awarding of grants and contracts to researchers for research with respect to the cause, cure, treatment, prevention, and earlier detection of breast cancer and with respect to the cultural barriers to accessing the health care system for early detection and treatment of breast cancer."

The passage of this Act was a significant feat. It contained the first cigarette tax increase to pass the Legislature in 27 years and created the most extensive breast cancer program ever launched by a state. The idea for the Act was conceived in December of 1991, and despite a strong lobbying campaign, the first legislative effort was defeated on the Assembly floor in August 1992, during the State's long budget impasse. AB 478 was reintroduced in February of 1993, and a lobbying strategy, including grassroots, Sacramento, and press activities, was undertaken to try to create a climate that would encourage the Legislature to pass the bill. A great deal of energy was unleashed, and after a long debate on the Assembly floor, the bill passed with the bare minimum of 54 votes in June 1993. Because of this slim margin, all amendments on the Senate side were placed into AB 2055, so that the tax provisions would not have to be reconsidered by the Assembly. The Senate focused on the programmatic aspects of the Act, amending the distribution of the dollars to prioritize access to services and research. Once the bills passed the Legislature, intensive effort was focused on convincing the Governor to sign the bills. An editorial in the San Francisco Chronicle and other factors led to his signature.

Mr. Young stated that the legislative intent of this Act regarding the types of research to be funded was carefully articulated in AB 2055. The intention is for the Council to examine and consider a broad range of research. In addition to those areas listed, he hopes the Council will examine the link between breast cancer and pesticides and other environmental carcinogens. The expertise of Council members will help the Program focus on areas where it can make the greatest contribution.

There were many early discussions about which State entity should manage and oversee the research program. The responsibility ultimately fell to UC because it is a world class research institution with experience managing grants of this magnitude. These discussions were followed by discussions as to what the relationship between the Council and UC should be. The legislative intent is for a vital partnership between UC and the Council. The Council's composition, including representation from survivors and advocates, the private sector, non-profits, scientists, and clinicians, establishes built-in tensions that will hopefully be a source of creativity to the Council in making its research agenda as effective as possible. Although ultimately advisory to UC, the Council's responsibilities for setting strategic objectives and priorities, using the members' networks to recruit researchers and proposals, working with UC to do outreach and establish appropriate peer review panels, and making funding recommendations based on

research priorities and scientific merit, are critical to the Program's success. Mr. Young encouraged the Council to make a serious attempt to set criteria by which the Program can be periodically evaluated. He also urged members to be involved in translating research to help real people. He hopes that the Program will become a national model of an effective, cutting-edge effort.

Mr. Young addressed questions from members regarding the problems inherent in funding the Program from a declining revenue source such as a tobacco tax, and what the long-term funding scenario looks like for the Program. Dr. Hopper has received indications that the program is in line to receive the current-year \$7 million deficiency appropriation around July 1, and Mr. Young indicated that he felt the \$17 million budget appropriation for FY 94-95 dollars is relatively secure. The Council will need to decide how to encumber those funds to multi-year research projects to give the Program maximum stability. Mr. Young encouraged the Council to be vigilant about securing the Program's funding. Drafters of the Act knew that the tobacco tax, as a declining revenue source, would be a major long term problem for BCRP support, but saw no other source of funding. Tobacco tax revenues are now projected to decline at approximately 4% per year, but if President Clinton succeeds in raising the federal tobacco tax by 75 cents, it would have a much more significant effect on the revenues for this Program. Hopefully, there will be sufficient revenues for four to five years, at which time the Program will have established its worthiness and additional sources of revenue can be pursued.

Council members expressed their gratitude to Mr. Young for his pivotal role in bringing the Breast Cancer Act to fruition. Assembly Member Friedman and Mr. Young will be available to the Council for information in the future.

Council Organization

AB 2055 is relatively specific in spelling out the functions of UC and the Council. Because the Council is to be self-governing, it must decide in the near future how to structure itself to carry out its responsibilities. As convener and chair of the Council's initial meeting, Dr. Hopper suggested, and the Council agreed, that a working subcommittee of four members be appointed to meet within the next three weeks. The subcommittee's charge would be to identify and bring back to the Council recommendations, and perhaps options, on various organization and governance issues such as leadership, voting, public participation, confidentiality of grant proposals, etc. The subcommittee will also discuss the need for written bylaws. The full Council could then respond to the subcommittee's recommendations and adopt working guidelines at its May meeting.

Ms. Pulskamp expressed concern that Council membership should include an African-American woman, and offered to postpone her own membership to assure such representation. Dr. Hopper expressed his appreciation and indicated that he would meet with her to discuss this further.

Approaches to Establishing Breast Cancer Research Program Priorities

A discussion document was circulated which outlined various issues the Council may wish to consider before setting priorities. Issues included: statutory requirements for the funded research, including addressing new and innovative approaches and not duplicating other research efforts; whether research priority areas should be focused on disease or treatment processes or scientific disciplines; and possible priority-setting procedures, including holding meetings and taking advantage of the research policy work already underway.

Council members expressed their desire to build on the existing work and priority-setting efforts of the Department of Defense, the National Cancer Institute, the Institute of Medicine, and the Department of Health and Human Services. An effort will be made to assemble documentation from these various sources to circulate to Council members. Council members who have copies of these reports or other information they would like to share with the full Council should get them to Beverly Pachner for distribution before the next meeting. The Council was also interested in the possibility of having Council members who participated in these various efforts report on their experiences. A suggestion was made that because of its completeness, the Institute of Medicine report to the Department of Defense be used as a basis to stimulate the Council's own decision-making process.

Relative to the discussion document, members seemed to lean towards establishing priorities with a process (e.g., etiology, prevention, treatment), rather than a disciplinary focus, hoping to promote interdisciplinary cross fertilization. In addition to those issues raised in the document, members raised many questions that the Council will need to consider in choosing its priorities. They included: how the Program's priorities can be set to work most synergistically with DHS's cancer control efforts and efforts to build a breast cancer infrastructure in California; how to assure that the Program's research is appropriately focused and cost effective; how the Program can take advantage, and address the special problems of, California's diverse population; how to engage scientists in explaining the relevance of their research to breast cancer in the application process; how to balance basic science versus applied research ultimately to produce results and push the edges of current knowledge; how to target efforts and pay special attention to relevance and yet define priorities broadly enough so as not to exclude good research that may be productive in the future; how and whether the California Program should differentiate itself from other research efforts nationally; how to assure that only high-quality research is funded in priority areas; and how the Program can most effectively promote the transfer of research into marketable and useful technologies and other applications.

Council members suggested bringing in speakers from federal and state programs (e.g., the California Department of Commerce) to discuss their efforts to facilitate the translation of research into marketable products. Such products would not only benefit breast cancer patients, but could enhance the State's economy. It was suggested that this might prove to be a way to fund the BCRP in the future. Some biotech research projects are in more advanced stages of development and the Council should consider how it can assist in bringing the process to fruition by getting products into clinical trials, etc.

The Council discussed at length the trade-offs between getting the Program started quickly and taking the time to be sure Program priorities are well-defined and that all necessary procedures are in place. Central to the planning process is determining a timetable for establishing the Program, based on when monies are available and when the first Call for Applications will be issued. According to the TRDRP grant process time-line, to award grants by the summer of 1995, the Program will have to set priorities, hire a staff, prepare application forms, recruit study section chairs, develop a mailing list, and issue a Call for Applications by this September, six months from now. Although a calendar year cycle or a system with multiple cycles throughout the year are possible, there may be practical problems. However, a time-line that is staggered from TRDRP cycle deadlines might be wise because of demands on staff.

Various timing strategies were discussed. Many felt that the Council needs to spend the time at the outset to define its priorities carefully, because the parameters chosen on research areas and on the amounts and lengths of possible awards will determine the kinds of proposals and researchers the Program will attract. Others felt that the Council should initially solicit applications broadly, believing that the Council will be unable truly to focus its priorities until it has received a round of proposals and is able to consider their merits and make concrete funding decisions. Suggestions were made to move forward right away with something for which the Council could readily determine priorities, while setting aside the balance of funds for a slower cycle for areas for which priorities are more difficult to determine. One suggestion was to allocate the first \$7 million from FY 93-94 for an early grant cycle, and then further evaluating priorities before allocating the FY 94-95 funds. Other suggestions to speed results were to focus initially on funding projects that are already underway, and to consider proposals peer-reviewed but not funded by the DOD process. An update on Program implementation will be needed for legislative oversight hearings in late April or May.

Status of Implementation of DHS Breast Cancer Early Detection Program

Liana Lianov, MD, MPH, Director of the DHS Cancer Detection Section, shared a summary handout and reported on DHS's progress in implementing the services component of the Breast Cancer Research Act. DHS's Breast Cancer Advisory Council held its first meeting Monday, March 21. In addition to Dr. Lianov, three members of the research Council also serve on this Committee. The Committee has started two work groups, one on outreach and one on eligibility.

The goal of DHS's Breast Cancer Early Detection Program is reduction in breast cancer mortality. Proposed Program components include screening and diagnostic services, targeted outreach, information and referral, provider training, and quality assurance. DHS plans to begin implementation July 1, 1994. Clinical services will be delivered and reimbursed through the Medi-Cal EDS system, which will involve 20,000 providers statewide. DHS also hopes to contract with breast cancer partnerships in each region for local outreach and assessment of local services. DHS is considering initial recommendations on the clinical procedures eligible for reimbursement and on client eligibility. Estimates are that the Program could serve approximately 65,000 of 200,000 potentially eligible women. DHS is moving quickly to award

contracts because it must allocate all of its funds in the fiscal year in which they are appropriated.

Members suggested seeking input from the West Oakland Health Center Project on cancer outreach in underserved areas, looking more closely at the trade-offs between funding additional screening mammography versus funding excision biopsies in certain cases, using mobile outreach units to reach a diffuse population, building in mechanisms to track women over time, and identifying accurate measures beyond just mortality to assess outcomes. Thus far, nothing has impacted mortality rates, and it was suggested that the Program's limits (increasing screening without a system for getting women into treatment) may themselves need to be evaluated. This, as well as the limitations of mammography and the perception of mammography in various cultures, may be research subjects helpful to DHS.

Follow-up Items

1. Members were asked to send any documents regarding research priorities that they would like to share with the Council to Beverly Pachner as soon as possible. She will distribute them before the next meeting.
2. The Council's next meeting was tentatively scheduled for the end of May. Members will receive additional information once the date is established.