

BREAST CANCER RESEARCH COUNCIL
Ligand Pharmaceuticals, Inc.
San Diego, California
11/15/96

MINUTES

ATTENDEES

Members Present: Lisa Bailey, Arlyne Draper, Jacquolyn Duerr, Robert Erwin, J. Patrick Fitch, Marco Gottardis, Susan Love, Carol MacLeod, Andrea Martin, Maria Pelligrini, Carol Pulskamp, Beverly Rhine, Carol Voelker, Suzette Wright

Staff: Mhel Kavenaugh-Lynch, Mary Kreger, Walter Price, Mary Ader

Members Absent: Shelly Adler

Guests Present: Jackie Gordon (San Diego/imperial Counties BCEDP Partnership)

The meeting was called to order at 9:30 AM by the Chair, Carol Voelker.

I. GENERAL COUNCIL MATTERS:

A. WELCOME AND INTRODUCTIONS

New appointees introduced themselves.

B. APPROVAL OF THE MINUTES OF THE 8/19/96 MEETING

The following additions/corrections were made:

1. Page 3, under TRC mechanism, add 10% for "Approach,"
2. Page 3, adjust the spacing for the TC mechanism scale;
3. Page 4, IV.A, add the names of Claymon, Shinagawa and Voelker for writing paragraphs summarizing past, present and future accomplishments and expectations for the 1996 Annual Report.

There being no further corrections or additions, the minutes were approved as corrected.

The Council discussed whether corrected and approved versions of the minutes should be distributed to all Council members. Council members agreed that they did not wish to receive copies of the amended minutes, as long as they were available on file in the BCRP office and on the WWW Home Page.

II. UNFINISHED COUNCIL BUSINESS

A. For-Profit Reimbursement of Grants

A discussion was led by J. Patrick Fitch and Robert Erwin about the options for requiring for-profit grantees to compensate the state in the event that they successfully market products originally developed with BCRP grant funds, based on the draft document included in the meeting packet.

Motion: At this time, the Breast Cancer Research Council recommends that all for-profit and non-profit organizations receiving BCRP funding be treated equally. To encourage the best proposals and the significant investment needed to take research and development results through the clinical and approval processes, no organization should be required to compensate the state in the event that a grant results in a revenue-generating product. (passed by unanimous vote)

A discussion followed regarding ways to encourage (but not require) institutions to donate to BCRP in the event that BCRP-funded research leads to a new product. Andrea Martin, Beverly Rhine, Carol MacLeod and Bob Erwin will draft a statement of encouragement to all beneficiaries of commercialization to donate funds to BCRP, that will be placed in the "Conditions of Awards" section of future Calls for Applications and Application Packets, as well as future Annual Reports. This statement will also be added to the end of the Policy Statement on For-Profit Reimbursement of Grants, after the recommendation section. The Council will receive a draft for approval.

The Council also recommended that the Recommendations and Conclusions of this Policy Statement be placed in the 1996 Annual Report, with an introductory paragraph which clarifies that this policy was adopted after two years of extensive discussion..

B. Publicity/Mechanisms for Reporting Research Results

Publicity updates were given by various Council members, based on discussions from the last meeting. Mhel Kavanaugh-Lynch and Andrea Martin met with Terry Lightfoot from the UC News and Public Information Office; Bob Erwin had contact with a CNN producer (Sharon Collins) who is interested in the 1997 meeting in Sacramento; Arlyne Draper contacted a CNN medical reporter (Dan Rutz), who is interested in visiting with Council and staff on his next trip to California; Carol Voelker has had a number of contacts with print media in Orange County (an article about one of the PI's has already been published; the Orange County Register will be doing a combined story on BCRP and BCEDP).

Suggestions were made to include a section on the annual progress report forms for PIs to include lay contacts and publicity. It was also suggested that we ask PIs (again, on the Annual Progress Report form) for permission to release their contact information as potential speakers for community groups, the press, etc.

Marco Gottardis offered to make 15-20 color slides for distribution for presentations to the lay public about breast cancer and the Council. Susan Love and Lisa Bailey volunteered to contribute slides from their collections. Patrick Fitch offered to write dialogue.

III. NEW COUNCIL BUSINESS

A. Cycle III Review Process

The Council evaluated the Cycle II Review Committee procedures for possible changes.

The requirement that the advocate reviewers be from outside California (as was the policy decided upon for Cycle II and upheld for scientific reviewers in both Cycles I and II) was discussed at length.

The Council expressed a need to increase the diversity of reviewers, including increasing representation of public health practitioners, clinicians and biotechnology industry. Various options were discussed for ensuring that grants were read not only by experts in the field, but also by people outside the field. It was suggested that the committees be more mixed in terms of areas of expertise. The concept of a “reader,” - a person outside the field who was asked to read a grant proposal, but not prepare any written statement, was suggested by Maria Pellegrini.

Motion: Carol MacLeod moved that the Cycle III Review Committees include the concept of readers who are outside the specific discipline on an experimental basis. The motion was seconded by Suzette Wright and passed unanimously.

The role of the California Advocate Observer was then discussed. In Cycle II, the Observer was present to bear witness to the review procedure and to observe the process and provide input and suggestions for changes to the Council. The extent to which the Observer should participate in the evaluation and discussion of grants was the subject of some debate. The potential for real and/or perceived conflict of interest was of most concern, while the suggestion to have California advocates involved in Program decisions was supported by many Council members. It was pointed out that California advocates are involved in numerous ways, including serving on the Council and participating in policy discussions (i.e., at the 1996

Advisory Meeting), and that any real or perceived conflict of interest would be of significant harm to the Program.

Motion: *Andrea Martin moved that the role of the California Advocate Observer remain the same as it was in Cycle II. The motion was seconded by Carol Pulskamp. The motion passed 11-1 with no abstentions.*

Finally, the number of advocate reviewers assigned to each committee was debated. It was suggested that the number of assigned advocate reviewers per application be increased from one to two (either by increasing the number of applications each advocate reviews, or increasing the number of advocate reviewers per Review Committee to more than the current two), to increase the number of advocate reviewers in proportion to the number of scientific reviewers. Some Council members felt it was appropriate for scientific reviewers to out-number advocate reviewers, and felt that trying to make the numbers equal might de-emphasize the unique role advocates play in the review process. Given that there are two advocates on each committee, both of whom can comment on each application, the Council felt that an increase was not necessary at this time. In order to emphasize the primary role the advocate reviewer plays, the advocate reviewer could report after the primary scientific reviewer (instead of after all three scientific reviewers, as previously). Not all advocate reviewers may feel comfortable doing this. It was suggested that the advocate reviewers be told in the letter which accompanies the applications that they may receive all grant applications (instead of only their assigned half of the applications) upon request.

Motion: *Carol MacLeod moved that the number of advocate reviewers per Review Committee remain at two and that the advocate reviewers be given the option of reporting after the primary scientific reviewer; include in the welcome letter to advocate reviewers the invitation to receive all grants being reviewed by their committee. The motion was seconded by Andrea Martin and passed with one abstention and no nays.*

B. 1997 Meeting for Reporting Research Results

The Committee Recommendations for the 1997 Meeting for Reporting Research Results, dated 11/14/96, were distributed and discussed. See Attachment 1.

1. There was an objection to exhibiting the Wall of Hope, because it is a for-profit enterprise. Several other possibilities were raised. Those who were offering suggestions (Suzette Wright, Carol Pulskamp, Arlyne Draper) will research these (along with their costs) and report to the Council.

2. Mary Kreger is investigating whether or not BCRP can accept corporate sponsorship for lunch and/or the abstract booklet. Once this is resolved, Arlyne Draper will make contacts.
3. Attendance may be more than anticipated by the list presented, since many PIs may bring others from their lab.
4. Sept. 12 and 13 is the Statewide ACS meeting in San Diego.
5. Are there any potential real or perceived conflicts of interest with BCRP accepting corporate sponsorship?
6. If sponsorship is not obtained for lunch, lunch will be paid for by individual attendees.
7. The committee requested nominations for 2 keynote speakers - one advocate and one scientist.

The Committee Recommendations were approved by consensus.

C. Staff/Council Interactions

Council requests at least 5 days lead time to review any materials that need their attention.

The extent of Council involvement in drafting documents (such as the Annual Report) was discussed.

IV. STAFF REPORT

The proposal for monthly investigator reports to BCRP staff and public was discussed and rejected.

The 1996 draft Annual Report is not yet prepared.

The Council discussed issues regarding BCRP accepting donations from private sources. They agreed that this would be appropriate.

BCRP current staffing was reviewed.

Cycle II grants have essentially all been funded. All grants on the "pay-if" list were also funded due to some grants being turned down or reduced in scope and budget.

Copies of all Cycle III application materials were provided.

A final version of AB2915, which was passed by the Legislature and signed by the Governor, as well as a summary of the key modifications it made in the Breast Cancer Act was reviewed.

The 1996 Compendium of Awards and current Newsletter were distributed.

The travel policy for Council members was reviewed. Council members who are traveling to a Council meeting from out of town are allowed to travel the night before and be reimbursed for their hotel stay. In addition, if a meeting lasts 2 days, members are reimbursed for the hotel stay on the intervening night.

V. ANNOUNCEMENTS

VI. DATE OF NEXT MEETING

The next BCRP meeting is scheduled for February 7, 1997. The following one will be May 16-17. Both will be in Oakland. There will probably be a meeting in August, and then the Scientific meeting in September.