University of California:

The Award and Administration of the Tobacco and Breast Cancer Research Grant Programs Need Improvement

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CALIFORNIA STATE AUDITOR

April 15, 1996 96101

The Governor of California President pro Tempore of the Senate Speaker of the Assembly State Capitol Sacramento, California 95814

Dear Governor and Legislative Leaders:

As requested by the Joint Legislative Audit Committee, the Bureau of State Audits presents its audit report concerning the University of California's (UC) administration of the Tobacco-Related Disease Research Program and the Breast Cancer Research Program. This report concludes that UC could not demonstrate that it allocates grant awards equitably because, consistent with National Institutes of Health practices, UC does not retain documents produced as a part of the grant award process for the programs. In addition, except for finding that UC indeed shredded documents and that a potential conflict of interest for a Breast Cancer Research Council member did exist but is mitigated, we were unable to substantiate other allegations. Finally, UC needs to improve its administrative oversight of the programs.

Respectfully submitted,

KURT R. SJOBERG

State Auditor

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Summary



Audit Highlights ...

We found that:

- ☑ Consistent with NIH practice, UC destroyed written comments and ballots that supported its decisions to award grants;
- ✓ UC's process for evaluating initial breast cancer program grants did not have the desired outcome;
- ✓ There was no evidence that certain researchers or institutions received preference in the grant award process; and
- ☑ UC paid unnecessary hotel and meal expenses.

The Legislature designated the University of California (UC) to administer the Tobacco-Related Disease Research Program and the Breast Cancer Research Program. Both programs receive funding based on cigarette and tobacco products taxes. The purpose of the Tobacco-Related Disease Research Program is to support research efforts in the prevention, causes, and treatment of tobacco-related diseases. The purpose of the Breast Cancer Research Program is to support research efforts in the cause, cure, treatment, earlier detection, and prevention of breast cancer. To accomplish these purposes, UC solicits research grant applications, evaluates those applications, and awards grants.

Our review focused on the process UC uses to award grants for each program and on whether that process is unbiased and equitable. In addition, we investigated several allegations received by our office concerning the awarding of the programs' funds. We also reviewed travel expenditures and the methods used by UC to record the programs' financial transactions. During our audit, we noted the following information:

- Consistent with National Institutes of Health (NIH) practice, UC destroyed peer reviewers' written comments and ballots that supported UC's decision to award grants to specific researchers.
- UC's process for evaluating initial applications for Breast Cancer Research Program grants did not have the Breast Cancer Research Council's desired outcomes. For example, there may have been too strong an emphasis on science by screening committee members.
- Although the Breast Cancer Research Council's subcommittee established to investigate the grant award process was chaired by a UC employee, we believe any actual conflict of interest was mitigated.
- We found no evidence that certain researchers associated with the Tobacco-Related Diseases Research Program received preference in the Breast Cancer Research Program grant award process.

- Although universities and research institutions were more successful than others in obtaining Breast Cancer Research Program grants from UC, they did not receive a disproportionate share of funding when compared to their volume of applications.
- UC incurred unnecessary travel and meal reimbursement costs.
 For example, UC paid more than \$10,100 in lodging costs for staff to attend multiple one- and two-day study-section conferences in San Francisco, approximately 10 miles from the staff's headquarters. In another example, UC paid for extra nights' lodging for travelers to obtain reduced-fare airline tickets without first calculating whether the airfare savings were greater than the extra lodging costs.
- UC did not properly record program expenditures in the correct fiscal year. For example, we found \$205,267 in grant expenditures recorded to an appropriation different than the appropriation that funded the grant.

Recommendations

To improve its administration over Breast Cancer Research Program and Tobacco-Related Disease Research Program funds, UC should take the following steps:

- Retain, for a minimum of three years, the ballots used to score grant applications, which support UC's evaluation of the applications and award of grant funds;
- Retain, for a minimum of three years, the written comments prepared by peer reviewers. These written comments also support UC's evaluation of grant applications and award of research grant funds;
- Prudently manage grant funds by minimizing program expenditures related to UC staff and consultants attending local conferences;
- Ensure that it realizes a savings when any traveler exchanges lower airfares for extended lodging costs; and
- Record grant expenditures to the appropriation that funded the grant.

Agency Comments

In its response to our report, UC stated that it has begun to implement two of the recommendations and will consider adopting the others after consulting with the tobacco program's Scientific Advisory Committee, the breast cancer program's Breast Cancer Research Council, and appropriate UC and state officials.

Introduction

ounded in 1868 as a state-supported public institution, the University of California (UC) was written into the state constitution in 1879 as a public trust administered under the authority of a governing board known as the Regents of the University of California (regents). The administrative body of UC is headed by a president, who is responsible for overall policy development, planning, and resource allocations.

A master plan for the development of higher education in California, enacted in 1960 and referred to as the "Donahoe Higher Education Act," designated UC as the primary state-supported academic agency for research with exclusive jurisdiction in public higher education over instruction in the profession of medicine, among other disciplines.

Tobacco-Related Disease Program

The voters of California approved the Tobacco Tax and Health Protection Act of 1988 (Proposition 99) in the November 1988 general election. This proposition imposed a tax on cigarette distribution as well as on the distribution of other tobacco products. Proposition 99 places money raised from the tax in a special fund to be used solely for treatment and research of tobacco-related diseases; fire prevention; environmental conservation and damage restoration programs; and school and community health education programs about tobacco. The proposition specifies that a minimum of 5 percent of the money raised from the tax imposed be deposited in the Research Account, one of six accounts created for tobacco tax funds.

To implement Proposition 99, the Legislature passed Chapter 1330, Statutes of 1989, creating the Cigarette and Tobacco Products Surtax Medical Research Program to support medical research into tobacco-related disease. The Legislature directed UC to establish and administer a comprehensive grant program to support research efforts in the prevention, causes, and treatment of tobacco-related diseases.

UC established the Tobacco-Related Diseases Research Program (tobacco program) in 1989 to administer the Cigarette and Tobacco Products Surtax Medical Research Program. The tobacco program is managed by the Vice President for Health Affairs, UC Office of the President, and is funded by budget appropriations that

represent the funds earmarked for the Research Account in accordance with Proposition 99. The goals of research supported by these funds are to enhance the understanding of the causes of tobacco-related disease and to develop more effective interventions for prevention and treatment of such disease.

Since fiscal year 1989-90, the tobacco program has awarded approximately \$132.1 million in research grants. However, as indicated in Table 1, the funding for this program has decreased substantially over the last three years because of a redirection of funds. The redirection of funds is currently being challenged in the courts. Appendix A provides a list of organizations that received grants.

Table 1
Funds Received by the Tobacco Program
(In Millions)

| Fiscal Year | Funds Received* |
|-------------|-----------------|
| 1989-90 | \$ 40.9 |
| 1990-91 | 31.9 |
| 1991-92 | 26.9 |
| 1992-93 | 23.7 |
| 1993-94 | 5.3 |
| 1994-95 | 4.0 |
| 1995-96 | 4.0 |
| Total | \$136.7 |

^{*}Funds received include appropriations for administrative costs and grant awards.

Breast Cancer Research Program

In 1994, the Legislature amended the Cigarette Tax Law, California Revenue and Taxation Code, Section 30101, to increase the tax-per-cigarette by one mill (\$.001). The Legislature created the Breast Cancer Fund as the depository for the additional cigarette tax revenues collected under the California Revenue and Taxation Code, Section 30461.6. Revenues deposited in the Breast Cancer Fund are allocated as follows: 50 percent to the Breast Cancer Control Program for the early detection of breast cancer (administered by the California Department of Health Services), 5 percent to the California Cancer Registry, and 45 percent to the Breast Cancer Research Program (breast cancer program). The purpose of the breast cancer program is to support research efforts in the cause, cure, treatment, earlier detection, and

prevention of breast cancer. Like the tobacco program, the breast cancer program is administered by the Vice President for Health Affairs, UC Office of the President.

The Breast Cancer Research Council (council) sets the overall strategic objectives and research priorities of the breast cancer program. The council consists of at least 13 and no more than 15 members appointed by the UC president from nominations submitted by relevant organizations. Statutes limit council membership to the following representatives: breast cancer survivors and advocates (4), scientists and clinicians (4), nonprofit health organizations (2), private industries (2), and a practicing breast cancer medical specialist (1). In addition, one nonvoting member represents the Breast Cancer Control Program.

During fiscal year 1994-95, the first year in which breast cancer program funds were available, UC awarded approximately \$19.1 million in research grants. Appendix B contains a list of the organizations that received grants.

Scope and Methodology

The purpose of this audit was to evaluate UC's administration of both the tobacco program and the breast cancer program. Specifically, we reviewed the process UC uses to award grants for each program to determine whether the process complies with applicable laws and regulations and UC's own policies for awarding grants. In addition, we reviewed any controls UC established to administer and monitor the use of the grant funds, and we analyzed whether those controls are consistent with state laws, regulations, and UC policies. Finally, we investigated several allegations received by our office concerning the awarding of funds within the programs.

To determine the process UC uses to award grants for both programs, we interviewed staff of the Vice President for Health Affairs within the UC Office of the President. In addition, we reviewed applicable laws, regulations, and UC policies. We also examined the materials prepared by UC to solicit applications from potential grant applicants to determine whether those materials are consistent with UC policies.

To determine whether the process UC uses to award grants is unbiased and equitable, we reviewed research proposal files, interviewed staff and individuals involved in the peer review process, and assessed any other available materials.

To determine whether UC's administrative controls over the programs' funds are adequate, we reviewed the policies and procedures used to account for the programs' funds. We also

reviewed travel expense records maintained for both programs to determine whether these expenses conformed to UC regulations and policies. Finally, we performed on-site audits of grant expenditures to determine if the funds were spent appropriately.

Allegations

During the course of this audit, we received allegations concerning UC's administration of both programs. Of the 18 allegations we received, 10 applied only to the breast cancer program; 2 applied only to the tobacco program; and 6 applied to both programs.

Eight of the allegations concerned improper influence, preference, or evaluation granted to some breast cancer program applicants by UC staff or external peer-review members. Specifically, the allegations concerned the amount of funding received by four institutions, the criteria used to evaluate grant applications, and the qualifications of the peer-review members.

To investigate these allegations, we interviewed UC staff and council members. Also, we reviewed grant applications, the criteria UC used to evaluate grant applications, and award files, to determine whether any evidence of improper influence existed. In addition, we analyzed the awards to determine whether a disproportionate number of grants went to large institutions. Finally, to determine whether the peer-review members appeared qualified, we reviewed their qualification statements.

Two allegations concerned improper shredding or altering of documents. To determine whether these activities occurred, we interviewed UC staff and others, and we examined grant application and award files. None of the complainants we interviewed were able to provide evidence that documents had been altered. In addition, during our review of grant files, we did not observe any evidence of altered documents. However, as we discuss in Chapter 1, UC's practice has been to destroy the grant reviewer's ballots and comments as well as other documents shortly after UC awards grants.

Two allegations related to the improper or duplicative use of tobacco program funds. To investigate these allegations, we identified several grants as potential recipients of duplicative funds. We reviewed the grant files and performed audit procedures at the institutions that had received funds for grants that we identified. We found no evidence related to these allegations that the institutions had spent grant funds for improper or duplicative purposes.

Four allegations concerned improper administrative procedures or improper influence over the council. To investigate these allegations, we interviewed UC staff and council members. The evidence provided by these interviews does not support the allegations. However, as we discuss in Chapter 2, poor administrative procedures exist.

One allegation concerned a potential conflict caused by a council member's employment by UC. The council member chaired a subcommittee formed to investigate allegations about the breast cancer program's Letter of Intent grant application process, among other procedures. Ultimately, the subcommittee determined that the Letter of Intent process did not produce the council's desired outcomes. We agree that, at a minimum, the council member's activities created an appearance of conflict of interest. As we discuss in Chapter 1, we believe that any actual conflict of interest was mitigated.

The last allegation dealt with improper transfer of tobacco program staff to the breast cancer program. To determine whether UC assigned costs to the correct programs, we reviewed the payment of personnel costs and the workload and duties of staff for both programs between November 1994 and May 1995, the period that staffing transitions took place. We found that UC had transferred grant administrators and related support staff from the tobacco program to the breast cancer program when tobacco program funds declined. However, we found no evidence that staff salaries were paid from the wrong program nor that personnel costs were inappropriately or unnecessarily being charged to the breast cancer program. The job skills required to be a grant administrator for each program were similar.

Chapter 1

The University of California Cannot Demonstrate That It Awarded Grants Fairly Because of Its Policy To Dispose of Certain Documents

Chapter Summary

uring our review, we found that the University of California (UC) does not retain documents produced as a part of the grant award process for the Breast Cancer Research Program (breast cancer program) and the Tobacco-Related Disease Research Program (tobacco program). Therefore, although consistent with National Institutes of Health (NIH) practice, UC cannot demonstrate that it allocates grant awards equitably. In addition, the Letter of Intent (LOI) process employed by the breast cancer program has not produced the desired results.

In investigating allegations related to the UC grant award process, we determined that, although the Breast Cancer Research Council's (council) subcommittee convened to review the LOI process was chaired by a UC employee, we believe that any actual conflict of interest was mitigated. Further, we found no evidence that certain researchers associated with the tobacco program may have received preferential consideration in the breast cancer program award process.

Finally, we found that UC awarded 77 percent of the breast cancer program grants to four institutions, including UC and its affiliates. However, universities and research institutions, although more successful than others, did not receive a disproportionate share of funding when compared to the volume of LOIs they submitted.

Background

The enabling legislation for the tobacco program and the breast cancer program states that the Legislature's intent is that the programs make grants solely to researchers within the State of California. The legislation also states the Legislature's intent is that UC model its grant-making process after the one used by the (NIH). The NIH uses an evaluation process commonly called "peer review."

Under the NIH peer-review process, a group of qualified scientists and researchers evaluate grant applications. These groups, typically called "study sections," consist of about 16 members. Two or three members, or "peer reviewers," of the study section review each application in detail and prepare written comments. The remaining study-section members read the applications but are not required to perform a detailed review or prepare written comments. This step is performed in advance of a meeting for all study-section members.

Next, the study-section members gather to discuss and score the applications. Leading the discussion are the peer reviewers who have performed the detailed reviews of the full grant applications. Each study-section member then scores the application using preestablished criteria and records the score on a ballot. The NIH uses these scores to rank all applications under consideration by score and by percentile; the rankings guide the NIH's National Advisory Councils in deciding on the funding order for applications.

Differences Between the UC and NIH Grant Award Processes

UC's tobacco and breast cancer programs award grants following a peer-review process modeled on that of the NIH. However, UC modified the NIH peer-review process in several ways.

First, tobacco program applications are prescreened by the program director and staff to determine if the applicant's proposed research is relevant to the tobacco program's objectives. If questions arise regarding the application's relevance to the program's objectives, a three-person ad hoc committee reviews the application and settles the question. At either point, if the application appears relevant to program objectives, it is advanced for review by a study section. If not, the application is eliminated from further consideration. Second, although the size of UC's study sections are similar to those of the NIH, the tobacco program always uses three peer reviewers per application, in contrast to the two or three peer reviewers used by the NIH.

The breast cancer program also differs from the NIH model. In its first and only completed grant cycle to date, the breast cancer program employed an LOI to solicit interested applicants. UC requested that interested applicants submit LOIs, five pages maximum, to describe their research. The breast cancer program evaluated the LOIs under a "mini" study-section process, designed to screen applications, and invited those that passed this initial screening to submit a full application. Full applications were subject to a study-section review similar to the process used in the tobacco program.



UC modified NIH processes for the tobacco and breast cancer programs.

The breast cancer program assigned four study-section members to perform as peer reviewers, compared with three used in the tobacco program and two or three used by the NIH. Additionally, one of the reviewers was a breast cancer patient advocate.

UC's Funding Decisions

The last step in UC's evaluation of grant applications is selection for funding. The tobacco and breast cancer programs differ slightly in the selection of grant applications for funding. Each program has an oversight body: the Scientific Advisory Committee (SAC) oversees the tobacco program, and the council oversees the breast cancer program. The enabling legislation for each oversight body provides varying degrees of authority. Both the SAC and council review and make funding recommendations for their respective programs; but final funding authority for both programs resides with UC's Vice President for Health Affairs. According to the tobacco program coordinator, the program generally tries to fund the same percentage of grants from each area of study. These areas of study are codified and include coronary heart disease, cerebrovascular disease, cancer, chronic obstructive lung disease, and other conditions or diseases related to smoking or tobacco use. According to the breast cancer program coordinator, the breast cancer program does not try to fund any specific percentage of grants in each study section. Rather, all proposed projects are considered for funding if their peer-review score is over a certain mark.

Grant applications are selected for funding in June of each fiscal year to begin July 1. Following selection, all applicants are provided with a summary statement—an edited, summarized version of the peer reviewers' comments. Generally, UC personnel from the tobacco and breast cancer programs provide the summary statement to the successful applicants first and then to the others. Each applicant, whether successful or not, can submit a grant application for each year that a call for grant applications is published.

Although Consistent With NIH Practice, UC's Destruction of Documents Does Not Allow UC To Demonstrate That It Awarded Grants Fairly

As part of our audit, we were asked to determine whether UC established an unbiased and equitable process for awarding grants. To do so, we documented the grant award process as it was described by program personnel and publications. However, we were unable to review some of the original documentation of the peer-review process because UC, in a practice similar to that of

Final funding authority for both programs resides with UC's Vice President for Health Affairs.

the NIH, destroyed the study-section members' ballots and peer reviewers' written comments. Both types of documents could have provided evidence supporting a conclusion as to whether or not the decision to fund or not to fund an application was unbiased and equitable. As a result, we could not validate that comments summarized by program staff correctly reflected reviewer comments or that scores summarized by program staff correctly reflected reviewer scores. The NIH also destroys the peer reviewers' written comments soon after it makes grant awards. In contacting other research grant funding organizations, we found that they retain such written comments for at least one year.

Because ballots and reviewer comments supporting funding decisions were destroyed, we could not validate whether the process was unbiased and equitable.

The tobacco and breast cancer programs use similar peer review processes for evaluating grant applications. The objectives of the processes are the same: to evaluate and recommend applications for funding via an open and competitive peer-review process. Documents produced during the peer-review process, such as the scoring ballot and peer reviewers' written comments, substantiate the scores assigned to an application. Individual peer reviewers and other study-section members prepare these documents, which are the basis for the applications' rankings, and they support UC's funding decisions.

At study-section meetings, each reviewer receives a scoring ballot. Each member uses the ballots to record a score for each application. The ballots are collected and tabulated at the close of the study section. Additionally, for both programs, UC instructs the peer reviewers to prepare written comments for each grant application. These comments support the scoring decisions made by peer reviewers and are intended to provide the applicant with UC program staff collect, edit, and constructive feedback. summarize the comments into a statement that is sent to the applicants. According to program staff, 60 days after the applicants receive their summary statements, the ballots and peer reviewers' written comments are destroyed, and only a copy of the summary statement is maintained in the grant file. Thus, following the grant award, the only evidence that remains of the peer-review process is information that has been transcribed or summarized by UC program staff. As a result, there is no way to review original documentation to assure that the objectives of the peer review were met.

Other organizations that fund grants retain original documents from one to ten years.

To compare the UC programs' practices with those of other research grant sponsors, we contacted three private organizations that fund such grants—the American Heart Association, the American Lung Association, and the Whitaker Foundation. Each uses a process similar to the NIH peer-review process to evaluate grant applications. However, each of these organizations retains the original documents supporting the grant award process, including the written comments prepared by peer reviewers. One organization retained these documents for 1 year, another for 3 years, and the other retained the documents for 10 years.

We believe that UC should retain the scoring ballots prepared by each study-section member for a minimum of three years. These ballots form the basis for any decision to fund or not to fund a grant application. Destruction of the ballots eliminates critical evidence that the grant award process is unbiased and equitable. Further, we believe that UC should also retain the written comments prepared by peer reviewers. These written comments, which program staff edit and summarize, are also important evidence that the grant award process is unbiased and equitable.

According to the tobacco and breast cancer program coordinators, UC's rationale for the destruction of ballots and comments is that the documents contain information that, if released, could be harmful to applicants' or reviewers' proprietary information, reputation, or academic freedom. In addition, according to the programs' executive director, the programs' established policies and procedures, as articulated in program announcements, are ". . . to maintain the confidentiality of certain documents and records and to discard them once they are no longer needed for legitimate program purposes. Protected documents and records are those which identify research grant applicants, their proposed research, evaluations of their proposed research, and the authorship of evaluations of particular applications." In addition, the executive director cited the following legal authorities for this policy: (a) UC's status under the California Constitution, Article IX, Section 9; (b) the Legislature's intent that the programs model their procedures after the NIH peer-review procedures, including NIH procedures to protect or discard certain confidential documents and records; (c) the California Public Records Act, Government Code Section 6250, et seq.; and other statutes.

We found that the breast cancer program call for LOIs states that "confidentiality will be maintained throughout the evaluation process. Only information regarding funded grants will be made public." In addition, the instructions to peer reviewers for both programs state that UC "assures applicants that their identities, the applications, and the reviews are held in confidence."

We believe that UC could take steps other than elimination of the ballots and written comments that would shield, if necessary, the identity of peer reviewers and the applications they review, but would preserve the documents for legitimate review, such as program oversight. Also, we believe that such review would qualify as a legitimate program purpose and, therefore, the established program policy, as described above, would require that the documents be retained. In addition, because UC believes it has both constitutional and statutory bases to protect the documents from unneeded access, retaining confidential documents for legitimate program purposes should not be a concern. Further, if UC believes that its program office is not

UC should retain scoring ballots and peer reviewer comments for a minimum of three years to provide needed program oversight. adequately secure from casual access by unauthorized individuals, the documents could be placed in UC archives with limited access until they are needed for a legitimate program purpose.

The Council's Subcommittee Concluded That the Letter of Intent Process Used by the Breast Cancer Research Program Did Not Produce the Desired Results

In its two levels of review in the breast cancer program's first grant cycle in fiscal year 1994-95, UC solicited and evaluated a brief application, called an LOI, using a mini peer-review process. According to a council subcommittee's report, the purpose of the LOI was "to provide a tandem screening process in which applications responsive to the call for LOIs would be invited for full application in order to (a) prevent an applicant whose LOI was not responsive to the call for LOIs from having to write a full application which (by virtue of its nonresponsiveness) would not be competitive for funding; (b) avoid unnecessary reviews of nonresponsive applications by the breast cancer program study sections; and (c) to delineate the types, subjects, and numbers of applications in advance of the full application process in order to assemble appropriate study sections."

According to the council's intention, the breast cancer program established several study sections to evaluate the LOIs. The study-section members applied criteria to each LOI and then voted whether to invite a full application. UC sent rejected LOI applicants a one-page checklist showing which criteria the LOI failed to meet. There was no opportunity for appeal; an applicant, if rejected, was encouraged to reapply in the next cycle. UC subjected to the peer-review process the full applications it had invited.

Following the completion of the LOI peer-review process, several concerns were raised against UC regarding the LOI peer-review process. Critics were concerned that UC evaluated the LOIs according to inconsistently applied criteria and, therefore, prematurely rejected some LOIs from advancing to the full peer-review process. In addition, critics thought that UC gave some researchers preference because they had previously received grants from the tobacco program, that some breast cancer peer reviewers had ties to the tobacco program, and that UC staff improperly influenced the review and outcome of the LOI process.

Because UC had not retained the ballots and reviewers' comments that supported the LOI process, we were unable to substantiate the allegation that UC evaluated the LOIs based on inconsistently applied criteria. Further, we could not validate that comments summarized by program staff correctly reflected evaluator

UC solicited and evaluated a brief application, called an LOI, using a mini peer-review process.



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The subcommittee found that the LOI evaluation process may have placed too much emphasis on science.

comments or that the evaluators' check marks were correctly transcribed. As part of the LOI peer-review evaluation, each evaluator had completed a checklist of criteria, and in some instances, added written comments. Following the LOI peer-review meetings, UC program staff transcribed the evaluator's check marks and comments onto a summary evaluation. However, the summary evaluation frequently did not include check marks or comments. For example, for 4 of 10 LOI files we reviewed, we found that the transcribed summary evaluation was either missing or did not contain check marks or written comments that would support the decision to invite or not invite an application.

After the allegation was made, the council convened a subcommittee to investigate the LOI process. The subcommittee concluded that, while the LOI process was good in theory, in practice it did not produce the desired outcomes. Specifically, the subcommittee found that "(1) some discrepancies between information provided to the applicants regarding research priorities, and information provided to screening committee [study-section] members regarding evaluation of same may have existed; (2) there may have been too strong an emphasis on the science by screening committee members; (3) an underrepresentative membership on the screening committee [study section] existed; and (4) inconsistency of screening committee procedures existed."

In addition, the subcommittee made four recommendations related to increasing the diversity of reviewers, six related to outreach to expand and diversify the pool of grant applicants, four to improve the clarity of program applications and other distributed information, six regarding new award mechanisms to attract a broad-based and integrated applicant pool, one to ensure research is complementary rather than duplicative of existing funded research, seven miscellaneous recommendations, and seven related to the role and activities of the council itself. In its October 1995 response to these recommendations, UC stated that it agreed with most recommendations and outlined specific steps it had taken, or planned to take, to implement the recommendations.

An Apparent Conflict of Interest Was Mitigated by the Results of the Subcommittee's Report

An additional allegation was leveled against the breast cancer program as a result of the subcommittee's report on the LOI process. Specifically, there was a concern that the subcommittee's report was biased because a conflict of interest existed: the subcommittee was chaired by a council member who was also a UC employee. We believe there was the appearance of a

conflict of interest because the subcommittee was chaired by a UC employee and because the investigation concerned a UC program and its administration. However, because the subcommittee concluded that the LOI process did not produce the desired outcomes and because it wrote 35 recommendations in 7 areas to change the breast cancer program's grant application review process for future grant cycles, we believe that any actual conflict of interest was mitigated. Further evidence mitigating the conflict was that the subcommittee contained council members who represented advocates, scientists, private industry, and nonprofit health organizations and that the full council modified and approved the final report.

No Indication of a Preference by UC in Awarding Breast Cancer Funds to Eight Former Tobacco Program Researchers

We reviewed whether some researchers were given preference for breast cancer program grants because they were previously associated with the tobacco program. Specifically, we reviewed the list of breast cancer grantees and determined that 8 of the 78 grants awarded went to researchers who had previously received grants from the tobacco program. We compared the eight grantees' breast cancer grant applications to their tobacco grant applications by reviewing the nature of the research and the research objectives. We found that, for all eight cases, the research objectives of the breast cancer grant applications were sufficiently different from the research objectives of the tobacco grant applications. Because the research objectives were different, and because only 8 of 78 (10 percent) of the breast cancer grants were awarded to tobacco program researchers, we do not believe there is an indication of a preference by UC to fund former tobacco researchers.

The 11 Study-Section Members Reviewing Both Tobacco and Breast Cancer Program Grants Appear to Be Qualified

In addition, we assessed the makeup of the breast cancer study section to determine whether its members were also associated with the tobacco program. The breast cancer LOI and grant application reviews were performed by 44 and 136 study-section members, respectively. For fiscal year 1993-94, 133 study-section members reviewed tobacco grant applications. We identified all the people who served as study-section members for the last tobacco grant cycle in 1993-94 and who also served in either the breast cancer LOI study section or the subsequent grant application study section. We identified 11 study-section members



Only 11 of 133 former tobacco program reviewers were also breast cancer program reviewers.



(8 percent) who were associated with the tobacco program and then the breast cancer program. Of the 11 former tobacco study-section members, we found that 1 participated only in the breast cancer LOI process, 6 participated only in the breast cancer grant application study section; and 4 participated in both.

We reviewed the qualification statements of the 11 former tobacco study-section members to determine whether they had experience in breast cancer research. Several members, rather than citing obvious direct experience, had listed fields of expertise that appeared more general in nature. Specifically, these members had expertise in biology, biochemistry, and psychology, among other disciplines, rather than specific knowledge of breast cancer or tobacco issues. Therefore, we concluded that it was not improper for the 11 study-section members identified to participate in both the tobacco and breast cancer programs' grant award processes.

Most Breast Cancer Grant Awards Went to University and Research Institutions

Finally, we reviewed the outcome of the grant award process. Specifically, we analyzed who received breast cancer program funds and how much they received. We found that UC awarded 77 percent of the grant award dollars to four institutions—UC and its affiliates, the University of Southern California, La Jolla Cancer Research Foundation, and SRI International. These four institutions submitted 336 (68 percent) of the LOIs and 178 (75 percent) of the full applications, and they received 60 (77 percent) of the grants awarded. Table 2 displays a list of organizations that applied for the breast cancer program grants and how they fared in the competition for awards.

Table 2
Organizations That Received
Breast Cancer Research Grants

| Name of Organization | Number of Letters of Intent Submitted | % | Number of Applications Submitted | % | Number of Awards | % | Amount Funded (In Thousands) | % |
|-----------------------------------|--|------|--|------|---------------------|------|------------------------------------|------|
| UC and affiliates* | 266 | 54% | 131 | 55% | 40 | 51% | \$ 8,281.8 | 43% |
| University of Southern California | 50 | 10 | 35 | 15 | 13 | 17 | 3,714.9 | 19 |
| La Jolla Cancer Research | | | | | | | | |
| Foundation | 12 | 2 | 7 | 3 | 5 | 6 | 1,859.3 | 10 |
| SRI International | 8 | 2 | 5 | 2 | 2 | 3 | 962.0 | 5 |
| Subtotal | 336 | 68 | 178 | 75 | 60 | 77 | 14,818.0 | 77 |
| Others | 157 | 32 | 58 | 25 | 18 | 23 | 4,332.2 | 23 |
| Total | 493 | 100% | 236 | 100% | 78 | 100% | \$19,150.2 | 100% |

^{*}UC affiliates include Lawrence National Laboratories, Charles R. Drew University, Harbor/UCLA Medical Center, Cedar-Sinai Medical Center, and Northern California Institute for Research.

We also analyzed the information displayed in Table 2 to determine the classification of each organization. We separated the organizations into universities, research institutions, hospitals, biotechnology organizations, and others.

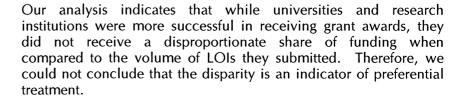
Table 3
Grants Awarded by Type of Organization

| Type of Organization | Number of Letters of Intent Submitted | % | Number of Applications Submitted | % | Number of Awards | % | Amount Funded (In Thousands) | % |
|-----------------------|--|------|--|------|---------------------|------|------------------------------------|------|
| University | 338 | 69% | 173 | 73% | 56 | 71% | \$11,667.8 | 61% |
| Research institution* | 84 | 17 | 41 | 17 | 16 | 21 | 5,149.6 | 27 |
| Hospital | 36 | 7 | 16 | 7 | 4 | 5 | 1,712.7 | 9 |
| Biotechnology* | 26 | 5 | 5 | 2 | 2 | 3 | 620.1 | 3 |
| Others | 9 | 2 | 1 | 1 | 0 | 0 | 0.0 | 0 |
| Totals | 493 | 100% | 236 | 100% | 78 | 100% | \$ 19,150.2 | 100% |

^{*}We determined the type of organization based on our inquiries of UC staff and individual organizations.



While universities and research institutions were more successful in receiving grant awards, they did not receive a disproportionate share of funding when compared to the volume of applications they submitted.



As indicated in Table 3, 422 LOIs submitted by universities and research institutions resulted in 72 grant awards totaling \$16.8 million. We converted these results into a success ratio—the ratio of grant awards to LOIs submitted. The combined success ratio for universities and research institutions was 17 percent. In contrast, hospital, biotechnology, and others submitted 71 LOIs and received 6 grant awards, totaling \$2.3 million. The combined success ratio for hospitals, biotechnology-based businesses, and others was 8 percent.

In addition, we compared the proportionate share of funding each group received to the volume of LOIs they submitted. The university and research institutions submitted 86 percent of the LOIs and ultimately received 88 percent of the funding. The remaining groups submitted 14 percent of the LOIs and received 12 percent of the funding. Thus, the ultimate funding for each of the two groups approximated its proportionate share of the LOIs submitted.

Statutes Require That All Researchers Have Equal Opportunity To Compete for Program Funds

There were concerns that breast cancer program funds were not allocated to the types of grants specified by statute. The California Revenue and Taxation Code, Section 30461.6, requires that innovative, creative, and nonduplicative research be funded. The section, however, precludes a requirement that certain portions of the funds be allocated to specific types of organizations, such as biotechnology organizations, by requiring all researchers, regardless of affiliation, to have equal access and opportunity to compete for program funds.

Because documents were destroyed and not available for review, we could not conclude whether the awards were consistent with statutes.

Although the 17 percent success rate of universities (56 awards from 338 LOIs) was higher than that of biotechnology organizations (2 awards from 26 LOIs, or 8 percent), there is no basis to conclude that university grant applications were not creative, or nonduplicative or that university innovative, less entitled to researchers were receive grants other researchers. In fact, the instructions to study-section members for the LOI and regular peer-review process required that members consider these criteria. However, the weight assigned to these criteria relative to other criteria, such as scientific merit, was a judgment made by the study-section members themselves. Because the documents stating the basis for these judgments were destroyed, we were not able to review them.

Nonetheless, as stated on page 13, the council subcommittee concluded that the LOI study-section members may have placed too much weight on the scientific merit of LOI applications. The subcommittee also made 12 recommendations to expand and diversify the pool of grant applicants and to develop new award mechanisms to attract a broad-based and integrated applicant pool. In its October 1995 response, UC agreed with the recommendations and stated it would increase outreach efforts and add a new award mechanism in the next funding cycle.

Finally, the council had an opportunity to review proposed grant awards and consider whether the proposed awards met the goals and priorities set by the council. After consideration, the council made a final recommendation to UC regarding which grant applications to fund. According to the breast cancer program executive director, although UC had the final decision, it accepted the council's recommendations.

Conclusion

UC destroyed the original scores and written comments prepared by its study-section members and retained only data transcribed or summarized by UC staff. As a result, although consistent with NIH practice, UC could not demonstrate that it allocates grant awards equitably. In addition, because UC does not retain the original documents, other interested parties, such as other oversight agencies, have no ability to review the grant award process.

We also reviewed several allegations related to both programs. Except for finding that UC indeed shredded documents and that a potential conflict of interest for a council member did exist but is mitigated, we were unable to substantiate the other allegations.

Recommendations

To administer the breast cancer program and the tobacco program properly, UC should retain, for a minimum of three years, the original ballots prepared by study-section members. These documents provide evidence that the grant award process is unbiased and equitable.

In addition, UC should retain, for a minimum of three years, the written comments prepared by peer reviewers. These documents also support UC's decision to fund or not to fund a grant application.

Chapter 2

The University of California Needs To Improve Its Administrative Oversight of the Tobacco-Related Disease and Breast Cancer Research Programs

Chapter Summary

he University of California (UC) needs to improve its administrative oversight for the Tobacco-Related Disease Research Program (tobacco program) and the Breast Cancer Research Program (breast cancer program). Specifically, we found that UC used program funding to pay for travel expenses for program staff and external study-section members that were not required for the proper administration of the programs. In addition, UC's accounting practices do not always follow state procedures.

UC Paid Unnecessary Lodging Costs in San Francisco for Program Staff

During our review of travel expenses for both programs, we found that UC paid for program staff to stay overnight in San Francisco. UC's Policy and Regulations Governing Travel, Section VII.D, specifies that subsistence expenses incurred within the vicinity of an employee's headquarters or residence shall not be reimbursed. Although the policy does not define what is meant by "within the vicinity," we reviewed the California Code of Regulations, Title 2, Section 599.616, for comparative purposes. This code section applies to state employees and prohibits payment of per diem expenses incurred within 25 miles of an employee's headquarters. Although UC employees are not bound by these regulations, we believe that these regulations provide a reasonable definition of "within the vicinity" and prudent guidance for the reimbursement of travel expenses. Furthermore, UC's policy, Section II.D.3, allows for an exception when extenuating circumstances exist. Staff requesting such an exception must specify the purpose, circumstance or need, dates of travel, and the name of the individual to whom the exception is to be granted. In addition, reimbursement of expenses claimed under such an exception is limited to actual costs and must be supported by receipts.

We reviewed invoices, paid by UC, from the Park Hyatt San Francisco hotel, approximately 10 miles from UC's Oakland headquarters. The invoices included charges for room rental, catered meals, and other costs for program staff and study-section members. These invoices relate to the tobacco program's study-section conferences held in April/May 1994 and the breast cancer program's Letter of Intent study-section conferences held in January 1995. Study-section conferences consist of multiple one- and two-day meetings attended by different peer reviewers.

UC paid for 71 nights' lodging for its staff to attend two San Francisco study section conferences.

During our review, we noted several instances in which UC paid for lodging expenses for tobacco program and breast cancer program staff who attended the study-section conferences in San Francisco. For example, UC paid for 14 nights of lodging expenses for one staff member to stay in San Francisco in April/May 1994. The room rate was \$140 per night. Table 4 provides a listing of lodging expenses for program staff for two study-section conferences held in San Francisco during fiscal years 1993-94 and 1994-95. We reviewed staff travel expense claims for documentation authorizing staff to attend the peer review in San Francisco and describing the extenuating circumstances in accordance with UC's Policy and Regulations Governing Travel. We did not find any such documentation. Additionally, when we requested an explanation from the executive director of the programs, he stated that he was not aware of the particular travel policy. For the two conferences we reviewed, the total lodging expenses incurred for UC staff totaled \$10,120.

Table 4

Lodging Expenses for Program Staff To Attend
Two San Francisco Study Section Conferences

| Program Personnel | Total Nights of Lodging | Total Cost of Lodging |
|----------------------|-------------------------------|--------------------------|
| Director | 17 | \$ 2,410 |
| Program staff | 35 | 5,000 |
| Administrative staff | 19 | 2,710 |
| Total | 71 | \$10,120 |

In addition to the two study-section conferences noted above, UC hosted four other conferences for the tobacco and breast cancer programs, which we did not audit. These study-section conferences were held between March 1991 and May 1995.

UC Paid for Excessive Meal Expenses

UC paid up to \$115 per person per day for meal costs during the study-section conferences held in April/May 1994 and January 1995. Instead of reducing their meal reimbursement claims for meals paid by UC, conference attendees were reimbursed up to \$37 per day for dinner expenses, the maximum allowed under UC's travel policy for daily meals.

UC's travel policy permits UC to arrange for hotels to furnish meals to groups attending conferences. The policy, however, also requires group members who have a portion of their meal expenses paid in this manner to claim reimbursement only for the remainder of their meal expenses.

We reviewed the associated meal costs for two of the six peer-review conferences hosted by UC: one in April/May 1994 and one in January 1995. We did not review the honorariums paid nor the airfare and incidental expenses for which the study-section members were reimbursed. We found that UC paid for catered breakfasts and lunches, at an average cost of \$33 and \$46 per meal, respectively. UC also reimbursed its staff and study-section members for dinner expenses, up to the \$37-per-day maximum. Thus, UC paid approximately \$115 for meals per person per day.



UC paid \$33 per person for catered breakfasts and \$46 per person for catered lunches.

UC Paid Expenses Not Required for the Proper Administration of the Programs

UC paid expenditures, related to study-section meetings, that were not required to administer the programs properly. We reviewed two of the study-section conferences hosted by UC. Specifically, we reviewed the expenses paid directly by UC for these two conferences. We found the following:

• UC paid approximately \$66,500 for lodging and catered meals for the 10 study-section meetings held in April/May 1994, which included 53 nights' lodging for seven program staff. In addition, UC paid a consultant more than \$22,000 to plan these meetings. This figure includes meal reimbursements of more than \$500; one meal claimed was \$77, more than twice UC's maximum reimbursement for meals per day. The consultant, whose business is based in Oakland, California, also received 20 nights' lodging at \$140 per night at the Park Hyatt San Francisco hotel while the meetings were in progress.

We reviewed the consultant's contract to determine why the consultant incurred 20 nights' lodging in San Francisco; the consultant's agreement with UC required the consultant to "ensure that staff materials, equipment, displays, and sound system are in place and operative at the start of each study-section meeting . . . be present for the duration of each event." However, in addition to the consultant's 20 nights' stay, six UC program staff stayed a total of 39 nights as well. We asked UC to describe the purpose of each program staff person's overnight stay. According to the program's executive director, the consultant, program staff, and administrative assistants were all required to participate in the setup of meeting rooms, the distribution of meeting materials, and the storage of meeting materials at the conclusion of each We do not disagree that these activities needed to be performed. However, we question whether proper administration of the tobacco program required the consultant and six program personnel to incur 59 nights of lodging expense to perform these duties.

UC paid \$52 per person for a luncheon for its program staff.

- UC's tobacco program held an administrative luncheon at the Park Hyatt San Francisco hotel, at a cost in excess of \$52 per person. According to the program's executive director, the luncheon was held to prepare program staff cognitively and emotionally for the upcoming study-section meetings mentioned above.
- UC allows the peer reviewers to extend their stay and will pay the additional hotel costs if the reviewers are able to book restricted low-airfare tickets that require a Saturday night's stay. We found that 51 of 148 tobacco program reviewers who required lodging stayed one or more nights beyond what meeting attendance would reasonably dictate and that UC paid for the extra nights' lodging. However, UC did not calculate for each individual traveler whether the actual savings realized were greater than the extra hotel and meal costs UC paid. As a result, UC has no assurance that for each traveler the added hotel and meal costs were less than the savings in airfare.

UC Has Inaccurate Program Accounting and Reporting

The California Government Code, Section 16304, requires that budget appropriations be encumbered in one year and expended within three years of approval by the Legislature. At the end of the three-year period, any unspent balance of an appropriation is then subject to the legislative budgeting process.

Expenditures for both programs were charged against incorrect fiscal years.

During our review of grant expenditures and administrative expenditures for both programs, we noted that UC did not record expenditures in the proper fiscal year. For example, we found that \$205,267 in grant expenditures for a grant awarded from the \$5.3 million budget appropriation for fiscal year 1993-94 were actually recorded as fiscal year 1992-93 expenditures. We also found \$69,200 in administrative expenses for an April/May 1994 conference recorded as fiscal year 1992-93 expenditures. recording expenditures to an appropriation different than the appropriation that funded the grant or administrative expense, UC maintains incorrect information related to the unspent portion of the program's budget appropriations. Furthermore, if the program understates its unspent budget appropriations in the third year after legislative approval of the budget, legislative fiscal committees will be unaware that funds are available for appropriation or reappropriation.

According to the executive director of the programs, he was unaware of a specific UC requirement to record expenditures to the period in which they relate. Further, the director stated that it takes at least three years to accomplish the research aims of most research projects. Because a variety of factors delay the start of many projects, the projects cannot be completed until a fourth year has elapsed.

Administrative Expenses, in Total, Did Not Exceed Statutory Limits

UC is authorized to spend no more than 5 percent of the tobacco program's Research Account balance for the purpose of administering the program. Similarly, the breast cancer program's administrative expenses are not to exceed 5 percent of the program's allocation. Table 5 displays our calculation of the administrative expenses for both programs, using program accounting records supplied by UC.

Although the administrative expenses for both programs, in total, did not exceed 5 percent, we noted that administrative expenses for the tobacco program did exceed 5 percent in fiscal years 1992-93 through 1994-95. However, the statutory requirements that limit administrative expenses do not specify whether such limits apply on an annual or cumulative basis. In addition, as previously discussed, we found administrative expenditures recorded in the wrong fiscal years. As a result, we cannot be certain that the figures below accurately compare administrative expenses to the related budget.

Table 5

Administrative Expenses as a Percentage of Annual Budget

| Tobacco Program | | | Breast Cancer Program* | | | |
|-----------------|------------------|----------------------------|------------------------|------------------|----------------------------|------------|
| Fiscal Year | Annual Budget | Administrative Expenses | Percentage | Annual Budget | Administrative Expenses | Percentage |
| 1989-90 | \$ 40,923,000 | \$ 688,875 | 1.68% | - | - | - |
| 1990-91 | 31,949,000 | 1,590,994 | 4.98 | - | - | - |
| 1991-92 | 26,852,000 | 1,334,806 | 4.97 | - | - | - |
| 1992-93 | 23,704,000 | 1,229,758 | 5.19 | - | - | - |
| 1993-94 | 5,348,000 | 567,837 | 10.62 | \$ 5,392,000 | \$201,541 | 3.74% |
| 1994-95 | 4,000,000 | 245,421 | 6.14 | 14,706,000 | 552,368 | 3.76 |
| Total | \$132,776,000 | \$5,657,691 | 4.26% | \$20,098,000 | \$753,909 | 3.75% |

^{*}Breast Cancer Program began on January 1, 1994.

Conclusion

UC needs to improve its administrative oversight for the tobacco and breast cancer programs. Specifically, we found that UC used program funds to pay for travel expenses that were not required for the proper administration of the programs. In addition, we found expenditures recorded to appropriations different than the appropriations that funded the grant or administrative expense.

Recommendations

To ensure adequate administrative controls over the programs, UC should take the following steps:

- Manage grant funds prudently by minimizing program expenditures related to UC staff and consultants attending local conferences;
- Ensure that it realizes a savings when a traveler exchanges lower airfares for extended lodging costs;
- Record grant expenditures to the appropriation that funded the grant; and

• Seek legislation that would allow UC four years, instead of three, to expend its research program funds.

We conducted this review under the authority vested in the state auditor by Section 8543 et seq. of the California Government Code and according to generally accepted governmental auditing standards. We limited our review to those areas specified in the audit scope section of this report.

Respectfully submitted,

KURT R. SJOBERQ

State Auditor

Date: April 15, 1996

Staff: Philip Jelicich, CPA, Audit Principal

Bill Shepherd, CPA

David Frizzell James Gabler Craig Lewis, CPA Sharon Smagala

Appendix A

Summary of Grant Awards Tobacco Program

| Organization Name | Awards Received | Total Funds Received |
|---|--------------------|-------------------------|
| Asian American Health Forum | 1 | \$ 153,533 |
| Beckman Research Institute of the City of Hope | 1 | 108,353 |
| California Institute of Technology | 8 | 1,953,683 |
| California Pacific Medical Center | 1 | 290,986 |
| California Public Health Foundation | 4 | 2,168,308 |
| Cedars-Sinai Medical Center | 7 | 2,229,603 |
| Charles R. Drew University of Medicine and Science | 1 | 323,095 |
| Children's Hospital Medical Ctr. of Northern California | 3 | 945,791 |
| Children's Hospital, Los Angeles | 4 | 1,583,858 |
| City of Hope National Medical Center | 4 | 1,012,062 |
| Doheny Eye Institute | 1 | 377,973 |
| Harbor-UCLA Research & Education Institute | 6 | 1,538,629 |
| Institute of Medicine | 1 | 50,000 |
| J. Gladstone Institutes | 4 | 1,098,389 |
| John Wayne Institute for Cancer Treatment & Research | 1 | 249,402 |
| Kaiser Foundation Research Institute | 2 | 1,091,707 |
| La Jolla Cancer Research Foundation | 9 | 1,782,668 |
| Lawrence Berkeley National Laboratory | 8 | 2,665,189 |
| Lawrence Livermore National Laboratory | 2 | 782,900 |
| Loma Linda Preventive Medicine Medical Group, Inc. | 1 | 121,461 |
| Loma Linda University | i | 377,968 |
| Long Beach Research Foundation | 1 | 180,399 |
| March of Dimes Birth Defects Foundation | 3 | 1,544,249 |
| Medical Biology Institute | 1 | 107,728 |
| Northern California Institute for Research & Education | 5 | 915,033 |
| Palo Alto Medical Foundation Research Institute | 2 | 711,444 |
| Public Health Foundation Enterprises, Inc. | 2 | 872,852 |
| SRI International | 9 | 3,937,103 |
| Salk Institute for Biological Sciences | 7 | 1,532,148 |
| San Diego State University Foundation | 10 | 6,304,628 |
| San Jose State University Foundation | 1 | 55,306 |
| Sidney Kimmel Cancer Center | 2 | 207,950 |
| Stanford University | 18 | 7,243,497 |
| The Rand Corporation | 2 | 402,993 |
| The Scripps Clinic & Research Foundation | 1 | 258,750 |
| The Scripps Research Institute | 15 | 6,645,780 |
| University of California, Berkeley | 21 | 5,117,183 |
| University of California, Davis | 38 | 7,839,652 |
| University of California, Davis | 14 | 4,015,698 |
| University of California, Los Angeles | 45 | 10,650,673 |
| University of California, Riverside | 5 | 1,291,572 |
| University of California, Kiverside University of California, San Diego | 66 | 11,898,677 |
| University of California, San Francisco | 77 | 22,057,980 |
| University of California, Sant Hancisco | 2 | 203,586 |
| University of California, Santa Cruz | 1 | 121,946 |
| University of Camorina, Santa Cluz University of Southern California | 39 | 16,570,880 |
| Veterans Medical Research Foundation of San Diego | 1 | 291,601 |
| Western Consortium for Public Health | 2 | 215,333 |
| Total | 460 | \$ 132,100,199 |

Source: University of California

Appendix B

Summary of Grant Awards Breast Cancer Program

| Organization Name | Awards Received | Total Funds Received |
|--|--------------------|-------------------------|
| Beckman Research Institute of the City of Hope | 1 | \$ 599,348 |
| California Pacific Medical Center | 1 | 468,484 |
| California Public Health Foundation | 1 | 69,090 |
| California School of Professional Psychology | 1 | 307,456 |
| Cancer Research Fund of Contra Costa | 1 | 668,486 |
| Children's Hospital, Los Angeles | 2 | 917,586 |
| City of Hope National Medical Center | 1 | 326,631 |
| Cytel Corporation | 1 | 395,947 |
| Geron Corporation | 1 | 224,150 |
| La Jolla Cancer Research Foundation | 5 | 1,859,352 |
| La Jolla Institute for Experimental Medicine | 1 | 97,279 |
| Northern California Cancer Center | 2 | 660,038 |
| SRI International | 2 | 961,996 |
| Stanford University | 4 | 281,146 |
| The Scripps Research Institute | 3 | 234,070 |
| University of California, Lawrence National Laboratories | 7 | 1,423,509 |
| University of California, Berkeley | 1 | 300,000 |
| University of California, Davis | 4 | 866,085 |
| University of California, Irvine | 3 | 642,878 |
| University of California, Los Angeles | 7 | 1,042,110 |
| University of California, San Diego | 8 | 1,292,157 |
| University of California, San Francisco | 10 | 2,715,095 |
| University of Southern California | 11 | 2,797,328 |
| Total | 78 | \$ 19,150,221 |

Source: University of California

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OFFICE OF THE PRESIDENT

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April 8, 1996

Mr. Kurt J. Sjoberg State Auditor 660 J Street, Suite 300 Sacramento, California 95814

Dear Mr. Sjoberg:

Enclosed is the University of California's official response to the California State Auditor's report on the University of California's administration of the Tobacco-Related Disease Research Program and the Breast Cancer Research Program. We understand our response will be incorporated into the audit report that is released.

Sincerely,

Richard C. Atkinson

President

Enclosure

cc: Provost C. Judson King

Senior Vice President V. Wayne Kennedy

Vice President William B. Baker Vice President Cornelius L. Hopper

THE UNIVERSITY OF CALIFORNIA'S RESPONSE TO THE REPORT ON THE STATE AUDIT OF THE TOBACCO-RELATED DISEASE RESEARCH AND THE BREAST CANCER RESEARCH PROGRAM

AUDIT FINDINGS

The state auditor's report on the University of California's administration of the Tobacco-Related Disease Research Program and the Breast Cancer Research Program indicates that:

- these programs have awarded and administered more than 500 research grants totaling more than \$150 million to investigators at more than 50 California institutions;
- the University has administered the programs in accord with the provisions articulated in the enabling legislation and applicable University policies and procedures.
- the research grants awarded were consistent with applicable statutes;
- the University has sought and implemented the recommendations of the programs' advisory committees, which the University appointed pursuant to the enabling legislation.

It is particularly important to note that the auditors found no evidence to support 17 of the 18 allegations they received about the University's administration of these programs. Although the report faults the University concerning the one remaining allegation—the practice of discarding peer reviewers' evaluation scores and comments when they are no longer needed by the programs—the auditors acknowledge that this practice is consistent with that of the National Institutes of Health (NIH). The enabling statutes for both the tobacco and breast cancer programs expressed the clear legislative intent that the University model the process of evaluating grant applications on the peer review procedures used by the National Institutes of Health (NIH) because it is the "gold standard" in the scientific community. NIH peer review is designed to assure that the application evaluation process is competent, objective, and minimizes conflicts of interest.

Although the University understands and can appreciate the auditors' interest in the retention of these program records for accountability purposes, we find most troubling the fact that the auditors chose to apply retrospectively a standard for record retention different than that which is implicit in the enabling legislation. In choosing a different standard, the report challenges the wisdom of the enabling statutes for the tobacco program authored by former Senator Garamendi (California Health and Safety Code section 424.55 [AB 816 of 1989], and for the breast cancer program authored by Assemblywoman Friedman (Section 9 of Stats. 1993 c. 661 [AB 2055] as amended by Section 2 of Stats. 1994 c. 483 [AB 3391]). In devising this alternative standard, we believe the audit deviated from the Joint Legislative Audit Committee's charge to measure the University's administration of these programs against applicable laws and regulations. The audit report cites the practices of three private research funding agencies to support their criticism of the tobacco and breast cancer programs' practice of discarding confidential documents when they no longer need them. The practice of these funding agencies is not an appropriate standard because their sources of funds and their private status are significantly different from the publicly-funded tobacco and breast cancer programs.

(2)

(3)

AUDITOR'S RECOMMENDATIONS AND UNIVERSITY'S RESPONSES

The following are the state auditor's recommended changes in the procedures for administering the tobacco and breast cancer research programs, and the University's responses to these

recommendations. The University has begun to implement two of these recommendations and will consider adopting the others after appropriate and necessary consultation with the Scientific Advisory Committee for the Tobacco-Related Disease Research Program, the Breast Cancer Research Council for the Breast Cancer Research Program, and other appropriate agencies.

1. <u>Recommendation</u>: Retain for three years the original evaluation score sheets and written evaluations submitted by the peer reviewers who evaluate the quality of research grant applications because these documents may be needed for program oversight.

Response: Following the practice of NIH, the University retains these documents as long as there is a legitimate program need for them—six to nine months—and then discards them. During this time, they are available to auditors as well as each program's statutorily-designated oversight committee. In fact, a subcommittee of the Breast Cancer Research Council reviewed such documents for the Letters of Intent in the first grant cycle. These confidential documents are protected from public disclosure by law. Confidentiality protects proprietary information or intellectual property in applications, and allows applicants to submit applications to other funding agencies without prejudice. The authorship of peer reviewers' expert evaluations is kept confidential to ensure that the programs benefit from their frank evaluations of applications. The University will explore options for retaining these confidential documents for longer than the current six to nine months for purposes of audit and oversight. Any change will have to provide a level of security ensuring the confidentiality of these documents which the University believes is necessary to the candor of any critical evaluation process.

2. <u>Recommendation</u>: Prudently manage grant funds by minimizing program expenditures related to UC staff and consultants attending local meetings.

Response: Cost-saving strategies have already been implemented for these program expenditures. It should be noted that these expenditures constitute a very small percentage of all program expenditures. The University travel policy for staff allows for exceptions where the need and appropriateness can be demonstrated. Although most, if not all, expenditures for staff travel that were questioned by the auditors were necessary and appropriate, they were not all adequately substantiated and documented. A procedure is being developed to obtain approval for exceptions to this University policy upon independent review of compelling evidence of programmatic need. Better documentation procedures, which will lead to more prudent management of funds for staff expenses, are being developed and implemented.

(4)

3. <u>Recommendation</u>: Ensure that the programs realize a savings when any traveler exchanges lower air fares for extended lodging costs.

<u>Response</u>: The practice of documenting savings for individual travelers has been initiated and will continue. It should be noted that, before adopting the practice of exchanging lower air fares for extended lodging costs, program staff first determined through the travel agency that there would be projected savings. Although the savings for individual travelers were not documented,

a retrospective analysis during the audit of the low airfares paid for the tobacco program's 1994 reviewers found an estimated \$24,000 savings.

(5)

4. Recommendation: Record grant expenditures to the appropriation that funded the grant.

Response: The auditors recommend that the University charge all program expenditures associated with a particular cycle of grant awards to the budget appropriation for the year which those grants are first awarded. The University's accounting policies and procedures allow for these expenditures to be made without regard to fiscal year. There is precedence for the current accounting practice in related State programs—the State has provided its own health and education departments the authority to expend Proposition 99 Education Account funds without regard to fiscal year (Section 39 of Stats. 1991 c. 1170 [SB 99], amending Section 27(b)(8) of Stats. 1991 c. 278).



The tobacco and breast cancer research programs' accounting practices for grant award disbursements comply with the University's accounting policies and procedures. These policies and procedures permit these programs to be managed in a way that is consistent with the scientific goals that were established by statute. The Legislature entrusted the administration of the tobacco and breast cancer programs to the University with full knowledge of the University's accounting policies and practices. It is, therefore, appropriate to judge the University's administration of these programs against a standard accepted by the Legislature rather than a different one, as recommended in the audit report.

Program staff will consult with appropriate University and State officials to confirm that current procedures conform with University policies and State laws. If necessary, either the way in which expenditures are recorded will be modified, or a change in the statute will be sought, as the report suggests.

Comments

California State Auditor's Comments on the Response by the California State University

o provide clarity and perspective, we are commenting on the University of California's (UC) response to our audit report. The numbers correspond to the numbers we have placed in the response.

- UC is incorrect when it implies that our recommendation contradicts legislative intent. As stated on page 7, the enabling legislation for the programs state it is the Legislature's intent that UC model its process on that used by the National Institutes of Health (NIH). As also noted on page 8 of our report, UC modified the NIH process in several ways, particularly for the breast cancer program. We presume that such modifications were intended to improve UC's administration of the programs. Our recommendation to retain important program records, in our opinion, represents another improvement to the programs and does not contradict the Legislature's intent.
- (2) UC is incorrect in stating that we deviated from the Joint Audit Committee's Legislative charge to measure UC's administration of the program against applicable laws and regulations. As required, we assessed UC's performance against NIH standards and attempted to evaluate whether the process for awarding grants was unbiased and equitable. As stated on page 10 of our report, although consistent with NIH practice, UC's destruction of documents prevented us from determining that its grant award processes were equitable. Therefore, we believe it is in the UC's and the public's interest to retain these critical records.
- We disagree that it is inappropriate to compare UC's document retention policies with the retention policies of privately funded programs. UC has provided no basis to show that the privately funded programs have different concerns about proprietary information, intellectual property, or peer reviewers' privacy. We believe that their practices suggest opportunities for UC to improve its administration of the programs.

- We disagree with UC's statement that most, if not all, of the travel expenditures for staff were necessary. We believe prior administrative approval would not justify taxpayer funds being spent on \$52 luncheons for staff or 71 nights' lodging within 10 miles of the UC's office for staff at up to \$150 per night.
- While UC's policy may have resulted in a net savings to the program, UC cannot ensure that each exchange of extended lodging expenses for reduced airfare results in a savings unless UC calculates and documents the savings on an individual basis.
- UC's statement that other state agencies have received legislative approval to encumber tobacco tax revenues in other state funds without regard to fiscal year supports our recommendation. However, even if UC receives the approval to encumber funds without regard to fiscal year, it would still be required to charge the expenditures to the appropriation that it encumbered to fund the grant. Thus, it would need to discontinue its present practice.

cc: Members of the Legislature

Office of the Lieutenant Governor

Attorney General State Controller

Legislative Analyst

Assembly Office of Research

Senate Office of Research

Assembly Majority/Minority Consultants

Senate Majority/Minority Consultants

Capitol Press Corps