Communication from the Task Force to Review the Proposed Guidelines Regarding Vendor Relations

Daniel Bikle, MD, PhD, Chair

May 9, 2007

Deborah Greenspan, DSc, BDS
Chair, UCSF Academic Senate
Office of the Academic Senate, Box 0764

RE: Recommendations for Divisional Response to the Proposed Guidelines Regarding Vendor Relations

Dear Chair Greenspan:

The Task Force to Review and Recommend Divisional Response to the Proposed Guidelines Regarding Vendor Relations consists of 12 members, including one member from each School Faculty Council and one member from each of the following committees: Academic Freedom, Academic Planning and Budget, Clinical Affairs and Research. One member is from the Department of Medicine, one member is from the School of Dentistry and one member is the UCSF Conflict of Interest Officer. The Task Force met three times, on February 22, April 2, and April 30, 2007.

As requested by Chair John Oakley, the Task Force reviewed the proposed guidelines (Part I of this communication) as well as three additional proposed policies (Part II of this communication). Part III of this communication identifies issues the Task Force would like to communicate to the Academic Council for their consideration while reviewing the Proposed Guidelines.

Part I – Review of the Proposed Guidelines Regarding Vendor Relations

At the first meeting, five issues emerged from the discussion as follows:

1. *De minimis*, e.g. the magnitude of the gift,
2. Food provided for general conferences,
3. Samples for patients (other than samples undergoing evaluation),
4. Travel and lodging required for training on equipment, and
5. Patient information documents.

The Task Force drafted and circulated questions regarding these issues to the Faculty Councils of the four Schools and the Clinical Affairs Committee. Using the feedback received in response to these questions, the Task Force discussed the issues further and formulated the following recommendations. Associate Dean Neal Cohen attended the April 2, 2007 meeting as an invited guest and provided a history of UCSF’s efforts to draft a vendor relations policy which contributed to the Task Force’s discussion.
**Issue 1: De minimis, e.g. the magnitude of the gift**  
*Proposed Guidelines Section IV. B. (lines 36-38)*  
The Task Force agreed with the proposed policy that there should not be a *de minimus*, that minor gifts from vendors to individual faculty should not be distributed on campus. Whether such gifts could be accepted by faculty members off campus was not in the purview of the Task Force.

**Issue 2: Food provided for general conferences on campus**  
*Proposed Guidelines Section V. B. 2. (lines 79-89)*  
The Task Force supported the proposed language that individual vendors should not directly provide food for recipients on campus. However, the Task Force recommends that vendors could provide funds to departments or divisions for educational events, and that vendors may be invited to provide information at events on campus, but may not do so unsolicited. The Task Force agreed that it was important that the proposed policy retain the statement “These funds (i.e., for food or meetings) will be managed in accordance with national continuing education accrediting body conflict of interest standards even when the meetings are not accredited continuing education programs” (lines 85 – 87).

**Issue 3: Vendor samples for patients**  
*Proposed Guidelines Section V. B. 3. (lines 90-101)*  
The Task Force agreed that the University should discourage the use of ‘drug closets’ in clinics for routine dispersal of samples to patients. The Task Force also noted that these “drug closets” are being eliminated because they are not in compliance with California state pharmacy laws. However, the Task Force supports that drugs and devices may be used for evaluation and education as stated in proposed policy. Further, the Task Force recommends setting a limit to the evaluation/education period. The majority of the Task Force agreed that a three-month evaluation period was appropriate. Should a provider or clinic need evaluation/education time beyond three months, the provider or providers in the clinic should develop a plan with the appropriate division or department to justify the extension of the evaluation and/or education period.

**Issue 4: Travel and lodging for training on equipment**  
*Proposed Guidelines Section IV. B. 2. e. (lines 58-63)*  
The Task Force accepted the proposed policy recommendation that free lodging, meals and travel for training purposes should be restricted to equipment that has already been purchased. The provision of the free travel, meals and lodging to the trainees should be written into the purchase contract. Prior to purchase all expenses involved with the evaluation of a piece of equipment are the responsibility of the purchaser. For demonstrations or training sessions which do not require substantial travel or lodging the Task Force needed clarification on the limits for free admission, refreshments and similar non-cash benefits to be provided by the vendor for the training session. For example, free admission and light snacks at trade fairs with multiple vendors were considered appropriate, but dinners put on by a single vendor for the purpose of discussing a product prior to its purchase was considered problematic.

**Issue 5: Patient information documents**  
Although not explicitly covered by the proposed policy, the majority of the Task Force agreed that providing patient information documents to patients in the clinics was acceptable as long as such documents were judged to be free of bias by the clinic chief or his/her designee. These documents should be
accompanied by a disclaimer from the relevant department or school indicating that the information was not an endorsement of either the vendor or the specific products described in the document.

**Part II – Review of Three Additional Issues Raised by the Brennan Report**

The Task Force also evaluated three additional issues raised by the Brennan Report that were not addressed explicitly by the current UCOP Proposed Guidelines and made the following recommendations.

1. **Faculty may not publish articles or editorials that are ghostwritten by vendor employees.**
   The Task Force defines ghostwriting as writing an article but not appearing as a co-author on the article. We recommend that faculty be discouraged from this practice as we feel it is unethical. Furthermore we recommend that the authors of publications should have access to the complete, accurately reported data set and analysis for all papers on which they are authors.

2. **“No strings attached” grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants).**
   The Task Force recognizes and supports that gifts for research are useful. However, totally unrestricted or unconditional gifts should be prohibited. Gifts to individual faculty members from vendors must come through University channels via gift administration and development departments and be specified as to their purpose, e.g. support of research or education by the recipient. This will ensure that the funds are used in compliance with existing University policies.

3. **All consulting agreements and unconditional grants shall be publicly listed (e.g., on an internet web site).**
   The Task Force applauds the effort to increase transparency for University faculty with respect to consulting agreements. We believe that the compensation plan disclosure forms provide the ability for the departments to evaluate the activities of individual faculty members for potential conflicts of interest. Other conflict of interest disclosure forms that are required of faculty provide additional University oversight. Furthermore, we encourage all faculty members to disclose their relationship(s) with the vendor(s) in publications and public lectures. However, we do not support additional public listing of such agreements. As noted in 2, the Task Force supports a policy that would prohibit unconditional grants that we interpret as “no strings attached” gifts.

   The Task Force is aware that not all consulting agreements are reviewed by the University, and we encourage the University to develop a mechanism for reviewing these for compliance with University policies.

**Part III - Other issues**

1. The Proposed Guidelines did not explicitly identify who was covered by the policy. For example, the Task Force seeks clarification about whether the policy will apply to volunteer faculty during their service at UCSF.

2. The Task Force requests clarification on how the proposed policy will be enforced.

3. UCSF does not have a consistent policy dealing with these issues across all schools, therefore we recommend that a task force be convened to develop at UCSF-wide vendor relations policy.
The Task Force hopes you will find these recommendations helpful in forming a response from the San Francisco Division to the Academic Council.

Signed,

The Task Force to Review and Recommend Divisional Response to the Proposed Guidelines Regarding Vendor Relations

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