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*Faculty Representative to the Board of Regents*  
*University of California*  
*1111 Franklin Street, 12th Floor*  
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July 12, 2007

**RORY JAFFE**  
**EXECUTIVE DIRECTOR, MEDICAL SERVICES**

**RE: Academic Senate Review of the Draft Proposed Guidelines Regarding Vendor Relations**

Dear Rory,

At its June 27, 2007, meeting, the Academic Council discussed the outcome of the Academic Senate's review of the proposed *Draft Guidelines Regarding Vendor Relations*. Although some respondents applauded the proposals' intent to increase transparency and accountability, most found the guidelines and proposed policies unacceptably vague, overbroad, and impinging on academic freedom. The Academic Council therefore respectfully requests that the UCOP Office of Clinical Services withdraw this proposal at this time. The Academic Council further requests that any revised proposal be submitted as a set of guidelines that would regulate policy at the broadest level and allow campuses flexibility at the campus level to act consistently with individual contexts and needs. Moreover, a revised proposal should offer a more comprehensive and forceful rationale than accompanied the present proposal.

Following is a summary of comments and recommendations received from the systemwide Senate committees and divisions who responded to this review. Please see the attached letters for the entirety of their responses.

**I. Proposed Guidelines Regarding Vendor Relations: Summary of Responses**

Applicability Unclear/Overly Narrow Policy: Unclear why the policy only applies to health sciences personnel and vendors from the pharmaceutical industry. UC personnel from other schools could have similar relationships with vendors, including, in some cases, pharmaceutical vendors (UCI, UCSC, UCPB).

*Recommendation*: UC should establish comprehensive guidelines to cover interactions between all vendors and all UC faculty and staff (UCI, UCLA, UCR, UCORP, UCPT). Including volunteer faculty (UCSF); other specific UC locations, schools and units (see full UCFW letter); and relationships between vendors and administrators (UCFW).

*Recommendation:* In Section III, Applicability, remove the word “human” from both lines 26 and 27, and add the word “veterinary” to the listing of health schools; in the interests of clarity, “residents” should be added to those to whom this policy applies, so that line 26 would read, “...all University employees, residents, and students....”.

*Recommendation:* Policy should be broadened to include vendors of most, if not all, areas regulated by the FDA, and similar products related to animal health (e.g., artificial joints, CT scanners, IV lines, animal drugs, human blood and tissues, etc.) (UCFW).

Clarification Necessary:

- Travel/Lodging: For demonstrations or training sessions which do not require substantial travel, and hence are not covered in the proposal, clarify the limits for free admission, refreshments, and similar non-cash benefits to be provided by the vendor for the training session (UCSF).
- Boundaries: The proposal does not define the physical boundaries of where the policy would be in effect, nor adequately clarify affected populations (UCPB).
- The policy should clarify that vendors cannot legally provide health care – i.e., different terminology should be used in Part V.C.3.a (UCPT).
- The policy (paragraph IV.B.2 (c)) should be amended to exclude gifts from domestic partners and relatives of domestic partners to the same extent that gifts from spouses and relatives of spouses are excluded. *See* California Family Code § § 297.5 (a) and (g). (UCFW)

Unintended Consequences: The policy may also eliminate positive benefits from vendor funding of educational or research programs.

- In particular, gifts addressed to The Regents that are intended to be given to an individual’s various donor’s accounts should not be prohibited (UCI).
- UCSF supports the use of drugs and devices for evaluation and education, as stated in proposed policy, but recommends setting a three-month limit to the evaluation/education period (UCSF).
- The guidelines as written would prohibit most casual interactions between clinicians and vendors and impose an unnecessary layer of bureaucracy and micro-management onto those interactions and the acceptance of even small gifts (UCAF).
- The proposal stigmatizes the acceptance of any gift from vendors, including bags containing conference materials at professional meetings and the like. Although aware of the research that suggests that even minor gifts can influence behavior, some felt that the regulations placed an unfair burden of guilt or refusal on the recipients of such gifts regardless of the context or the gift’s triviality (UCPB).
- There are certain situations in which the provision of pharmaceutical or device samples (i.e., glucose meter, medical or dental implants) may be of enormous benefit to indigent patients (UCLA, UCSD – see recommended language for V.B.3 in appended letter).
- Policy does not mention gifts (samples) from a vendor to a clinic or unit that has one person sign for them, and be responsible for their receipt (UCFW).

Implementation/Enforcement Mechanisms Unclear: Proposal is unclear as to how it will be implemented, and how faculty would be held accountable for violations. The proposal appears redundant with the Faculty Code of Conduct (UCI, UCSC, UCSF, UCFW). If implemented, the policy should be revisited and assessed in a few years (UCSD).

Policy Intrudes on Local Authority: The system-wide proposal is an unjustifiable intrusion by central administrative authorities into decision-making that should best be left in the hands of individuals, or their departments, under the guidance of local leadership (UCLA, UCPB).

*Recommendation:* Amend Section V.G to call on all schools and units to develop a comprehensive curriculum to instruct faculty, staff, and trainees on relations with industry (UCLA, UCSD).

#### Issues Not Covered by Policy

Patient information documents: providing patient information documents to patients in the clinics is acceptable as long as such documents are 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 (UCSF).

## **II. Three Additional Proposed Policies: Summary of Responses**

#### General Comments:

- The principles covered by the three appended policies could be better covered by a broad ethics statement (UCI).
- Because no actual policy text accompanies the three proposals, UCPB is unwilling to offer any commentary on policies that are not accompanied by a written text.

### **i. “Faculty may not publish articles or editorials that are ghostwritten by vendor employees.”**

Policy is Unacceptably Vague: need to define “ghostwritten” (UCB, UCLA, UCSD).

Policy is Redundant: see the Faculty Code of Conduct, APM 015, which prohibits all forms of “intellectual dishonesty” (UCB, UCSB, UCSD; UCAF, UCFW).

Policy is Too Narrow: and should cover other undesirable behaviors, such as vendor-supported ghostwritten data analysis, which should also be disclosed (UCD).

Policy Infringes on Academic Freedom: and should be redrafted to avoid any suggestion that it applies to legitimate collaborative research in which the role of the participants is fully disclosed (UCD, UCFW).

#### Drafting Suggestions:

“All sources of authorship of any article or editorial must be fully disclosed in the piece itself.” (UCB)

### **ii. “No strings attached’ grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants).”**

Policy Infringes on Academic Freedom: source-based restrictions are inconsistent with academic freedom, as evidenced by the Senate’s position on the proposed ban on tobacco funding (UCB). Need to define “grant”: depending on how it was defined, the policy could seriously limit the opportunities for faculty to engage in research and to present their work (UCD). “No strings attached” funds for research that lack specific requirements are very difficult to secure; and a ban on such funding opportunities would prevent faculty from exploring ideas outside the

mainstream of granting agencies – infringing on academic freedom and impairing the mission of the University to discover and disseminate new knowledge (UCAF).

Policy Unacceptably Vague: The no-strings grant or gift mechanism is the most efficient method to get the materials into the University system and, if this were barred, it could form a significant impediment to research (UCLA). Further clarification is needed (UCLA); for instance, clarify that personal payment to an individual faculty member is inappropriate (UCSD, UCSF). In general, clarify “individual” – e.g., does this include graduate students and academic personnel? (CCGA)

**iii. “All consulting agreements and unconditional grants shall be publicly listed (e.g., on an internet web site).”**

Policy is Redundant with Proposed Policy (ii): however, if (ii) is rejected, then (iii) would seem to be a potentially desirable alternative (UCB).

Policy is Redundant with Existing UC Policy: faculty members already report consulting income and other grants on a regular basis to the University. There are procedures for disseminating such information to those outside of the University. Research integrity is already required by the Faculty Code of Conduct. Posting this information to the web would take the information out of context (UCSD, UCSF, UCAF). However, the University should consider developing a mechanism for reviewing consulting agreements for compliance with University policies; at present, not all agreements are reviewed by the University (UCSF).

Policy Overly Narrow: a policy focused exclusively on health sciences faculty is discriminatory. The policy should be generalized to all segments of the faculty, as well as to other sources of funding. Alternately, health science faculties should develop their own policies to govern interactions with pharmaceutical vendors (UCB, UCLA).

Academic Freedom Concerns: such as disclosure of consulting relationships (e.g. a law professor providing advice to the attorneys representing a politically or socially disfavored client); and general freedom of association and privacy concerns (UCD, UCSD). Such a vague policy is a prima facie assault on academic freedom (UCLA).

On behalf of the Academic Council, I applaud the spirit of the proposed *Draft Guidelines Regarding Vendor Relations*, and look forward to the receipt of another draft of this policy for the Council’s review. Please advise me if you disagree with proceeding in this fashion.

Sincerely,



John B. Oakley, Chair  
Academic Council

Encl: 15  
Copy: Academic Council  
María Bertero-Barceló, Executive Director



May 9, 2007

JOHN OAKLEY  
Chair, Academic Senate

Subject: *Draft proposal on the relationships between (pharmaceutical) vendors and clinicians*

On April 30, 2007, the Divisional Council (DIVCO) of the Berkeley Division considered the issue cited above, along with the comments of the divisional Committee on Academic Freedom (ACFR) and Committee on Research. Specifically, DIVCO discussed the following three proposed provisions of the policy:

- (1) Faculty may not publish articles or editorials that are ghostwritten by vendor employees.
- (2) "No strings attached" grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants).
- (3) All consulting agreements and unconditional grants shall be publicly listed (e.g., on an Internet web site).

With respect to (1), the discussion in DIVCO echoed the concerns raised by ACFR:

... while this proposal does not seem to impinge upon academic freedom, it does not seem well-formulated, not least because "ghostwritten" is a vague term, and leaves open the possibility that a vendor's employee might contribute substantially to an article or editorial, without necessarily "ghostwriting" the piece as a whole. We would suggest, as an alternative formulation, a positive requirement that "All sources of authorship of any article or editorial must be fully disclosed in the piece itself." Moreover, this item might be redundant with respect to the Faculty Code of Conduct, APM 015 which already prohibits all forms of "intellectual dishonesty," which would include presenting another's work as one's own. It would also seem consistent with the proposal to require, as many journals already do, full disclosure in publications of all other affiliations and financial relationships with healthcare vendors.

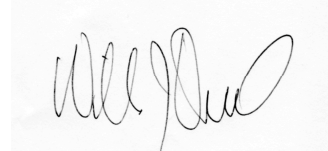
DIVCO discussed the prohibition on "no strings attached" grants or gifts, and noted that source-based restrictions are inconsistent with academic freedom, as evinced by the Senate's position on the proposed ban on tobacco funding.

DIVCO agreed with ACFR's assessment of (3): "we note that under the current formulation, since unconditional grants have just been banned under (2), it is unclear to what this clause will apply. However, if (2) is rejected, then (3) would seem to be a potentially desirable alternative."

DIVCO also raised concerns that a policy focused exclusively on health sciences faculty is discriminatory. It also is concerned that such a policy could be generalized to the other segments of the faculty, as well as to other sources of funding.

DIVCO recommends that the proposed policy be completely reconsidered, or that health science faculties develop their own policies to govern interactions with pharmaceutical vendors.

Sincerely,

A handwritten signature in black ink, appearing to read "William Drummond", is centered on a light gray rectangular background.

William Drummond  
Chair, Berkeley Division of the Academic Senate

Cc: Christopher Kutz, Chair, Committee on Academic Freedom  
Miguel Villas-Boas, Chair, Committee on Research  
Lili Vicente, Senate Assistant, Committee on Academic Freedom  
Diane Sprouse, Senate Analyst, Committee on Research



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April 12, 2007

**John Oakley, Chair**

Assembly of the Academic Senate  
Academic Council  
1111 Franklin Street, 12<sup>th</sup> Floor  
Oakland, CA 94607-5200

RE: [Draft Proposal on the Relationships Between \(Pharmaceutical\) Vendors and Clinicians](#)

The draft proposals were forwarded for review by all of the standing committees of the Davis Division and the chairs of the college/school Faculty Executive Committees. Generally, comments were supportive of the Proposed Guidelines Regarding Vendor Relations. However, there is concern regarding application of this policy on our campus where students and faculty from the medical and veterinary schools as well as the main campus so often share the same lab bench, if not supplies. Specifically we see some challenges relating to defining the individuals to whom this policy would apply. Would the graduate student from the vet school who is working in part on a project with one of the medical school faculty be prohibited from accepting gifts?

Regarding the three proposed policies, concerns were raised:

1. Faculty may not publish articles ghostwritten by vendor employees.

The idea of ghostwritten articles or editorials was surprising to many committee members and found to be at odds to the high standards most of us hold for academic senate members. The proposed policy would not infringe the academic freedom of faculty if it was drafted with sufficient care to avoid any suggestion that it applied to legitimate collaborative research which fully disclosed the role of the participants.

2. Prohibition of "no strings attached" grants or gifts directed to individuals from vendors (excluding competitive grants).

Use of the term grant was ambiguous and, depending on how it was defined, the policy could seriously limit the opportunities for faculty to engage in research and to present their work. Would the selection of a faculty member to present an endowed lecture, for example, be prohibited on the grounds that the grant (or honorarium) provided did not involve a competitive selection process? We would need to see

the specific language of this proposal in order to evaluate its impact on the academic freedom of faculty.

3. All consulting agreement and unconditional grants shall be publicly listed (e.g., on an internet website).

Such a policy implicated freedom of association concerns, but these concerns were probably of limited weight in the context of health care professionals and pharmaceutical vendors. As a general matter, the disclosure of consulting relationships in other contexts (e.g. a law professor providing advice to the attorneys representing a politically or socially disfavored client) implicates important academic freedom issues.

Sincerely,



Linda F. Bisson  
Professor of Viticulture and Enology  
Chair of the Davis Division  
of the Academic Senate





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(949) 824-2215 FAX

April 30, 2007

John Oakley, Chair, Academic Council  
1111 Franklin Street, 12<sup>th</sup> Floor  
Oakland, CA 94607-5200

**RE: Review of Relationships of Pharmaceutical Vendors and Clinicians**

At its April 24, 2006, meeting the Irvine Division's Senate Cabinet unanimously opposed the Draft Proposal on the Relationships of Pharmaceutical Vendors and Clinicians based on reports from the Irvine Council on Faculty Welfare and the Council on Research, Computing and Library Resources. While the faculty support the principle of the proposed policy, they voted unanimously to reject it on the grounds that it is overly detailed and attempts to regulate faculty behavior in a way that is not appropriate. Moreover, the second half of the proposal to regulate relations between pharmaceutical vendors and UC clinicians was ambiguous and vague. We offer the following comments that could help to clarify the Senate Cabinet's opposition to this *Draft Proposal*:

1. The three policies that were appended to the original draft were either redundant or may be better covered by other mechanisms. Like the original draft, the three appended policies were considered to be overly detailed and felt that the principles of the proposal could be better covered by a broad ethics statement.
2. The proposed "ghost-writing" prohibition policy may also be too narrow and does not cover other undesirable behaviors, such as vendor-supported ghost data analysis, which should also be disclosed.
3. The proposal said nothing about how faculty would be held accountable for violations and made no mention of revising the Faculty Code of Conduct, to which faculty are accountable.
4. It is not clear why guidelines are proposed only for Health Science personnel and vendors from the pharmaceutical industry. Since UC personnel from other Schools could have similar relationships with vendors, including, in some cases, pharmaceutical vendors, UC should establish comprehensive guidelines.
5. The proposed measures for preventing abuse of vendor-UC relationships may also eliminate positive benefits from vendor funding of educational or research programs. In particular, gifts addressed to The Regents that are intended to be given to an individual's various donor's accounts should not be prohibited.

The Irvine Division appreciates the opportunity to consider this issue. If you have any questions, please do not hesitate to contact me.

A handwritten signature in black ink that reads "Martha McCartney". The signature is written in a cursive style with a large, sweeping loop at the end of the last name.

Martha McCartney, Senate Chair

C: Pauline Yahr, Chair, Council on Faculty Welfare

Alex Veidenbaum, Chair, Council on Research, Computing and Library Resources

Maria Bertero-Barcelo, Executive Director, Academic Senate



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May 8, 2007

Professor John Oakley  
University of California Academic Senate Chair  
1111 Franklin Street, 12<sup>th</sup> Floor  
Oakland, CA 94607

**In Re: Draft Proposal on the Relationship between Pharmaceutical and Medical Device Vendors and Clinicians**

Dear John,

Thank you for the opportunity to opine upon the Draft Proposal on the Relationship Between (Pharmaceutical) Vendors and Clinicians. Upon receipt, I sent the document to all standing committees of the UCLA Senate for review with the specific request that Council on Planning and Budget (CPB), Committee on Academic Freedom, the Council on Research (COR) and the Executive Board opine. I also invited several of the Faculty Executive Committees to opine with a specific request of the School of Medicine. While the assessments of the proposal varied, the consensus at UCLA is that this proposal, as currently written, should not be supported. Please allow me to explain.

UCLA is supportive of the intent of this proposal to eliminate improper influence, as well as the appearance of improper influence, on decision-making in the University's medical schools. The Faculty Executive Committee of the David Geffen School of Medicine at UCLA already has adopted policies to guide interactions between vendors and University faculty, staff, and trainees; these policies currently are being implemented. A copy of these guidelines is attached.

The Executive Board and the School of Medicine FEC found broad areas of agreement between the UCLA Medical School guidelines and the system-wide proposal. There are, however, several areas where the proposal can be strengthened. First, the definition of "vendor" is too narrow in that it focuses exclusively upon items "that are provided upon prescription or at the suggestion of a health care professional." Many of the faculty, staff, and trainees in our medical schools work in clinical laboratories and/or are involved both in medical research as well as in patient care. Given the fact that these guidelines focus exclusively on patient care, the system-wide proposal establishes a *de facto* double standard where in their clinical duties, faculty, staff, and trainees will be unable to accept gifts and have unsolicited visits, whereas in their laboratory-based and research duties, gifts and unsolicited visits still will be acceptable. This double standard will be at best confusing, and at worst corrosive to the morale of faculty, staff, and trainees. Furthermore, because some gifts still are permitted, the improper influence still can exist. The UCLA Medical School guidelines do not distinguish between clinical and non-clinical vendors: all gifts and unsolicited visits from industry are banned. The Executive Board and Medical School FEC urge the Senate to broaden the definition of vendor to eliminate this double standard. Along

these same lines, the term “Pharmaceutical” should be deleted from the title of the proposal, because this policy clearly should affect any industry dealing with a medical school.

Second, although gifts of token value (e.g., pens, notepad, etc.) are banned under the proposal, there is no provision to remove such industry-branded items from clinical areas. Technically, pens and other industry promotional items still may be displayed and utilized in clinical areas as long as no individual employed or enrolled at the University has been the recipient. This is a major loophole in the proposal because clinical areas and medical schools are and will continue to be littered with promotional materials. The UCLA guidelines specifically prohibit any industry-branded items in any clinical or medical school facility. Under our guidelines, the only materials that may be provided by industry are those that have been vetted by a peer-review or continuing medical education process. We strongly suggest that the proposal be modified to close this loophole.

Third, there is at least one area in which the proposal is inappropriately stringent, namely the total ban on pharmaceutical and device samples. Samples are of promotional value to industry and considerable research indicates that use of samples may, under some circumstances, increase health care costs by encouraging use of more expensive branded pharmaceuticals when less expensive generic medication would be just as effective. There are, however, certain situations in which the provision of pharmaceutical or device samples (i.e., glucose meter, medical or dental implants) may be of enormous benefit to indigent patients. Frequently, a newer branded medication may offer significant advantages to a patient and the patient could not afford the medication except for the availability of samples. In some circumstances, no generic medication may be yet available due to patent restrictions. Ultimately, the individual health care professional is best positioned to determine what course of action is in the best interest of his or her patients. The actions of individual physicians should be subject to oversight, but this oversight should be provided by local leaders who are aware of the particular circumstances of local medical practice. For these reasons, the UCLA faculty has concluded that the system-wide proposal is an unjustifiable intrusion by central administrative authorities into clinical decision-making that should best be left in the hands of the individual physician, under the guidance of his or her local medical leadership. The UCLA guidelines discourage use of samples except when they clearly are in the best interests of the patient, and acknowledge that sample also is regulated by the Department of Pharmacy. We urge the Senate to modify the system-wide proposal to defer to the clinical judgment of individual physicians and their local leadership.

Finally, the UCLA faculty believes that the system-wide proposal does not adequately deal with the issue of teaching faculty, staff, and trainees about relationships with industry. The strict limitations imposed by this proposal are likely to create “vendor-free” zones in UC Health Sciences Centers. As a result, medical/dental students and residents graduating from UC schools may be grossly unprepared to deal with industry representatives when they enter residency programs at other institutions or complete residency and enter into practice. The UCLA guidelines call on the faculty of the schools to develop a clear curriculum to instruct trainees on relations with industry, and we believe that the system-wide proposal should be modified to call on all schools to develop a comprehensive curriculum.

### **Three additional proposed policies**

Of the UCLA committees responding to this segment of the proposed policies, only the Council on Research opined favorably. The Executive Board, CPB, AFC, and Medical School FEC found significant deficiencies with the language as proposed.

The three proposed policies are not well defined and it therefore is difficult to provide meaningful comments. As they currently drafted, the proposed policies raise serious concerns regarding academic freedom. It is unclear what is meant by policy (i) that bars faculty from publishing articles “that are ghostwritten by vendor employees.” Faculty members have broad discretion in their decision to be listed as an author on manuscripts, so long as they believe that they have made substantial intellectual contributions to the work. This right of the faculty should not be infringed upon without clear intellectual

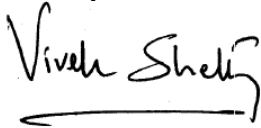
and ethical justification. Until the term “ghostwritten” is defined, the intent of this policy remains unacceptably vague. Certain common legitimate practices may be banned to the detriment of the faculty. For example, medical faculty members regularly publish articles in collaboration with industry scientists and, as a legitimate part of these collaborations, articles are written in small or large part by industry scientists. Would this be banned by the proposed policy? Further clarification is needed.

Similarly, proposed policy (ii) banning “no strings attached’ grants or gifts” is unacceptably broad and vague. There are certain situations in which such grants or gifts are extraordinarily helpful in the conduct of legitimate biomedical research. For example, faculty members frequently obtain Federal grants to perform clinical research involving medications or devices. Conduct of these research projects may be enhanced by no-strings attached grants or gifts of medication or devices to the investigator; these gifts may help offset budget cuts from the granting agency, or permit the investigator to expand the parent research project. The no-strings grant or gift mechanism is the most efficient method to get the materials into the University system and, if this were barred, it could form a significant impediment to research. Again, further clarification is needed.

Finally, the intent of proposal (iii) is unclear. What is the purpose of listing consulting agreements and unconditional grants on a public website? This proposal suggests that faculty members who consult or accept such grants should be subject to special scrutiny, or that such engagement with industry should be avoided. Either of these is a dubious proposition at best, considering that many of our finest faculty members engage in these activities. Furthermore, it is not clear why health science faculty should be singled out for this type of scrutiny while consulting and unconditional grants from industry are common in other schools. Some consideration should be given to the possibility of listing all consulting and research activities of all faculty on a public website. This vague proposal, however, is not justified and on its face is a veiled assault on academic freedom.

Thank you again for the opportunity to opine on this matter. I am attaching the responses from UCLA’s Council on Planning and Budget, Council on Research, and Academic Freedom Committee. Please do not hesitate to contact me should you have any questions.

Sincerely,



Vivek Shetty  
Senate Chair  
UCLA Division

Cc: María Bertero-Barceló, Systemwide Academic Senate Executive Director  
Jaime R. Balboa, CAO UCLA Academic Senate

## **Draft Guidelines on Industry Activities for the David Geffen School of Medicine at UCLA and the UCLA Medical Enterprise**

### **Introduction**

The purpose of these guidelines is to establish clear direction for faculty, staff, and trainees of the David Geffen School of Medicine at UCLA, and the UCLA Medical Enterprise, in their interactions with industry representatives. Relationships with commercial interests in the health care sector frequently promote the educational, clinical, and research missions of the School of Medicine and the Medical Enterprise. These interactions also may, however, create conflicts of interest, improper influence on decision-making, or the appearance of impropriety. Recent research indicates that industry activities, such as the provision of gifts of nominal value, may affect health care provider behavior and decisions. The Faculty Executive Committee of the School of Medicine believes that these guidelines will enhance positive and constructive working relationships with industry and minimize any questions about improper influence of sales and marketing activities in the School.

### **I. Gifts and Compensation Provided by Industry**

- A. Gifts are defined as items of any value received by a member of the faculty, staff, or student body for which the recipient has not provided adequate consideration in return. Examples of gifts under these guidelines would include pens, notepads, textbooks, meals, and payment for attending a meeting. This definition is somewhat broader than that contained in the State Fair Political Practices Act (FPPA), which governs University of California employees and aims to remove bias from their decisions. These guidelines supplement the provisions of the FPPA and University Business and Finance Bulletin G-39 (Conflict of Interest Policy) in order to reduce the potential influence of vendors on the decisions made by faculty, staff, and trainees in the School of Medicine. Honoraria and associated travel for a specific service rendered (e.g., speaker's fee) are not considered gifts because these are payments for a service. Competitive grants also are not considered gifts. Informational materials that have been produced under Accreditation Council for Continuing Medical Education (ACCME) guidelines or published under a peer review process are not considered gifts. UCLA faculty, staff, and students should be familiar with the University's Conflict of Interest Policy (<http://www.ucop.edu/ogc/coi/text.html>) and University general gift guidelines (<http://www.ucop.edu/ogc/coi/appendd.html>).
- B. Gifts from industry should not be accepted anywhere on the UCLA campus or at any clinical facility operated by the UCLA Medical Enterprise. In addition, UCLA faculty, staff, and trainees should not accept gifts at any non-UCLA-operated clinical facilities such as other hospitals or clinics. The School of Medicine strongly encourages faculty and non-faculty medical staff at any affiliated program never to accept any personal gift from industry at any location under any circumstances.

- C. Individuals must continually strive to avoid the appearance that clinical care decisions are influenced by outside commercial interests, or by any benefits expected or received from any company. All offices and clinical care areas (i.e., rooms in an outpatient clinic, patient waiting areas, or hospital space) should be free of any materials that bear the name of a particular product or company (e.g., pens, papers, notepads, etc.). Individuals may not accept gifts, gratuities, meals, or compensation for listening to a sales talk by an industry representative, for prescribing or changing a patient's prescription, or for attending a CME or non-CME activity (unless the individual is a speaker or is otherwise actively participating or presenting at the event).
- D. Pharmaceutical or device samples have the potential to inappropriately influence clinical care of patients. For example, samples may encourage a physician to prescribe a new branded costly medication when older generic inexpensive medications may have the same or greater proven efficacy and safety. At the same time, the ready availability of no-cost samples may be of benefit for patients of limited financial means or where treatment adherence is an issue. UCLA faculty, staff, and trainees should utilize pharmaceutical or device samples (i.e., glucose meters) only within policies established by the Medical Enterprise (i.e., logging in of samples), and when these samples clearly enhance patient care. Samples should not be used simply as a convenience or because of the encouragement of industry representatives. Samples should not be solicited or obtained by faculty, staff or trainees for personal use or for use by family members.

## **II. Access to Clinical and Non-clinical Areas by Sales and Marketing Representatives**

- A. Sales and marketing representatives are not permitted in any clinical areas except to provide in-service training on devices and other equipment already purchased, or to provide demonstrations that may be of benefit to patients and where no purchase is required. Under those circumstances, representatives are allowed only by appointment.
- B. Sales and marketing representatives are permitted in non-clinical areas by appointment only. Appointments will normally be made for such purposes as:
  - 1. In-service training of personnel for research or clinical equipment or devices already purchased;
  - 2. Evaluation of new purchases of equipment, devices, or consideration of addition of new pharmaceuticals to the hospital medication formulary.
- C. While appointments may be made at the discretion of any faculty member, the overall activity of sales and marketing representatives is subject to the oversight of division chiefs, department chairs, medical staff leadership, and other designated officials of the SOM and the Medical Enterprise.

### III. Industry Support for Educational and Other Professional Activities

- A. All events that receive industry support and are sponsored by the School of Medicine or the Medical Enterprise must be compliant with ACCME Standards for Commercial Support *whether or not CME credit is awarded*. This includes not only educational events, but also other professional activities such as faculty or staff meetings, regardless of whether these events occur on or off the UCLA campus.
- B. Industry grants to support educational or professional activities must comply with ACCME Standards and must be administered by departments or divisions and not by individual faculty. Faculty, staff, and trainees should become familiar with the ACCME Standards for Commercial Support. The Standards may be found at [www.accme.org](http://www.accme.org). Divisions and departments are advised to maintain records of compliance with the ACCME Standards. Guidance on interpretation of ACCME standards may be obtained from the Office of Continuing Medical Education in the School of Medicine or, for the clinical neurosciences, the Office of Professional and Community Education in the Semel Institute.
- C. Industry representatives may not directly provide meals or other types of food for any educational or professional activity of the School of Medicine, anywhere on the UCLA campus or at any facility operated by the Medical Enterprise. Faculty, staff, and trainees are strongly encouraged not to accept such meals at any location under any circumstances.
- D. Faculty and medical staff should evaluate very carefully their own participation in meetings and conferences that are fully or partially sponsored or run by industry because of the high potential for perceived or real conflict of interest. Individuals should actively participate in meetings and conferences supported in part or in whole by industry (e.g., giving a lecture, organizing the meeting) only if the meetings and conferences follow these guidelines:
  1. Financial support provided by industry is fully disclosed by the meeting sponsor;
  2. The lecturer is solely responsible for the content of the lecture. The lecturer is expected to provide a fair, balanced, and where possible evidence-based assessment of therapeutic options and to promote balanced discussion of the topic. The lecturer prepares his or her slides and other educational materials and does not delegate this to industry sponsors;
  3. The meeting organizer is not required by an industry sponsor to accept advice or services concerning speakers, content, or meeting organization as a condition of the sponsor's contribution of funds or services;



- E. These provisions do not apply to meetings of professional societies that may receive partial industry support, or other meetings governed by ACCME Standards, where outside organizations take responsibility for ensuring that presentations are free of commercial influence.
- F. Industry sales representatives have the same access to the official educational offerings of the University as other members of the general public. Generally, these are official courses of the University or CME programs in accordance with ACCME guidelines. Faculty or departments should not offer preceptorships to industry representatives without involvement of the Office of Continuing Medical Education in the School of Medicine or, for the clinical neurosciences, the Office of Professional and Community Education in the Semel Institute.

#### **IV. Student and Other Trainee Interactions with Industry**

- A. All students, residents, trainees, and staff should receive training from the School of Medicine regarding potential conflicts of interest in interactions with industry.
- B. Industry support of students and trainees should be free of any actual or perceived direct benefit to the company providing the funds. Funds must be provided to an academic unit of the School of Medicine specifically for the purpose of education and must comply with all of the following provisions:
  - 1. The School of Medicine department, program or division must oversee the activity to be funded, and certify that the funded activity enhances the goals of the training program.
  - 2. The School of Medicine department, program or division must have sole discretion to determine how the funds are to be used. If the funds are intended to support educational activities or professional expenses of a trainee or trainees, the department, program, or division should have total discretion in deciding which students or trainees receive support.
- C. These provisions do not apply to educational programs for trainees at national or professional society meetings, awards, or travel grants presented by professional societies, where outside organizations take responsibility for ensuring that the activities are free of commercial influence.

#### **V. Faculty, Staff, and Trainee Disclosure of Relationships with Industry**

- A. In scholarly publications, faculty, staff, and trainees must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors ([www.icmje.org](http://www.icmje.org)).

- B. Faculty with supervisory responsibilities for students, residents, trainees or staff should ensure that conflicts or potential conflicts of interest do not affect or appear to affect his or her supervision of the students, resident, trainee, or staff member.
- C. Faculty or staff having any personal financial interest or indirect financial interest as defined by University policy, or whose spouses, registered domestic partners, or dependent children having such interests, in companies that might substantially benefit from the decisions made within their University duties must refrain from participating in or influencing these decisions under the provisions of the California Political Reform Act. This does not apply to financial interests in investment funds where the individual does not have separate and direct control over the investment in the company. Provisions of the act may be viewed at <http://www.ucop.edu/ogc/coi/disqual.html>.
- D. All faculty should fulfill their obligation to disclose outside professional activities to the School of Medicine under the provisions of the Academic Personnel Manual section 025. The provisions of this policy may be viewed at <http://www.apo.ucla.edu/call/append19.htm>.
- E. For disclosure requirements related to educational activities, faculty, staff, and trainees should abide by the ACCME Standards for Commercial Support ([www.accme.org](http://www.accme.org)).



# MEMORANDUM

Academic Senate Executive Office  
Los Angeles Division  
3125 Murphy Hall  
140801

***Revised March 1, 2007***  
February 28, 2007

TO: Vivek Shetty, Chair, Academic Senate

FR: Malcolm Gordon, Chair, Council on Planning and Budget

RE: Proposal on the Relationships Between (Pharmaceutical) Vendors and Clinicians

The Council on Planning and Budget discussed the Draft Proposal on the Relationships Between (Pharmaceutical) Vendors and Clinicians at its meetings on January 22, February 5, and February 26, 2007.

A CPB member was assigned as the lead reviewer and presented a response for Council's discussion. The members provided their input and the enclosed revised response was endorsed.

UCLA's CPB therefore recommends that this draft proposal be sent back to the drawing board.

Please feel free to contact me if you have any questions.

Thank you.

cc: Jaime Balboa, Chief Administrative Officer, Academic Senate  
Elizabeth Bjork, Vice Chair, Academic Senate  
Linda Mohr, Assistant Chief Administrative Officer, Academic Senate

**COUNCIL ON PLANNING AND BUDGET  
REVIEW OF DRAFT PROPOSAL ON THE RELATIONSHIPS BETWEEN  
(PHARMACEUTICAL) VENDORS AND CLINICIANS**

This draft has been generated by UCOP in response to an article in JAMA referred to as the Brennan article in which Brennan et al. have determined that patient care and physician professionalism are jeopardized by inadequate controls on the relationship between vendors and clinicians. Following a newspaper article in which Stanford University described its policy, and stimulated by the Brennan article recommendations, the UC System has decided it would like to position itself as a leader in this area. There is the UCOP draft and a newer draft which has already been circulated by FEC at the Geffen School of Medicine.

The hypothesis of the Brennan article is that the regulations which the pharmaceutical firms have implemented to regulate themselves more stringently to prevent profit seeking behavior from influencing patient welfare are inadequate. They are inadequate because of physician behavior and have not resolved what Brennan and his co-authors perceive as a crisis to the standing of the medical profession. Brennan et al. have called upon AMC's to more strongly regulate and prohibit many practices which they conclude constitute conflicts of interest with drug and medical device companies in order to prevent further undermining of the physician's commitment to their patient's best interest and to scientific integrity. They state current guidelines by many organizations are inadequate because none provide monitoring mechanisms or define responsibility for compliance. Brennan et al. cite several references which purport to show that the impulse to reciprocate for even a small gift is a powerful influence on human behavior. Therefore, any gift given to a physician irrespective of its value will undermine the physician's objectivity toward the vendor, incline the physician to reciprocate, and purchase the vendor's product, and this desire to reciprocate will supersede consideration of the patient's best interest, ultimately undermining patient care and trust.

They recommend that all gifts (zero dollar amount) to physicians be prohibited. They further recommend prohibition of gifts comprising a long list of items including sample drugs, CME courses, etc. Additional recommendations include the posting of vendor provided grants on the internet, distribution of grant funding to the institution and not to individuals.

The article suggests that physicians are incapable of separating marketing from science. The suggestion that accepting a free pen or bagel is going to cloud the physician's professional judgment is provocative. The quality of the social science research cited in the article is called into question, particularly as it relates to skilled, highly regulated physician professionals dedicated to delivery of best patient care.

Nonetheless, despite the numerous controls in place to insure that regulations of the Political Reform Act which govern University of California employees are upheld, UCOP has made this issue a priority.

To that end the Draft has been developed. It prohibits gifts from vendors to individuals (e.g. food for conferences, payment for travel education, etc.) however the vendor may instead donate funds to a unit of the University such as a department or division. Free samples to an individual are outlawed; vendors may donate their product for evaluation or educational purposes to a unit of the University if the administrative head approves the donation.

Three recommendations in the Brennan report are excluded from the current draft proposal because they are in the purview of the Academic Senate. They are: 1) faculty may not publish articles or editorials that are ghostwritten by vendor employees, 2) "No strings attached" grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants), and 3) "All consulting agreement and unconditional grants shall be publicly listed" (e.g., on an internet web site).

UCOP requests that the System-wide Senate Review of the Draft be divided into two parts. The first review would be a review with the aforementioned three items excluded and the second System-wide Senate review would focus on the three additional proposals.

Conclusion:

Overall, the current Draft is problematic and difficult to support. It will certainly prevent vendors from supplying bagels, lunches, and free samples on hospital grounds. There is no reason to believe, however, that converting these donations to cash donations to University units will have less influence on purchasing patterns. It might have the opposite effect. Typically, the staff or nurse who partakes of the doughnut has far less purchasing influence than a unit director. This draft is unlikely to have impact outside University bounds, such as at meetings, etc. There, the issue of enforceability is problematic. There is a free market and vendors cannot be prevented from marketing their product. One can strongly advise people not to take free pens or notebooks, etc. when at a meeting but unless the vendors cease offering the free supplies, people will continue to take them.

UCLA already has numerous controls in place in order to comply with Political Reform Act.

With regard to the three excluded items "ghost writing" is of concern. There are strict regulations in place regarding authorships and a description of the role of authors listed in a publication is required by most reputable journals. "Ghost writing" would appear to subvert these policies. The Committee does not believe that unrestricted research grants should be disallowed. They should be carefully monitored, as they currently are. With

regard to the third item, web publication may have a negative impact on confidentiality agreements with industry and therefore should not be implemented.

It is not clear why the UCLA Geffen School of Medicine circulated a document prior to System-wide Review. The proposed UCLA Geffen School of Medicine Document is more restrictive. In section I.B it is recommend gifts from industry not be accepted anywhere on the UCLA campus or at any clinical facility operated by the UCLA Medical Enterprise or at any non-university operated clinical facility and it is recommended faculty and non-faculty staff never accept any personal gift from industry at any location under any circumstances. This latter prohibition is unenforceable as are items in section IIIC regarding not accepting food at any locations under any circumstances.

In order to achieve any measure of compliance the prohibitions need to reasonable and realistic.

The financial impact of the proposed changes is uncertain. It is likely that faculty travel allowances will need to be increased. The impact of these proposed regulations on CME sponsored courses is also uncertain. At many CME courses, the vendors have a booth, supply funds to help sponsor the meeting, and supply refreshments, etc. Will these regulations disallow this?

Also to be considered is the hampering of the dissemination of information. The prohibition displaying posters with a vendor's name on it in the workplace is problematic insofar as some posters contain information on how to operate a given device and are used as reference during the initial phases of device use.

Further exploration of the financial implications of these proposed regulations should be clarified lest a set of rules be established which are unworkable.

Before UC adopts any new set of rules for a complex area like this one serious consideration should be given to ensuring that those rules meet a few fundamental criteria.

- 1) They should not needlessly duplicate already existing rules that effectively deal with some or all of the same issues.
- 2) They should provide significant value added to the existing rules.
- 3) They should be as realistic and as consistently enforceable as possible.
- 4) They should be as explicit as possible with respect to their jurisdictional scope, both with respect to groups of people affected and geographic locations affected.
- 5) They should avoid intruding upon central issues of academic freedom.

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# MEMORANDUM

Academic Senate Executive Office  
Council on Research  
Los Angeles Division  
3125 Murphy Hall  
140801

**DATE:** April 13, 2007

**TO:** Vivek Shetty, Chair, Academic Senate

**FROM:** Council on Research Meeting April 6, 2007

**RE:** Draft Proposal on the Relationship between Pharmaceutical and Medical Device Vendors and Clinicians – Part II

UCLA's Council on Research (COR) discussed the above-entitled action item during their April 6, 2007 meeting. As requested by UCOP, this review is the second system-wide Senate review and considers the portion of the UCOP proposal dealing with the three policies regarding articles or editorials ghostwritten by vendor employees, vendor grants directed to individuals, and public listing of consulting agreements and unconditional grants. These three items were removed from the UCOP draft because they felt that they are in the purview of the Academic Senate and would therefore require significant Senate review prior to approval and should be discussed by FECs and Academic Senate committees.

## **Background**

Chair Oakley of the Assembly of the Academic Senate asked for a System-wide Senate review of this draft proposed by the UCOP Office of Clinical Services, a process driven in part by an article that appeared in JAMA last year, referred to as the "Brennan article." This paper focused on the many conflicts of interest between clinicians' delivery of patient care and the marketing desires of pharmaceutical and medical device manufacturers to sell their products. In summary, the authors reviewed results from social science research indicating that the current practice of self-regulation of marketing fails to protect patient interest satisfactorily, requiring more stringent regulation for academic medical centers. This article also referenced a Pharmaceutical Research and Manufacturers of America publication (2003), which reported that vendors evaluate the market impact of their expenditures and support those demonstrating an increased use of their products. This paper provided compelling arguments that this continuing conflict of interest in academic medical centers jeopardizes the standing of both clinical and research activities and described specific recommendations to regulate these customs.

## **The UCOP Proposed Policies**

1. Faculty may not publish articles or editorials that are ghostwritten by vendor employees.
2. "No strings attached" grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants).
3. All consulting agreements and unconditional grants shall be publicly listed (for example on an internet web site.)

### Opinion on Policy #1

Medical school faculty teach medical students not only the necessary facts in becoming a physician, but also act as mentors training these students in their ethical responsibilities as new physicians and scientists. Articles and editorials ghostwritten by industry employees can give the impression that faculty's opinions are influenced more by vendors than by research results. Further, research reports written by undisclosed authors may be construed as academic dishonesty and mislead committees that examine research productivity in determining academic promotion. Therefore, faculty should be prohibited from signing ghostwritten documents. Also, in scholarly publications, faculty, staff, and trainees must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors ([www.icmje.org](http://www.icmje.org)).

### Opinion on Policy #2

"No strings attached" grants to individuals are essentially gifts from vendors. Recent research demonstrates that gifts of even nominal value are likely to influence provider behavior and thus give the appearance of favoritism. Therefore, vendor gifts are likely to influence faculty behavior to prescribe or promote the vendors' products and should be prohibited.

### Opinion on Policy #3

To promote scientific progress, Academic Medical Centers (AMCs) should be able to accept grants for general support of research (no specific deliverable products) from pharmaceutical and device companies, provided that the grants are not designated for use by specific individuals. As long as the institution stands between the individual investigator and the company making the grant, the likelihood of undue influence is minimized but certainly not eliminated. To better ensure independence, scientific integrity, and full transparency, consulting agreements and unconditional grants should be posted on a publicly available Internet site, ideally at the academic institution. This is important because company-funded research is more likely to produce positive results and on occasion companies have restricted the dissemination of research results unfavorable to their products. Grants and consulting should not be prohibited but must be transparent and subject to peer-review. This disclosure will likely reduce vendors' influence on the outcome of the research by allowing the public to critically assess the research findings.

Sincerely,

A handwritten signature in black ink, appearing to read "Ajit K. Mal". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Ajit K. Mal, PhD  
Chair, UCLA Council on Research





# MEMORANDUM

UCLA Academic Senate Office  
3125 Murphy Hall  
140801

February 8, 2007

To: Vivek Shetty, Chair  
UCLA Academic Senate

From: Hossein Ziai, Chair  
UCLA Academic Freedom Committee

Re: Senate Item For Review: Draft Proposal on the Relationships Between  
(Pharmaceutical) Vendors and Clinicians

The Academic Freedom Committee has been asked by UCLA's Academic Senate leadership to comment on a proposed policy regarding relationships between pharmaceutical vendors and clinicians. The committee was somewhat surprised to be addressed on this matter, since we do not consider it to be primarily an academic freedom issue, but rather a medical staff concern related to patient care and hospital procedures. However, to the extent that it does appear to dramatically limit certain routine and commonplace professional interactions of those members of the UCLA faculty involved in clinical activities, we are grateful for the opportunity to comment.

The proposed policy would in effect end and prohibit all casual interactions between clinicians and vendors, limiting them to formalized and highly proscribed meetings, scheduled in advance by appointment, and would abolish the acceptance of even nominal goods such as refreshments at an educational seminar (even when the vendor's products are not the focus of discussion), pens and pads of paper, by clinical faculty members and clinical trainees. While intended to eliminate any appearance of favoritism or influence by or for any particular manufacturer, the rules proposed seem overly draconian and frankly rather demeaning when applied in this way to a group of highly intelligent and dedicated professional colleagues. Considering that our clinical faculty are not private practitioners but are first and foremost academicians, highly critical thinkers and scientists, who are part of a large, medical school-wide practice plan and therefore can hardly benefit personally from particular drugs or procedures they prescribe, this proposal seems to be a solution in search of a problem. To bar them from conversing about potentially critical medical information with another professional during business hours, simply because the latter individual is employed by a commercial entity, appears to us to violate some degree of academic freedom, not to mention freedom of speech, both of which must be accorded to all of our faculty, whether they work in the Medical Center or on North Campus.

We are also concerned about the broad and rather vague definition of "vendor". As written, it includes not only pharmaceutical manufacturers but also device manufacturers. The latter routinely place very costly equipment in the Medical Center and the UCLA Clinical Laboratories for beta-testing and evaluation, making new

technology available to our patients which could otherwise not be afforded. Are these to be considered "gifts" as well, and outlawed? Could this even extend beyond the medical setting, so that a humanities professor accepting a free textbook from a publisher for evaluation could be perceived as unduly influenced to obligate his students to purchase the book as the text for a class?

We would also like to add that the proposal recognizes that banning all gifts from vendors to individuals -- especially in our interconnected circles, where people in various branches of the medical field are often each other's spouses, parents, siblings, and the like -- is too onerous; it therefore provided an exception for "A gift from an individual's spouse, child, parent, grandparent, grandchild, brother, sister, parent-in-law, brother-in-law, sister-in-law, nephew, niece, aunt, uncle, or first cousin or the spouse of any such person, unless the donor is acting as an agent or intermediary for a vendor." But consider what it excludes:

Paul, a research science executive at a pharmaceutical company or medical device company, is dating Margaret, a professor at UCLA Medical School. He can't give her presents.

Paul wants Margaret to marry him. He can't give her an engagement ring.

(If Paul and Margaret were instead Penelope and Margaret, they couldn't give each other gifts ever, since they couldn't, at least under current law, become each other's spouses.)

Margaret turns Paul down, and marries Bill, another professor at UCLA. Margaret's other friends at the pharmaceutical company want to give Margaret and Bill wedding presents. They can't give them presents.

All this applies even if Margaret's friends are friends of hers from college, who knew her for many years before everyone went to work at their current jobs.

Margaret's sister Sarah, who does marketing at the medical device company, wants to give Margaret a Christmas present. She is a "vendor," since she is "the agent of a company that ... produces or markets ... devices." Ah, she says, but it's OK, since I'm Margaret's sister, and thus exempted by B.2.c. Not so fast! If she is "acting as an agent ... for a vendor," then she still can't give the present. Now in a sense she's not acting as an agent, since she's giving the present on her own. But the whole point of the policy, as I understand it, is to bar gifts by "agents" of companies even when they purport to be just giving the gifts on social occasions (or else there'd be no need for the family exception in B.2.c). So Margaret is an "agent" for purposes of being considered a vendor, but to give the gift she has to argue that she isn't "acting as an agent." That's at least ambiguous and confusing.

All this could be solved, to some extent, by reframing B.2.c to exclude not just familial relationships but also dating relationships and friendships, and to allow gifts of a

magnitude normally given in the context of the relationship (a \$30,000 car given by a friend wouldn't be allowed, but a \$30,000 engagement ring given by a lover would be allowed). But more broadly, the difficulty with framing exceptions such as B.2.c, and the fact that the draft -- doubtless developed after a considerable amount of careful work on the drafters' part -- prohibited actions as normal as the giving of engagement rings or presents among lovers, suggests that the whole project of banning all gifts and then having detailed exemptions listing 16 different categories of excluded people (why not grand-uncles, by the way?) is a mistake.

Moreover, with all the myriad problems facing health care in the United States, and in microcosm here at UCLA -- large uninsured and underserved populations, medical errors, budget crises, etc. -- this issue seems rather trivial in comparison, and we question whether there is any demonstrable harm (as opposed to *perceived* harm) arising from these practices. Of course, we are referring here to practices of a reasonable magnitude -- not all-expenses-paid vacation junkets to the Caribbean, practices which have already been effectively barred by AMA policy and are unlikely to involve any faculty at UCLA. We are aware that this movement began at Stanford and has quickly been imitated by other schools, but we would hope that UCLA would not rush to join that stampede without thinking through all the issues and ramifications carefully. Our clinical faculty colleagues deserve better than to be served with a set of admonitions that are about on the same level as a mother instructing her five-year-old child not to accept candy from strangers.



CHAIR, ACADEMIC SENATE  
RIVERSIDE DIVISION  
UNIVERSITY COLLEGE BUILDING, RM 225

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April 10, 2007

John Oakley  
Professor of Law  
Chair, UC Systemwide Academic Senate  
1111 Franklin St., 12th Floor  
Oakland, CA 94607

**RE: DRAFT PROPOSAL ON THE RELATIONSHIPS BETWEEN (PHARMACEUTICAL)  
VENDORS AND CLINICIANS**

Dear John,

The Committee on Faculty Welfare, the Committee on Research and the Committee on Academic Personnel have reviewed the draft proposal on the relationships between pharmaceutical vendors and clinicians.

The Committee on Academic Personnel made no recommendations, while the Committee on Faculty Welfare pronounced “omnia bene,” praising the policy for explicitly clarifying the boundaries of these relationships. In contrast, the proposal excited a great deal of discussion in the Committee on Research.

While generally sympathetic to both sets of proposed restrictions, a large majority of COR wondered why such a policy should apply exclusively to clinicians and pharmaceutical vendors when many other groups of faculty have relationships with vendors which may well generate similar conflicts of interest or the appearance of favoritism. The limitation to clinicians seemed based on the fact that most faculty merely spend their own grant money on vendors’ products while clinicians routinely influence others (i.e. patients) to use vendors’ products. Yet this distinction becomes considerably muddier when we remember other forms of faculty participation in promoting or approving products. Two examples suffice to make the point: 1) when faculty are involved in activities related to government regulation or regulatory approval of products; and 2) when they develop guidelines for best practices. Regulating these relationships with a series of policies such as those proposed here raises the specter of a dizzying array of discipline specific regulations and micro-management. The committee therefore recommends against adopting these single-issue regulations and instead recommends that a broad policy be developed to cover interactions between all vendors and UC faculty and staff. This policy should regulate the practices described in these proposals and in general while adhering to the principles of Academic Freedom. The Committee on Research would be pleased to review such a policy if/when it is proposed.

Yours faithfully,

Thomas Cogswell,  
Professor of History; and  
Chair of the Riverside Division



OFFICE OF THE ACADEMIC SENATE

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 LA JOLLA, CALIFORNIA 92093-0002  
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May 11, 2007

Professor John Oakley  
 Chair, Academic Senate  
 University of California  
 1111 Franklin Street, 12<sup>th</sup> Floor  
 Oakland, California 94607-5200

Re: Systemwide Review of the Draft Proposal on the Relationships Between (Pharmaceutical) Vendors and Clinicians – Parts I and II

Dear John:

In response to your request of January 3, the San Diego Divisional Committees on Academic Freedom and Faculty Welfare and the Health Sciences Faculty Council reviewed the “Draft Proposal on the Relationships Between (Pharmaceutical) Vendors and Clinicians.” The Senate Council considered the Draft Proposal at its meetings on April 4 and May 7, 2007. A variety of comments and concerns, some conflicting, were raised.

#### Draft Policy – Proposed Guidelines Regarding Vendor Relations

The Divisional Committee on Faculty Welfare did not see that the case for a new policy had been made. Senate Council’s discussion with the Chair of the Health Sciences Faculty Council, however, convinced Council members that such a policy was necessary, especially since some areas of current policies are ineffective, often because of laxness in enforcement. Caution was expressed about the implementation of Section V.B.2 restricting vendor support of continuing medical education efforts; such restrictions could have a significant negative effect on those very efforts.

Section V.B.2-3 stipulates that vendors may only donate equipment or other goods to a unit of the University rather than to a specific individual. What constitutes an “appropriate unit” is not clearly defined, neither is the “administrative head” who would be approving the donation. Unless these terms are clearly defined and are placed at the local level, the implementation of this provision could lead to cumbersome bureaucratic procedures.

The Health Sciences Faculty Council was particularly concerned about the language restricting sample drug donations. Currently, such donations are used in free clinic situations, as well as with other low-income and indigent patients. While many pharmaceutical companies have established programs to supply free medications to the needy, significant periods of time can elapse until a determination of eligibility is delivered, and samples are useful in such settings to bridge indigent patients and thereby enhance the quality of their medical care. The proposed restrictions would limit such important University public and outreach activities and also detract from significant educational opportunities for our trainees. We recommend that Section V.B.3 be amended to read (addition is underlined):

“...Sample donations are restricted to the amount necessary for evaluation or education, and are not intended to stock the University for patient care purposes on an on-going basis. Exceptions can be made for samples destined for use in University-sanctioned free clinics, and for the short-term use of samples in regular clinics for low income and indigent patients awaiting eligibility for other means of obtaining low cost or free medications, provided that there is institutional oversight and no direct involvement of pharmaceutical representatives in patient care settings.”

In Section III, Applicability, the Health Sciences Faculty Council recommends removing the word “human” from both lines 26 and 27, and adding the word “veterinary” to the listing of health schools, on moral and ethical grounds and from a public relations point of view. Further, HSFC recommends that in the interests of clarity “residents” be added to those to whom this policy applies, so that line 26 would read, “...all University employees, residents, and students....”.

The Health Sciences Faculty Council also recommends Section V.G be expanded to include a statement that related instruction should be added to the curricula of all health sciences schools (medicine, dentistry, nursing, pharmacy, and veterinary) to aid students in forming their own policy for dealing with pharmaceutical and other sales representatives when they enter practice.

Proposed Statement i: Faculty may not publish articles or editorials that are ghostwritten by vendor employees. The Health Sciences Faculty Council was concerned that this statement was not clear and thought the term “ghostwritten” needed to be defined carefully. There is a broad spectrum of interactions between faculty and vendors that might fall under this policy statement, some appropriate and others clearly inappropriate, reflecting varying degrees of participation in the speech or article preparation process. The Committee on Faculty Welfare noted that existing policy on academic integrity covers the clearly inappropriate end of the spectrum.

Proposed Statement ii: “No strings attached” grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants). Any faculty member has the right to set up funds from gifts through the UCSD Foundation; the Foundation’s existing policies and procedures ensure that the funds have “no strings attached.” Reviewers agreed that it would be inappropriate for a faculty member to receive payment personally; if this statement is intended to prohibit that situation, the wording should amended to correctly reflect this intent.

Proposed Statement iii: All consulting agreement and unconditional grants shall be publicly listed (e.g., on an internet website). Reviewers noted that faculty members already report consulting income and other grants on a regular basis to the University and that there are procedures for disseminating information to those outside of the University. Posting this information to the web would take the information out of context. Indiscriminate access to such data could increase the likelihood that people unaware of the University’s existing institutional controls could misrepresent the nature of the relationship between faculty members and pharmaceutical companies. Reviewers thought this would not be an appropriate use of public listing and could even be considered a violation of privacy.

In summary, reviewers noted a number of areas that need further work. The Senate Council’s discussion emphasized the complexity of the issues involved, noting the tension between the need for education and information management. The need for an enforceable policy is obvious, and there are mutual benefits and needs for which a “one-size fits all” policy may have unintended consequences. If implemented, perhaps this policy should be revisited in a relatively short period of time (e.g., two years) to assess its impacts.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry C. Powell", with a long horizontal flourish extending to the right.

Henry C. Powell, Chair  
Academic Senate, San Diego Division



Tamara Maimon, Director  
500 Parnassus, MUE 230  
San Francisco, California 94143-0764  
(415) 476-3808 Fax (415) 514-3844

Deborah Greenspan, DSc, BDS, Chair  
David Gardner, MD, MS Vice Chair  
Mary J. Malloy, MD, Secretary  
Jean Olson, MD, Parliamentarian

May 10, 2007

John Oakley, JD  
Professor and Chair  
University of California Academic Senate  
1111 Franklin Street, 12th Floor  
Oakland, CA 94607-5200

**RE: Divisional Response to the Proposed Guidelines Regarding Vendor Relations**

Dear Chair Oakley:

I am in receipt of the attached communication from the UCSF Academic Senate Task Force to Review the Proposed Guidelines Regarding Vendor Relations. Upon review of the document, the Task Force identified five key issues for consideration. With feedback from the Faculty Councils of the Schools of Dentistry, Medicine, Nursing and Pharmacy, as well as the Committees on Academic Freedom and Clinical Affairs, the Task Force generated the attached report. I support and concur with the recommendations of the Task Force and forward you these recommendations so that you may take them under consideration.

Please contact me should you have any questions or need additional information.

Sincerely,

David G. Gardner, MD, MS  
Vice Chair  
San Francisco Division

enclosure: Communication from the Task Force to Review the Proposed Guidelines Regarding Vendor Relations 05.09.07

cc: Maria Bertero-Barcelo, Executive Director, UC Academic Senate



## **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, eg. 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**

Daniel Bikle, MD, PhD, Task Force Chair, School of Medicine Faculty Council Chair

Brian Alldredge, PharmD, Associate Dean, School of Pharmacy

Gary Armitage, DDS, MS, School of Dentistry Faculty Council

Lisa Bero, PhD, Committee on Research

H. Quinn Cheng, MD, Committee on Clinical Affairs, School of Medicine Faculty Council

Stuart Gansky, DrPH, Committee on Academic Freedom

Sharad Jain, MD, Department of Medicine

Susan Lee, DMD, School of Dentistry

Deanna Ruth Rutter, JD, UCSF Conflict of Interest Officer

Jean Ann Seago, RN, PhD, Committee on Rules and Jurisdiction, School of Nursing Faculty Council

Norman Oppenheimer, PhD, Committee on Academic Planning and Budget



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Joel Michaelsen, Chair  
Claudia Chapman, Executive Director

May 14, 2007

John Oakley, Chair  
Academic Council

RE: Proposed Policies re Pharmaceutical Vendor Relations

Dear John:

The Santa Barbara Division has completed its review of the proposed policies regarding Pharmaceutical Vendor Relations. The College of Letters and Science Faculty Executive Committee, and the Councils on Research and Instructional Resources, and Faculty Issues and Awards were asked to comment. The comments received are confined to the three proposed policy statements.

Coming from a campus that has no medical school, our comments are made in light of how the proposed policies may also affect other parts of the University. There was agreement with the first of the proposed policies: that there should be no gifts to individuals. It was noted that the restrictions in the first and second proposed policies already exist on a broad level in the Faculty Code of Conduct, and that present conflict of interest policies would apply. There was agreement on the second proposed policy in the context in which it is meant; however, questions were posed whether the policy could be expanded to disallow non-competitive grants to other principal investigators.

A note of caution was raised regarding the listing of all such grants on, for instance, the internet. The concern was that publication of such documents on the internet could lead to misrepresentation of such agreements. However, in the interest of transparency it was suggested that the proposal read that

“iii. All consulting agreement and unconditional grants should be publicly available.”

Sincerely,



Joel Michaelsen  
Divisional Chair



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SANTA CRUZ DIVISION  
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May 1, 2007

John Oakley, Chair  
Academic Council

RE: System-wide Review of Draft Proposal on the Relationships Between (Pharmaceutical) Vendors and Clinicians

Dear John,

Consistent with our long-standing practices, the UC Santa Cruz Division asked its committees to provide guidance on a matter of consultation. We received recommendations from two committees: Committee on Academic Freedom (CAF) and Committee on Research (COR). I base my response mostly on the comments of COR.

We agree with the overall premise that UC faculty, researchers, and students should not be involved in relationships with vendors or others that may create the appearance of bias or misrepresentation of scientific research (not to mention actual bias, fraud, or more serious violations of university policy). Thus, we welcome the proposal. Nonetheless, we have three concerns with the proposed guidelines as they are currently written.

First, we are surprised that the specific behaviors that are to be prohibited under new guidelines are not already covered by university policies on research and academic integrity.

Second, we wonder how the new policies are to be enforced. Indeed, if these activities are (essentially) prohibited by existing rules, and this has not helped to prevent them, then adding new, more explicit policies about specific activities, departments/programs, or vendors is unlikely to make much difference. Without enforcement, guidelines such as these will do little good, and may actually raise questions about UC's commitment to honor them.

Finally, we are baffled as to why the proposed policies are to be so narrowly restricted as to their application. As written, the new policies would apply "...to all university employees and students who are at human health care locations or in human health schools (e.g., medicine, dentistry, nursing, pharmacy)." If new policies are needed to prevent bias, fraud, and/or misrepresentation, why are they needed only for this small group of UC employees and researchers?

Sincerely,

A handwritten signature in black ink, appearing to read "Faye J. Crosby".

Faye J. Crosby, Chair  
Academic Senate  
Santa Cruz Division





COORDINATING COMMITTEE ON GRADUATE AFFAIRS (CCGA)  
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rwu@ucdavis.edu

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April 9, 2007

JOHN OAKLEY, CHAIR  
ACADEMIC COUNCIL

**RE: Draft Proposal on the Relationships Between (Pharmaceutical) Vendors and Clinicians**

Dear John,

Over the past couple of months, the Coordinating Committee on Graduate Affairs has discussed in earnest both the UCOP *'Proposed Guidelines Regarding Vendor Relations'*, and the three points laid out your memorandum from January 3, 2007. Overall, members agreed that the UCOP proposal represents a good step towards regulating vendors. Therefore the committee supports this proposal as a step towards regulating vendor relations, but members recognize that it does so in an imperfect world. That said however, they also feel that drafters of this document (for purposes of future revisions) should be mindful of the integral relationship between the three other elements addressed below.

On these three points, members accepted the first and third points (items i. and iii.) wholeheartedly. In the second point members would like to specify graduate students and academic personnel. Therefore, they would like it reworded as follows: "No strings attached' grants or gifts directed to **individuals graduate students and academic personnel** from vendors shall be prohibited (this excludes competitive grants)." Although prohibited to graduate students and academic personnel, they felt that such grants might be allocated to academic units in conformity with Vendor Relations V.A, V.B, and V.C.

Thank you for giving us the opportunity to comment on this important issue. If you have any questions, please let me know.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Reen Wu".

Reen Wu  
Chair, CCGA

cc: CCGA

Executive Director Bertero-Barcelo





**UNIVERSITY COMMITTEE ON ACADEMIC FREEDOM**  
**JEROLD THEIS, CHAIR**  
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April 13, 2007

**JOHN OAKLEY**  
CHAIR, ACADEMIC COUNCIL

**Re: Systemwide Review of a draft UCOP Proposal on the Relationships between  
Pharmaceutical Vendors and Clinicians**

Dear John,

The University Committee on Academic Freedom (UCAF) has reviewed a proposed policy from the Office of the President entitled "Proposed Guidelines Regarding Vendor Relations," as well as three additional proposed policies:

- i. Faculty may not publish articles or editorials that are ghostwritten by vendor employees:
- ii. "No strings attached" grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants).
- iii. All consulting agreement and unconditional grants shall be publicly listed (e.g., on an internet web site).

UCAF focused its discussion on the three additional proposed policies, particularly item ii, which we strongly oppose. We found the other two proposals to be mostly inoffensive, but also redundant with current policy and thus unnecessary. With regard to item ii, UCAF concluded that prohibiting faculty members from accepting no-strings-attached monetary gifts or grants from a pharmaceutical vendor could potentially be a serious blow to the freedom and ability of UC faculty to conduct research. "No strings" attached funds for research that lack specific requirements are very difficult to secure. A ban on such funding opportunities would prevent faculty from exploring ideas outside the mainstream of granting agencies. It would not only infringe on academic freedom, but also impair the mission of the University to discover and disseminate new knowledge.

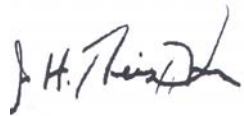
We believe there are sufficient mechanisms, protocols, and safeguards in place at the University to ensure ethical practices and to prevent conflicts of interest. These policies exist both on the individual campuses, and in systemwide regulations such as the Faculty Code of Conduct. For instance, current University policy requires "no strings" grants to go through the same sponsored projects firewalls as other proposals. Item i, which would prohibit faculty from publishing articles or editorials that are ghostwritten by vendor employees, is redundant and unnecessary as such behavior is already prohibited in the Faculty Code of Conduct.

In addition, item iii appears to contradict item i, if the “unconditional” grants noted in i are also assumed to be no-strings-attached grants. Such grants would be prohibited in item i, yet item iii requires that they be publicly listed along with consulting agreements.

We are concerned that the Proposed Guidelines as written would prohibit most casual interactions between clinicians and vendors and impose an unnecessary layer of bureaucracy and micro-management onto those interactions and the acceptance of even small gifts. UCAF acknowledges that there are legitimate concerns about the influence of pharmaceutical vendors on individual faculty as well as more general concerns about corporate influence and the “privatization” of the University. However, limiting faculty freedoms in this way is unproductive and deflects from serious conflict of interest issues. Moreover, it is difficult to imagine a fair and practical policy that would effectively regulate gifts of pens and calendars.

In short, UCAF recommends against Academic Council endorsement of this proposal.

Sincerely,

A handwritten signature in black ink, appearing to read "J. H. Theis". The signature is fluid and cursive, with a large initial "J" and "H".

Jerold Theis  
Chair, UCAF

cc: Director Bertero-Barceló  
UCAF



UNIVERSITY COMMITTEE ON RESEARCH POLICY (UCORP)  
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March 15, 2007

**JOHN OAKLEY, CHAIR  
ACADEMIC COUNCIL**

**RE: Draft Proposals on the Relationships Between (Pharmaceutical) Vendors and Clinicians**

Dear John,

At its February 12, 2007 meeting, and again at its March 12, 2007 meeting, the University Committee on Research Policy (UCORP) discussed the Draft Proposals on the Relationships Between (Pharmaceutical) Vendors and Clinicians. While the committee agrees in principle with the Draft Proposals and finds their goal laudable, UCORP cannot endorse them at present.

UCORP disputes neither the evidence of conflict of interest nor the appearance of favoritism following the acceptance of gifts, meals, etc., from (pharmaceutical) vendors. UCORP, however, views this as part of a larger problem, one not restricted to the relationships between (pharmaceutical) vendors and clinicians. Members submit that similar practices occur in other fields, such as agri-business. As a result, the committee cautions against a proliferation of issue- and discipline-specific prohibitions amounting to an unwieldy set of regulations and micromanagement. UCORP would prefer a more broadly conceived policy embracing universally high standards to govern the relationships between any and all vendors and UC faculty and staff. We believe such a policy would both adhere to and be consistent with the definition of Academic Freedom propounded by the Academic Senate, as well as effectively regulate the practices in question.

We thank you for the opportunity to comment on this topic.

Sincerely,

Wendy Max, Chair  
UCORP

cc: Maria Bertero-Barcelo, Executive Director, Academic Senate  
UCORP



UNIVERSITY COMMITTEE ON PLANNING AND BUDGET  
Christopher Newfield 2006-2007 Chair  
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April 12, 2007

**JOHN OAKLEY**  
**ACADEMIC COUNCIL CHAIR**

**Re: Draft Proposals on Vendor-Clinician Relationships**

Dear John,

UCPB has had two discussions of the UCOP proposals regarding vendor-clinician relations. The second discussion included the Director of Clinical Services, Rory Jaffe, who was kind enough to explain the purpose and rationale of the proposals that have come to us from his office.

We note first that there are actually four proposals. We are commenting here only on the "Proposed Guidelines Regarding Vendor Relations." The three other proposals mentioned in the Senate cover letter to us are the following:

- i. Faculty may not publish articles or editorials that are ghostwritten by vendor employees:
- ii. "No strings attached" grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants).
- iii. All consulting agreement and unconditional grants shall be publicly listed (e.g., on an internet web site)

No actual policy text accompanies the latter three proposals. UCPB is unwilling to offer any commentary on policies that are not accompanied by a text. We recommend that all Senate bodies refrain from commentary on these proposals until they have been embodied in a written proposed policy.

As for the guidelines regarding vendor relations, our discussion was largely negative. Though members agreed with the general need to keep marketing at a distance from patient care, there was widespread skepticism that these guidelines were the way to do this. Committee members made these criticisms on the proposal:

- It offers a one-size-fits-all blanket approach to vendor relations throughout the UC system. Many members felt that the worst problems were already managed or could best be managed at the level of a particular school or department rather than through a systemwide policy handled by UCOP.
- The policy does not acknowledge the needs of units that mix personnel from different institutions. At UCLA-Harbor General hospital, for example, the policy would apparently

place UC personnel under restrictions that would not apply to colleagues with different affiliations in the same units.

- The policy unfairly singles out medical personnel. Questions were raised as to whether relations between textbook salespersons and faculty on general campuses should remain unregulated while relations between pharmaceutical vendors and clinical personnel should be regulated.
- It stigmatizes the acceptance of any gift from vendors, including bags containing conference materials at professional meetings and the like. Although members are aware of the research that suggests that even minor gifts can influence behavior, many felt that the regulations placed an unfair burden of guilt or refusal on the recipients of such gifts regardless of the context or the gift's triviality.
- It does not define the physical boundaries of where the policy would be in effect nor adequately clarify affected populations.

UCPB recognizes that the public wants universities to provide objective scientific knowledge about all subjects, whether the subject be the value of a specific medical procedure or the interpretation of a painting from the Italian renaissance. We recognize that this involves the avoidance of both the appearance and the reality of financial interests that may compromise professional judgment, and that universities are currently under intense public scrutiny regarding the ethical conduct of academic research. At the same time, the committee does not believe that the current proposal represents a useful step in that direction. We recommend that the Senate ask the Office of Clinical Services to withdraw this proposal at this time. Any revised proposal, we suggest, should be submitted as a set of guidelines that would regulate policy at the broadest level and allow campuses flexibility at the campus level to fit with individual contexts and needs. Moreover, a revised proposal should offer a more comprehensive and forceful rationale than was the case this time around.

Sincerely,

Christopher Newfield  
UCPB Chair

Copy: UCPB  
Executive Director Bertero-Barceló



UNIVERSITY COMMITTEE ON PRIVILEGE AND TENURE (UCP&T)  
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March 20, 2007

**JOHN OAKLEY, CHAIR  
ACADEMIC COUNCIL**

**RE: UCP&T Review of Draft UCOP Proposal on the Relationships Between  
(Pharmaceutical) Vendors and Clinicians (12/11/06)**

Dear Chair Oakley:

Several members of the University Committee on Privilege and Tenure (UCP&T) have provided comments on the UCOP “Proposed Guidelines Regarding Vendor Relations,” including detailed comments from one divisional P&T committee (UCI), which are appended to this document.

The consensus of UCP&T is to support the proposal, including the three additional policy components of the proposal that were circulated for subsequent review, with the understanding that the proposal is consistent with current UC research integrity policies. Some members expressed reluctance to comment on the components of the proposal that may have implications for faculty covered by the Health Sciences Compensation Plan, with which non-clinicians are unfamiliar. In particular, this pertains to the proposed component relating to public listing of consulting agreements and unconditional grants.

The committee also offers the following observations:

- The policy should be relevant for all health care delivery situations and personnel in all medical sciences.
- The policy should clarify that vendors cannot legally provide health care (i.e., different terminology should be used in Part V.C.3.a).
- The policy should be relevant for relations with vendors of medical devices and related products, as well as vendors of pharmaceuticals.

Sincerely,

Kathleen Montgomery, Chair  
UCP&T

cc: UCP&T  
Maria Bertero-Barcelo, Executive Director

March 9, 2007

**KATHLEEN MONTGOMERY, CHAIR  
UNIVERSITY COMMITTEE ON PRIVILEGE AND TENURE**

**RE: PROPOSAL ON THE RELATIONSHIPS BETWEEN (PHARMACEUTICAL)  
VENDORS AND CLINICIANS**

The Irvine P&T Committee has examined the proposed university policy on Relationships Between (Pharmaceutical) Vendors and Clinicians. We are supportive of the policy as presented but have several comments for both stages of the proposed policy.

- The proposed policy seems to codify what is standard practice at UC Irvine.
- This sensible policy should be implemented in all health care delivery situations.
- There does not seem to be any infringement of faculty academic freedom that might lead to involving the Committee on Privilege and Tenure.
- Line 115 suggests that vendors actually provide health care in certain situations. This is not the case. Vendors may consult with the health care provider on technical matters, but they do not provide health care. We recommend that this distinction be made very clear.
- The treatment of gifts by vendors is made quite clear and should be followed and respected by all.
- The issue of travel to accomplish training on new devices/equipment is more complex than suggested by the proposal as there may be significant economies and advantages to conduct the training at centralized sites. In such cases, UC faculty benefit from such sessions where travel costs are paid for by the vendors, but procedural safeguards should be established whereby both the vendors and recipient faculty should provide an accounting of what was provided or received and at what cost. Further, such training procedures and costs should be part of the vendors' proposals and factored into the contracts with the university, as is suggested by the proposal
- Is there a reason why the title of the policy refers to the pharmaceutical industry and not the medical device industry as well? We feel that the policy should cover the wide variety of industries that have vendor-type relations with faculty and their schools. Examples might be IT companies or private equity investors. We recommend that the related industries should be more expansively spelled out.

- Similarly, there is concern that coverage of this proposed policy should be more clearly articulated to include a variety of health care professions such as schools of medicine, pharmacy, nursing, dentistry, veterinary medicine, health sciences, and other related schools.

Several weeks ago, contrary to the initial request, we were asked to comment on Part II of the proposal also by the March 15 deadline. Our comments closely follow the recommendations of Dr. Jaffe.

1. Faculty may not publish articles or editorials or circulate academic papers as their own that are ghostwritten by vendor employees or consultants.
2. “No strings attached” grants or gifts directed to individuals from vendors or related foundations shall be prohibited, though this excludes competitive grants.
3. All paid consulting agreements and unconditional grants shall be immediately reported to the relevant dean and to the campus chancellor and will be publicly listed (e.g. on a specially designated internet web site).
4. We do suggest that consideration should be given to a policy that would allow UC faculty to work with colleague scientists at various research labs, commercial or not, but in ways that would provide guidelines so as not to compromise their roles as university faculty.

We hope these comments are helpful while indicating our support of the policy.

On behalf of the Committee,

David H. Blake, Chair  
Committee on Privilege and Tenure





UNIVERSITY COMMITTEE ON FACULTY WELFARE (UCFW)  
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June 8, 2007

**JOHN OAKLEY, CHAIR  
ACADEMIC COUNCIL**

**RE: UCFW Comments on Draft Proposal on Relationships Between (Pharmaceutical) Vendors and Clinicians**

Dear John,

UCFW has considered the draft proposal and submits the following comments:

*1. Paragraph IV. Definitions, B.2 (c), should be changed to include domestic partners and their relatives.*

Under IV. B.2 (c), Gifts from an individual's spouse and various relatives of an individual's spouse are excluded from the definition of a gift prohibited by the policy. The exception does not specifically include gifts from an individual's domestic partner, relatives of a domestic partner, or the domestic partner of a relative of the individual. Failure to treat domestic partners equally with spouses violates California law. *See* California Family Code §§ 297.5 (a) and (g):

(a) **Registered domestic partners shall have the same rights, protections, and benefits**, and shall be subject to the same responsibilities, obligations, and duties under law, whether they derive from statutes, administrative regulations, court rules, government policies, common law, or any other provisions or sources of law, **as are granted to and imposed upon spouses**.

(g) **No public agency in this state may discriminate against any person or couple on the ground that the person is a registered domestic partner rather than a spouse** or that the couple are registered domestic partners rather than spouses ....

Paragraph IV. B. 2.(c) should be amended to exclude gifts from domestic partners and relatives of domestic partners to the same extent that gifts from spouses and relatives of spouses are excluded.

*2. Paragraph III. Applicability limited to employees at human health care locations or schools.*

UCFW does not understand the rationale for limiting this policy to employees and students who are at human health care locations or in human health schools. If the policy is adopted, it should probably apply to students and employees at:

- animal health care locations or schools

- schools of public health
- units involved in health care promotion and advocacy activities
- off-site clinics, or other facilities such as those operated as part of student services
- hospitals operated or managed by UC employees
- engineering schools who do health-related research
- other units that do health-related research

### *3. Applicability Limited to Pharmaceutical Vendors & Clinicians?*

The title of the proposal suggests that its applicability is limited to pharmaceutical vendors and clinicians, but the definition of vendor in IV. C. covers producers and marketers of drugs, devices, nutritional products, or other products or services that are provided upon prescription or at the suggestion of a health care professional. This definition seems both too broad (producers and marketers of nutritional products would include farmers, grocers, etc.) and too narrow (marketers of CT scanners, artificial joints, IV lines, blood and tissues, etc. may not be included). UCFW suggests that if the policy is adopted, it should be broadened to include vendors of most, if not all, areas regulated by the FDA, and similar products related to animal health. For example, artificial joints, CT scanners, IV lines, animal drugs, human blood, human tissues, etc.

Another question is whether the policy also covers relationships between vendors and administrators. UCFW believes that if the policy is adopted, it should also cover vendor-administrator issues.

### *4. Paragraph V.B.3: Policy – Gifts and Compensation Provided by Vendors*

The policy states that samples are prohibited from a vendor to an individual. However, we are aware of some clinics that still accept samples and require that one physician sign for them and be responsible for their receipt. The policy makes no mention of such a gift from a vendor to a clinic or unit that has one person sign for the samples.

### *5. Brennan Proposal I: Faculty May Not Publish Articles or Editorials That Are Ghostwritten by Vendor Employees*

UCFW is strongly opposed to this proposal as it comes precariously close to impinging on faculty academic freedom under APM 010. Further, it is our understanding that the Faculty Code of Conduct applies in such circumstances and therefore believes this proposal unnecessary and duplicative.

### *6. Other: Monitoring and Enforcement*

The policy should include explicit provisions on monitoring and enforcement if it is to be taken seriously.

Sincerely,

Susan F. French, Chair  
UCFW

Copy: UCFW  
Maria Bertero-Barcelo, Executive Director, Academic Senate