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Assembly of the Academic Senate
Academic Council
1111 Franklin Street, 12th Floor
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January 3, 2007

SYSTEM-WIDE SENATE COMMITTEE CHAIRS

DIVISIONAL SENATE CHAIRS

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

Dear System-wide Senate Committee and Divisional Senate Chairs:

On behalf of Chair Oakley, the above document, drafted by staff at the University of California Office of the President (UCOP) is being forwarded for your review and comments. As background information, in the wake of what is referred to in the documentation as the "[Brennan](#)" article (*Health Industry Practices that Create Conflict of Interest – A Policy Proposal for Academic Medical Centers, Reprinted JAMA, January 25, 2006-Vol 295. No 4.*), medical schools, including UC medical schools are reviewing their policies or developing policies with respect to pharmaceutical vendor relationship. UCOP-Office of Clinical Services has proposed a set of policy on the relationship between vendors and clinicians in part to: 1) position UC as a leader in this area; and 2) coordinate potentially conflicting efforts on the campus. Since Clinical Services would like to expeditiously move to approve this proposal, the UCOP reviewers **removed** two items in the Brennan proposal that are in the purview of the Academic Senate and would therefore require significant Senate review prior to approval. The two draft policies removed from current consideration are: 1) Faculty may not publish articles or editorials that are ghostwritten by vendor employees; and 2) "No strings attached" grants or gifts directed to individuals from vendors shall be prohibited (this excludes competitive grants). In addition a third item was also excluded from the proposed UC policy at this time. That policy would require that "All consulting agreement and unconditional grants shall be publicly listed (e.g., on an internet web site)." The reason why the third proposed policy was pulled from the proposal as provided to us by UCOP is ". . . that faculty in the medical school compensation plan can personally enter into certain consulting agreements without the review of prospective approval of the University. To bring those into the public list may require revisiting the compensation plan."

After discussing the issue and UCOPs desired for expeditiously approving a policy, the Academic Council agreed that the **proposed proposal would be considered in two parts and therefore would undergo two stages of Systemwide Senate review:**

1. **The first Systemwide Senate review would consider the [UCOP proposal](#) as presented **without the three additional proposed policies**. In addition, the Academic Council has requested some additional information. It was brought up at the Council meeting, that some campuses have already implemented standards of behavior and practice for relationships with pharmaceutical company vendors. **It would be extremely helpful if we could receive copies of the policies, as well as any information you can provide on what has worked and what has not worked. With this****

information in hand, we are hoping to identify “best practices” that can be implemented across all campuses.

Review Deadline: For this review, **System-wide Committees and Divisions** are asked to please submit responses by: **March 10, 2007.**

2. The second Systemwide Senate review will focus on the **following 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).**

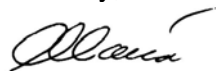
In order for the Academic Council to finalize a position with respect to **these three proposed policy** during the 06-07 academic year we would very much appreciate receiving responses by the dates listed below:

For **System-wide Senate Committees** please submit responses by: **April 10, 2007**
For **Divisions** please submit responses by: **May 10, 2007**

As a reminder to System-wide Committee Chairs, please note two points regarding the practice that the Academic Council has established for general reviews:

1. **Request for comments are sent out to all System-wide Committees. Each committee may decide whether or not to opine.** Please notify the Senate Office either directly by emailing me or through your Committee Analyst, if your committee chooses not to participate in this review.
2. Whenever time permits the **Committee response due date is typically set a month before that of Divisions.** This two-stage review allows the Academic Council to conduct both a preliminary and a final discussion of the matter at hand. It also gives the Divisions the benefit of the committees’ considerations for their own deliberations.

Cordially,



María Bertero-Barceló, Executive Director
Academic Senate

Encl: The UCOP Proposal - <http://www.universityofcalifornia.edu/senate/underreview/Proposed.pharmaceutical.policies.0107.pdf>
The “Brennan” Proposal - <http://www.universityofcalifornia.edu/senate/underreview/brennan.pdf>
Various related articles - <http://www.universityofcalifornia.edu/senate/underreview/pharmaceutical.articles.0107.pdf>
<http://www.universityofcalifornia.edu/senate/underreview/gift.pdf>
http://www.universityofcalifornia.edu/senate/underreview/post-training_behavior.pdf
<http://www.universityofcalifornia.edu/senate/underreview/social.science.pdf>

Copy: Academic Council Chair John Oakley
Divisional Senate Directors
Academic Senate Committee Analysts

1 Proposed Guidelines Regarding Vendor Relations

2 **I. Policy**

3 **II. Purpose**

4 The Political Reform Act, which governs University of California employees, aims to
5 remove bias from their decisions. The University of California Policy and Guidelines
6 Regarding Acceptance of Gifts and Gratuities by Employees under California’s Political
7 Reform Act (January 2001) adds the following statement:

8 In addition to compliance with the requirements of law,
9 University officers and employees must avoid the
10 appearance of favoritism in all of their dealings on behalf
11 of the University. All University officers and employees
12 are expected to act with integrity and good judgment and to
13 recognize that the acceptance of personal gifts from those
14 doing business or seeking to do business with the
15 University, even when lawful, may give rise to legitimate
16 concerns about favoritism depending on the circumstances.

17 Recent research shows that certain health care vendor activities allowed under the
18 Political Reform Act, such as the provision of gifts of nominal value, may affect provider
19 behavior and give the appearance of favoritism. This policy supplements the provisions
20 of the Political Reform Act and University Business and Finance Bulletin G-39 (Conflict
21 of Interest Policy) in order to reduce the influence of vendors on the decisions made by
22 University of California health care professionals.

23 This policy establishes minimum standards for campus implementation of vendor
24 relationship policies. Nothing in this policy prevents campuses from going further.

25 **III. Applicability**

26 This policy applies to all university employees and students who are at human health care
27 locations or in human health schools (e.g., medicine, dentistry, nursing, pharmacy).

28 **IV. Definitions**

29 The terms “individual”, “gift” and “vendor” have special definitions for the purpose of
30 this policy.

31 A. **Individual:** An employee or student working or training at human health care
32 locations or in human health schools.

33 B. **Gift to an individual:** payment to an individual or provision to an individual
34 of free or discounted items, medical samples for personal use, food, or travel
35 when the individual is not providing a service of similar or greater value to the
36 vendor. For example: pens, notepads, free textbooks, free meals, payment for
37 attending a meeting, and samples are all considered gifts. Honoraria for a specific
38 service rendered (e.g., speaker's fees) are not considered gifts.

39 1. A gift to the University is considered a gift to the individual under any
40 of the following circumstances:

41 a) The gift is conveyed by the vendor directly to the individual.

42 b) The vendor selected or participated in selecting the ultimate
43 recipient of the gift.

44 2. Exclusions from the definition of a gift:

45 a) Items provided for a discount or free as part of a University
46 contract;

47 b) Prizes or awards from bona fide competitions (e.g., a
48 competitive grant);

49 c) A gift from an individual's spouse, child, parent, grandparent,
50 grandchild, brother, sister, parent-in-law, brother-in-law, sister-in-
51 law, nephew, niece, aunt, uncle, or first cousin or the spouse of any
52 such person, unless the donor is acting as an agent or intermediary
53 for a vendor;

54 d) Free admission, and refreshments and similar non-cash
55 nominal benefits provided to an individual during the entire event
56 at which the individual gives a speech, participates in a panel or
57 seminar, or provides a similar service;

58 e) Free admission, and refreshments and similar non-cash
59 nominal benefits provided to an individual during a training
60 session provided by the vendor for the purpose of training the
61 individual in the use of the vendor's product. Note that free travel
62 or lodging would be a gift. If free training is anticipated, it shall be
63 referenced in the purchase contract for the vendor's product;

64 f) A rebate or discount that is made in the regular course of
65 business to members of the public without regard to their status as
66 a health care worker (e.g., a coupon in the newspaper for a
67 discount on a pain reliever).

68 C. **Vendor:** a company or its representative or the agent of a company that either
69 produces or markets drugs, devices, nutritional products, or other products or
70 services that are provided upon prescription or at the suggestion of a health care
71 professional.

72 V. Policy

73 A. Applicability of state law

74 1. All employees of the University of California are subject to the
75 conflict-of-interest provisions of the Political Reform Act. This policy
76 supplements those provisions.

77 B. Gifts and Compensation Provided by Vendors

78 1. Gifts from vendors to an individual are prohibited.

79 2. In circumstances where the gifts were in part supporting the mission of
80 the University (e.g., food for conferences, payment for educational travel,
81 and samples for evaluation), there are appropriate alternatives that can
82 enable the vendors to continue to support the University's mission. For
83 example, to replace the free food or payment for educational travel,
84 vendors may donate funds to a unit of the University (e.g., department or
85 division) to support meetings. These funds will be managed in accordance
86 with national continuing education accrediting body conflict of interest
87 standards even when the meetings are not accredited continuing education
88 programs. Donations or gifts will not have an effect on a vendor's ability
89 to communicate with University employees or trainees.

90 3. Free samples, supplies, or equipment designated for an individual are
91 considered a gift and are prohibited. Vendors may donate their product for
92 evaluation or educational purposes to a unit of the University if the
93 administrative head of the unit approves the donation. Sample donations
94 are restricted to the amount necessary for evaluation or education, and are
95 not intended to stock the University for patient care purposes on an
96 ongoing basis. These donations are subject to the policies of the
97 University, including those addressing drugs, devices, and investigational
98 items.

99 a) In addition to the limited sampling described above, the
100 University may dispense sample supplies to patients when the
101 supplies are either packaged or purchased by the University.

102 C. Interaction between vendors and University personnel

- 103 1. Financial relationships between the vendor and the University or
104 individuals at the University shall not affect the ability of the vendor to
105 make sales calls.
- 106 2. Unsolicited visits made by vendors are not permitted. Vendors may
107 make sales calls only at the invitation of appropriate University personnel.
108 Such sales calls may only occur in non-patient-care areas. Exceptions can
109 occur by local policy when it is determined that there is a compelling need
110 for the call to occur in a patient care area. For sales calls in a patient care
111 area, patient privacy laws (including HIPAA) will be followed. The
112 vendor may not access patient information during a sales call unless the
113 patient has given written authorization to do so.
- 114 3. Vendors may also enter patient care areas when:
- 115 a) Providing health care (see examples below); or
 - 116 b) Servicing equipment, including installation and removal; or
 - 117 c) Invited for specific vendor service at the request of a
118 representative of the University for its health care operations; or
 - 119 d) Acting as a member of the general public (e.g., as a patient).
- 120 4. Unless acting as a member of the general public, the vendor will agree
121 to a confidentiality agreement to protect the health information of our
122 patients. The following are acceptable in lieu of a confidentiality
123 agreement:
- 124 a) a HIPAA business associate agreement,
 - 125 b) a determination that the vendor is acting as a member of a
126 covered entity (as defined by HIPAA), or
 - 127 c) provisions to ensure that the vendor does not have access to
128 protected health information.
- 129 5. Examples of a vendor providing health care:
- 130 a) An orthopedic device manufacturer or its representative
131 determines and delivers the appropriate range of sizes of a
132 prosthesis for the surgeon to use during a particular patient's
133 surgery.
 - 134 b) The device manufacturer or its representative is present in the
135 operating room, as requested by the surgeon, to provide support
136 and guidance regarding the appropriate use, implantation,

137 calibration or adjustment of a medical device for that particular
138 patient.

139 c) A representative of a medical device manufacturer views health
140 information, such as films or patient records, to provide
141 consultation, advice or assistance where the provider, in her
142 professional judgment, believes that this will assist with a
143 particular patient's treatment.

144 D. Committees overseeing purchase decisions

145 1. Hospital and medical group formulary committees and other
146 committees overseeing purchases of medical devices, nutritional products,
147 or other products or services that are provided upon prescription or
148 suggestion of a health care professional, will follow the Political Reform
149 Act regulations, which include restrictions on the participation of
150 individuals who have financial relationships with vendors affected by the
151 purchase decisions.

152 E. Vendor preceptorships

153 1. Vendor preceptorships are educational programs for vendor
154 representatives. Vendors have the same access to the official educational
155 offerings of the University as other members of the general public.
156 Generally, these are official courses of the University or continuing
157 education programs under the auspices of the University's continuing
158 education departments and in accordance with national continuing
159 education accrediting body guidelines. Departments may not produce
160 vendor preceptorships without oversight by the continuing education
161 department

162 F. Publicity of industry support

163 1. California's Public Records Act (Government Code sections 6250 et
164 seq.) provides that information about industry support of the University is
165 a public record.

166 G. Education

167 1. All individuals to whom this policy applies shall receive training
168 regarding interactions with vendors.

169 **VI. Appendix**

170 A. References

- 171 1. University of California Policy and Guidelines Regarding Acceptance
172 of Gifts and Gratuities by Employees under California's Political Reform
173 Act (January 2001)
- 174 2. Political Reform Act and the regulations of the Fair Political Practices
175 Commission
- 176 3. Privacy provisions of the Health Insurance Portability and
177 Accountability Act (HIPAA)
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181 Cohen JJ, Goldman J, Kassirer JP, Kimball H, Naughton J, Smelser N.
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183 proposal for academic medical centers." JAMA. 2006 Jan 25;295(4):429-
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186 physicians from industry." JAMA. 2003 Jul 9;290(2):252-5.
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188 of restricting contact between pharmaceutical company representatives
189 and internal medicine residents on posttraining attitudes and behavior."
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192 sample medications on the prescribing practices of family physicians." J
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195 just a gift?" JAMA. 2000 Jan 19;283(3):373-80.

196 B. Other relevant guidance

- 197 1. The Federal Department of Health Services Office of Inspector
198 General has published compliance guidance, including the following
199 (Federal Register, Vol. 68, No. 86 pp 23731- 23743:
200 ... the anti-kickback statute prohibits in the health care
201 industry some practices that are common in other business
202 sectors. In short, practices that may be common or
203 longstanding in other businesses are not necessarily
204 acceptable or lawful when soliciting federal health care
205 program business.
- 206 The anti-kickback statute is a criminal prohibition against
207 payments (in any form, whether the payments are direct or

208 indirect) made purposefully to induce or reward the referral
209 or generation of federal health care business. The anti-
210 kickback statute addresses not only the offer or payment of
211 anything of value for patient referrals, but also the offer or
212 payment of anything of value in return for purchasing,
213 leasing, ordering, or arranging for or recommending the
214 purchase, lease, or ordering of any item or service
215 reimbursable in whole or part by a federal health care
216 program. The statute extends equally to the solicitation or
217 acceptance of remuneration for referrals.

218 * * *

219 While educational funding can provide valuable
220 information to the medical and health care industry,
221 manufacturer grants to purchasers, GPOs, PBMs and
222 similar entities raise concerns under the anti-kickback
223 statute. Funding that is conditioned, in whole or in part, on
224 the purchase of product implicates the statute, even if the
225 educational or research purpose is legitimate. Furthermore,
226 to the extent the manufacturer has any influence over the
227 substance of an educational program or the presenter, there
228 is a risk that the educational program may be used for
229 inappropriate marketing purposes.

230 To reduce the risks that a grant program is used improperly
231 to induce or reward product purchases or to market product
232 inappropriately, manufacturers should separate their grant
233 making functions from their sales and marketing functions.
234 Effective separation of these functions will help insure that
235 grant funding is not inappropriately influenced by sales or
236 marketing motivations and that the educational purposes of
237 the grant are legitimate. Manufacturers should establish
238 objective criteria for making grants that do not take into
239 account the volume or value of purchases made by, or
240 anticipated from, the grant recipient and that serve to
241 ensure that the funded activities are bona fide. The
242 manufacturer should have no control over the speaker or
243 content of the educational presentation. Compliance with
244 such procedures should be documented and regularly
245 monitored.

246 * * *

247 Manufacturers, providers, and suppliers of health care
248 products and services frequently cultivate relationships
249 with physicians in a position to generate business for them
250 through a variety of practices, including gifts,
251 entertainment, and personal services compensation

252 arrangements. These activities have a high potential for
253 fraud and abuse and, historically, have generated a
254 substantial number of anti-kickback convictions.

255 * * *

256 Absent unusual circumstances, grants or support for
257 educational activities sponsored and organized by medical
258 professional organizations raise little risk of fraud or abuse,
259 provided that the grant or support is not restricted or
260 conditioned with respect to content or faculty.

261 C. Other definitions

262 1. **Health care** (45CFR160.103) means care, services, or supplies related
263 to the health of an individual. Health care includes, but is not limited to,
264 the following: (1) Preventive, diagnostic, therapeutic, rehabilitative,
265 maintenance, or palliative care, and counseling, service, assessment, or
266 procedure with respect to the physical or mental condition, or functional
267 status, of an individual or that affects the structure or function of the body;
268 and (2) Sale or dispensing of a drug, device, equipment, or other item in
269 accordance with a prescription.

From: Rory Jaffe
Sent: Wednesday, December 06, 2006 12:12 PM
To: Maria Bertero-Barcelo
Cc: John Oakley
Subject: RE: Possible item for academic senate: vendor relationships with personnel in the medical sciences

Background

Due to the recent appearance of many published research studies showing the adverse effects of vendor relationships on physician objectivity, and the “call to arms” of the Brennan article, medical schools across the country have been reviewing their policies regarding vendor relations. Simultaneously, I have been visiting the campuses to discuss conflict of interest and kickback issues. Then Stanford came out with their new vendor policy and managed to make a big splash in the newspapers. As a result of all these events, many of the UC campuses have started to look at this issue, but have been facing local challenges. I was specifically asked by one medical school dean (Jerry Levey at UCLA) to work on a central solution to the problem and discovered there was significant interest at the campuses for a central solution. I talked with Nancy Capell about the process for going about this, then I discussed this with Rory Hume and with his assent, put together a group of seven people selected by the deans of the 5 4-year medical schools and the 2 dental schools (these being the schools with the most healthcare vendor interactions). These seven people worked with me to evaluate the applicability of the Brennan proposals to the University. The proposed policy represents the consensus of that group. Every vote was unanimous save the one on banning routinely supplying drug samples—one representative still has misgivings, though his dean does want the ban.

After developing a preliminary version, this policy was then circulated to a wider group, including the deans of the medical schools, dental schools, nursing schools, and pharmacy schools, hospital administrators, medical practice plan leadership, OGC, etc. The version you now have includes comments from this larger group.

Approval

As to ultimate approval, that is an interesting question. My plan had to have all the affected deans, as well as Rory Hume, have final sign-off on this policy. Given the wide interest, this may spread a bit (e.g., the Provosts at some of the campuses may be a factor). I will be seeking Rory Hume’s guidance on this as we get to the finish line. This policy will also require union notice (and 30 days to respond). Assuming everything else goes as planned, I should be able to get this out to the unions by early January.

Timeline

The goal was to get this approved quickly (well, at least quickly in terms of UC speed), and defer some of the more difficult issues to a later date to allow further deliberation. The motivation was twofold:

- 1) Position UC as a leader, rather than a laggard, in this area. Places across the country are working on this, and I fear we may be seen as dilatory on this important issue.
- 2) Coordinate the potentially conflicting efforts on the campuses. The campuses were going ahead with their efforts, and with a number of discrepancies in scope and particulars, creating a confusing situation.

As part of this goal, two Brennan proposals endorsed by our committee were omitted from the policy, as those were felt to be squarely within the purview of the academic senate, and probably would require significant review before senate approval. We thought that by doing that, the remaining policy could be reviewed on a more expeditious schedule.

The proposals omitted from the draft and referred to the academic senate 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)

One of my questions to you is whether you want to consider those two proposals together with the current draft policy or place those on a separate time-table. For example, if system-wide review is not necessary for the policy as currently drafted, will that significantly shorten the time to issuance? Do you believe that it is important to address the two proposals (if approved by the academic senate) at the same time as the issues addressed in the current draft?

There is a third proposal omitted from the current draft that also will pose difficulties, and I am not sure whether you want to review this now or wait until later:

- 3) All consulting agreements and unconditional grants shall be publicly listed (e.g., on an internet web site). While the committee was in favor of transparency in this regard, this goal is complicated by the fact that faculty in the medical school compensation plan can personally enter into certain consulting agreements without the review or prospective approval of the University. To bring those into this public list may require revisiting the compensation plan. I will be proceeding to review this issue in more detail, but anticipate it will take some time to resolve.

	
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