

Dean's Council (DC)

July 21, 2008

Minutes

Present: Dr. Albertsen, Dr. Egan, Dr. Gould, Dr. Koeppen, Dr. Kuchel, Dr. Lalande, Dr. Nissen, Dr. Pappano, Dr. Simon

Excused: Dr. Deckers, Dr. Fortinsky, Mr. Gillon, Dr. Jacob

Guest: Dr. Hepworth

The meeting was called to order at 3:40 p.m.

1. The minutes of the June 16, 2008 meeting were unanimously approved.

2. Nominees for the Research Misconduct Committee

The Dean's Council was asked to nominate faculty to replace Dr. Wikel on the Research Misconduct Committee. The names of potential nominees were distributed prior to the meeting. The DC recommended five faculty. Their names will be forwarded to Dr. Deckers, who will choose Dr. Wikel's replacement.

3. The Policy and Guidelines for Interactions Between the University of Connecticut School of Medicine and the Biomedical Industry

Dr. Nissen presented "The Policy and Guidelines for Interactions between the University of Connecticut School of Medicine and the Biomedical Industry" (attached). She explained that a committee comprised of individuals from various areas within the Health Center was formed to create an institutional policy on relationships with pharmaceutical, biotech, medical device, and hospital research equipment and supply companies. The Office of Graduate Medical Education already has a policy in place for residents (as required by the Accreditation Council for Graduate Medical Education), which was used as a template. Dr. Nissen emphasized the need for a policy, noting that most academic medical centers already have a policy in place. Dr. Koeppen explained that the DC only has purview over the School of Medicine and, therefore, if the policy is approved, it does not become an institutional policy by the DC's action. If the intent is to have the policy apply Health Center-wide, it would need to be reviewed by the Corporate Compliance Committee and the School of Dental Medicine. If, after review by these bodies, the policy is revised significantly, it would be brought back to the DC for approval.

Discussion primarily pertained to the section in the policy on site access by sales and marketing representatives. The policy states the following: "Sales and marketing representatives are not permitted in direct patient care areas except to provide in-service training on devices and other equipment, and then, only by appointment. Pharmaceutical representatives are excluded from all patient care areas. Patient care areas are defined as areas in which protected health information is audible or visible." Some members found this to be draconian and inconvenient since pharmaceutical representatives often provide drug samples which are stored in patient care areas. Dr. Nissen explained that the intent of the policy is to prevent lingering of sales representatives in patient care areas. However, the policy does allow meetings with sales reps in a private area near a patient care area, but only by appointment.

Another concern was the prohibition of meals for students, trainees, staff, and faculty directly funded by industry. However, it was noted that the policy allows for unrestricted educational grants that may be provided by industry to departments, residency programs, or the Medical School and which may be used to purchase food for a conference. There are also other ways to solicit donations for funding for food for residents in addition to the food stipend they are provided when on-call. Dr. Nissen added that the GME office is also looking for innovative ways to solicit donations from graduates in support of graduate education.

Following discussion, the Dean's Council unanimously approved the policy. Dr. Koeppen will now determine what steps need to be taken for approval of the policy at the institutional level.

4. Old Business

Dr. Koeppen provided an update from Dr. Jacob regarding the Dean's Council's suggestion that Provost Nicholls be asked to meet on a regular basis with faculty leadership from the Schools of Medicine and Dental Medicine. The purpose of the meetings would be to facilitate information flow between the Storrs campus and the Health Center. Dr. Jacob met with Provost Nicholls, who was supportive of the idea but also wanted the Deans from the two Schools included in the meetings.

Dr. Jacob proposed to the DC that each of the policy-making Councils within the School of Medicine governance structure (Education, Clinical, Research, Public Issues, and Dean's Councils) select a representative to attend the meetings.

Dr. Koeppen was asked why a representative from the Oversight Committee was not included, and he explained that they are not a policy-making body. However, Dr. Hepworth, who is the Oversight Committee's liaison to the Dean's Council, urged that the Oversight Committee be included, and the Dean's Council agreed.

Following discussion, the Dean's Council supported Dr. Jacob's proposal, with the inclusion of the Oversight Committee, and agreed that if we move forward, each of the Councils will select their representative.

The meeting was adjourned at 4:40 p.m. The next meeting will be held on Monday, August 18, from 3:30-5 p.m. in the Walker Academic Affairs Conference Room, AG-070.

Respectfully submitted,

Lynn Donatelli

The pharm. industry spends 21 billion dollars a year on marketing, with 90% directed towards physicians; which is approximately \$8,000-\$15,000 per physician.

A committee was created in the summer of 2007 to create an institutional policy that addressed relationships with pharmaceutical, biotech, medical device and hospital research equipment and supply companies. After six months of meeting every two weeks for approximately one hour, we created such a policy.

There was much discussion around the benefits of the pharm. industry and medical device manufacturers as well as the conflicts inherent in the relationship between industry and the medical profession. The benefits discussed included their commitment to research, new product development and their investment in continuing medical education (CME) that have helped countless patients. The conflicts centered around industry's fiduciary responsibilities to their shareholders and their profit motive. When the line between patient welfare and profit-seeking behavior gets fuzzy, the relationship can become unhealthy.

Academic medical centers need to take the lead and live by effective guidelines to regain the public trust and put objectivity and scientific integrity first and foremost.. Scientific researchers earn their reputation for integrity through double-blinded studies, objectivity, training in human research ethics, and by avoiding conflicts of interest that would undermine their reputations. Why should it be different for clinicians and physicians in training?

With that said, we were charged with defining an institutional policy that addressed the relationship between industry and students, resident physicians, physicians, and ancillary medical staff.

At the time we were tasked with creating this policy, many of the major medical societies published position statements, including the American Medical Association, the American College of Physicians, the Accredited Council for Graduate Medical Education, the American Medical Student Association, and even the Pharmaceutical Research and Manufacturers of America (PHRMA). In addition, we were being bombarded with countless articles in the public sector (NY Times, Hartford Courant) focusing on the perceived conflict of interest between industry and physicians. Moreover, state legislatures, with increasing pressure from their constituents, were starting to pay closer attention to this issue. Minnesota, Maine, Vermont, Nevada and New Mexico actually created laws requiring drug makers to disclose payments to doctors. Minnesota took the lead and collected data from 1990 to 2005 which showed that industry paid to doctors, nurses and other healthcare workers 57 million dollars. Forty million went to clinics, research centers and other organizations for the purpose of continuing medical education, sitting on committees to prepare guidelines, and financing research. Most polling done of the people of that state determined that they viewed it as unacceptable for doctors to be paid by drug companies.

There is now scientific evidence that gift-giving creates a reciprocal obligation that is powerful. The erosion of public trust in the profession of Medicine is real and growing and the public wants physicians to be completely free from potentially compromising relationships. As an academic medical center, we should help facilitate a relationship with industry that supports research and discovery in Medicine without allowing the money and influence to consciously or subconsciously change the way we take care of our patients or the way we teach our students, residents and peers.

With that said, here is the policy we created.

The Policy and Guidelines for Interactions between the University of Connecticut School of Medicine and the Biomedical Industry

PURPOSE OF POLICY:

This policy establishes guidelines for the interaction of medical staff, faculty, students and trainees with industry representatives. Interactions with industry occur in a variety of contexts, including, but not limited to, the following:

- Marketing of new pharmaceutical products, medical devices, and research equipment and supplies
- Training for newly purchased devices
- Development of new medical devices
- Educational support of medical students and trainees
- Continuing Medical Education
- Scholarly publications
- Off-site interactions

Many aspects of these interactions are positive and important for the promotion of educational, clinical, and research missions at the University of Connecticut School of Medicine. The interactions of physicians and private industry can result in the exchange of information which hastens medical progress. However, they can introduce commercial bias resulting in unfavorable public perceptions. There is substantial recent evidence that indicates that aspects of this relationship can alter the judgment and decision-making of physicians. Conflicts of interests arising from financial ties amongst physicians, their staff and industry also have the potential to influence a physician's attitudes and practice.

The goal was to develop a policy that guides faculty, staff, trainees and students in their interactions with industry in order to insure an ethical environment that is consistent with patient safety and privacy. The policy supports the integrity of: clinical decision-making, research, educational/training programs, and the reputation of faculty, staff, trainees and students. These guidelines reflect legal standards as well as ethical standards promoted by the University of Connecticut School of Medicine.

STATEMENT OF POLICY:

Interactions with industry should be conducted so as to avoid conflicts of interest. The scope of this policy includes the following interactions with industry:

1. Gifts and compensation
2. Site access by sales and marketing representatives
3. Provision of unrestricted educational funds and scholarships to students and trainees
4. Financial support for professional activities of faculty, trainees and students.
5. Disclosure of relationships with industry
6. The training of students, trainees, staff, and faculty regarding potential conflicts of interest in industry interactions

1. **Gifts and Compensation:** Faculty, staff, trainees, and students are prohibited from accepting personal gifts from industry. Recent legislation addressing gifts to the University and its employees was signed by Governor Rell in March 2007. This legislation states that that “all gifts of goods and services provided to the University in furtherance of the University's mission are allowed. However, gifts directly and personally provided to a state employee from regulated donors in order to attend a conference, symposium, or other event, are still prohibited.” Other provisions of the bill include “a new exemption to the definition of a ‘gift’ that does allow a state employee to receive product training from a vendor if the training is offered to all its customers.” In the spirit of these principles:
 - A. Personal gifts that may result in recommendation of a product or performance of an action may not be accepted. For example, meals **directly funded** by industry may not be provided to students, trainees, staff and faculty. Unrestricted educational grants, however, may be provided by industry to departments, residency programs, or the medical school and used to purchase food for a conference. Please refer to the AMA’s guidelines on gifts to physicians from industry at <http://www.ama-assn.org/ama/pub/category/4263.html> and the Accrediting Council for Continuing Medical Education’s “Standards for Commercial Support” at <http://www.accme.org/> , as well as http://www.acgme.org/acWebsite/positionpapers/pp_index.asp
 - B. A “gift of travel and/or lodging is acceptable if they are (necessary expenses) for appearance, for speech, or for participation at an event in the employee’s, staff’s, trainee’s, student’s official capacity.” Official capacity is defined as a University employee being asked to participate in events, speak, appear, or write an article, and the employee’s official position or authority was a significant factor in the decision to extend the invitation. Then it will be deemed to be in his or her official capacity. (University of Connecticut Guide to the State Code of Ethics).
 - C. Individuals must not accept compensation for listening to a sales talk by an industry representative.
 - D. Individuals must not accept gifts or compensation for prescribing or changing a patient’s prescription.
 - E. Individuals must not allow patient care decisions to be influenced by personal financial gain.
2. **Site Access by Sales and Marketing Representatives:** Unrestricted access to patient care areas by pharmaceutical representatives is prohibited. Interactions between sales representatives and practitioners should serve the purpose of introducing practitioners to new medications and providing access to medications. All pharmaceutical representatives who work in patient care areas are required to receive HIPAA training at the University of Connecticut.

The following guidelines should be followed with regards to site access:

- A. Sales and marketing representatives are not permitted in direct patient care areas except to provide in-service training on devices and other equipment, and then, only by appointment. Pharmaceutical representatives are excluded from all patient care areas. Patient care areas are defined as areas in which protected health information is audible or visible.
- B. Sales and marketing representatives are permitted in non-patient care areas by appointment only. Appointments can be made for purposes of in-service training for research or clinical equipment or devices already purchased and for evaluation of new purchases of equipment, devices, or related items. Appointments for the purpose of providing free drug samples or to offer information to prescribers can be made at the discretion of the prescriber.
- C. Prescribers may accept free drug samples or drug vouchers from industry for distribution to patients only. Samples may not be used by physicians for personal use or for distribution to their families.
- D. *Free drug samples may never be sold.*

3. Provision of Unrestricted Educational Funds and Scholarships to Students and Trainees: Support of students and trainees by industry in the form of scholarships for training, reimbursement of travel expenses for educational meetings, and/or other non-research funding in support of scholarship or training must be free of actual or perceived conflict of interest and be in the form of “unrestricted educational grant”. The following standards apply:

- A. For scholarships in training, the trainee must be selected by the University of Connecticut program designated to receive the scholarship grant. There must be no quid pro quo for either the selected trainee or the program.
- B. Funds must be directed to the department/program/program designee and not to the individual trainee or student.
- C. For educational meetings or programs, the Dean, Program Director, or designee must agree to the educational merit of the financial support and the trainee/student must be not be under quid pro quo obligation to the industry.
- D. Industry-sponsored merit awards will be evaluated individually.

4. Industry Support for Professional Activities and Educational Events in which Faculty, Staff, Trainees and Students Participate: UConn School of Medicine Faculty are required to participate in clinical, scientific, and/or educational meetings as part of their professional obligations as faculty. Staff, trainees and students are similarly encouraged to participate. In this spirit:

- A. Faculty, staff, trainees, and students need to be fully aware of the ACCME standards for industry support. The ACCME standards provide guidelines for evaluating all forms of industry interaction. The standards can be found at www.accme.org.
- B. All professional and educational events sponsored by the School of Medicine must be in compliance with ACCME standards for industry support. If CME is awarded, then an institutional policy set forth by the Office of Continuing

- Medical Education, in reference to the letter of agreement for commercial support, must also be upheld. (<http://cme.uhc.edu/cme/policies.html>)
- C. Faculty, staff, trainees or students who participate, organize, or deliver lectures or educational conferences, sponsored by industry, must comply with ACCME standards. (Appendix A).
 - D. Industry support for academic activities in which faculty, staff, trainees and students participate must comply with UConn's Policy related to consulting and honorarium; specifically, if payment, remuneration or honorarium are retained by the individual, this activity must be considered a consulting activity and may be undertaken pursuant to the policies and procedures described on Section I. Consulting under Article XV.M of *The University of Connecticut Laws and By-Laws, Twelfth Edition*. (Appendix B).

5. Disclosure of Relationships with Industry/Conflicts of Interest:

- A. UConn faculty with actual or potential conflicts of interest related to institutional decisions must disclose and/or recuse themselves from these deliberations. This includes institutional decisions on equipment or drug procurement. Specifically, individuals with institutional decision-making roles must disclose financial interests that they or immediate family members have in companies that might benefit from the decision. The purchasing unit will decide whether the individual must recuse him or herself from the purchasing decision. For disclosure requirements related to educational activities, see the ACCME Standards for Commercial Support.
- B. Faculty with supervisory responsibilities for student, residents, trainees or staff should ensure that faculty conflict or potential conflict of interest does not affect or appear to affect his/her supervision of the student, resident, trainee or staff member.
- C. Faculty, residents, trainees and students must be in compliance with ACCME standards for commercial support for disclosure requirements related to educational activities. (<http://www.accme.org/> , as well as http://www.acgme.org/acWebsite/positionpapers/pp_index.asp)
- D. UConn faculty, as per the Code of Conduct adopted by the University of Connecticut, must disclose financial conflicts of interest to University Administrators and manage such conflicts in accordance with existing policies and procedures. This includes properly acknowledging sponsorship of research in publications and presentations.
- E. UConn faculty engaged in research must provide specific written information on financial interests related to their work at UConn on an annual basis to the Office of Research Compliance. Investigators are responsible for insuring that an updated UConn Health Center Conflict of Interest Financial Disclosure Form shall be completed and filed at times during the year that there is change in their financial interests.

- 6. Training of Students, Trainees, Staff, and Faculty Regarding Potential Conflicts of Interest in Industry Interactions:** All students, trainees, staff and faculty shall receive training regarding interactions with industry.