

[In these minutes: Draft Individual Business or Financial Conflict of Interest Policy, February 11, 2010 AHC-FCC Meeting Update]

## **ACADEMIC HEALTH CENTER STUDENT CONSULTATIVE COMMITTEE (AHC SCC) MINUTES**

**WEDNESDAY, FEBRUARY 24, 2010**

**5:00 - 6:00 p.m.**

**488 CHILD REHAB CENTER**

[These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate; none of the comments, conclusions, or actions reported in these minutes represent the view of, nor are they binding on the Senate, the Administration, or the Board of Regents.]

**PRESENT:** Daniel Stein (chair), Nathan Bell (Clinical Lab Sciences), Brandon Burk (Pharmacy-Duluth), Robb Garni (Dentistry), Rebecca Klismet (Pharmacy-Twin Cities), Meredith Lukasek (Nursing-Twin Cities), Meghan Mason (Public Health), Megan Meyer (Dental Therapy), Hilary Reich (Medical School – 3<sup>rd</sup> Year), Eden Sonn (Nursing – Rochester), Paul Syverson (Veterinary Medicine), KauChee Vang (Clinical Lab Sciences – Rochester)

**REGRETS:** Paul Anagale (Medical School-Duluth), Ganesh Babulal (Occupational Therapy), Andy Wicks (Physical Therapy), Tanya Wilber (Dental Hygiene)

**ABSENT:** Ashley Johnson (Occupational Therapy – Rochester),

**OTHERS ATTENDING:** Giselle Boertjens, Barbara Brandt, Sean Corvin, Brianne Keeney, Philip Kieffer

**GUESTS:** Lynn Zentner, director, Office of Institutional Compliance

**I).** Daniel Stein convened the meeting and welcomed all those present.

**II).** Mr. Stein welcomed Lynn Zentner, director, Office of Institutional Compliance, who was invited to provide information on the draft Individual Business or Financial Conflict of Interest policy.

Ms. Zentner began by sharing information on the history of the development of the draft Individual Business or Financial Conflict of Interest policy. Since the mid 1990's, the University has had both a Board of Regents policy and an administrative policy, which govern individual conflicts of interest. A few years ago, as greater scrutiny was brought to bear on medical school faculty across the country who had lucrative consulting arrangements with pharmaceutical and medical device manufacturers, institutions of higher education, to include the University, began to examine their existing policies to determine whether they needed to be revised and strengthened. This, then, was the impetus for looking the University's current administrative policy and determining that revisions were needed, stated Ms. Zentner. The policy, once finalized, will have University-wide application; its application will not be limited to the health sciences, or the Medical School. This policy, in its final form, will apply to all faculty and staff, and, in addition, to anyone who has responsibility for the design, conduct or reporting of research across the University.

Ms. Zentner provided the following further background. In early 2008 or late 2007, a Conflict of Interest Task Force within the Medical School was convened, chair by Leo Furcht and Denis Clohisy. This task force issued its final report in August 2008, which outlined a number of standards that the Task Force felt the University should implement in the Medical School context. The report also detailed the rationale for the proposed standards.

At approximately the same time that the Task Force report was finalized, the Institute on Medicine as a Profession (IOM) began to look at medical school conflict of interest policies across the country, and identified some as best practice policies and others as weak policies. Staff of the Office of Institutional Compliance (OIC) at the University undertook a review of the policies posted on IOM's website. In addition, the Office of the General Counsel (OGC) assigned a law clerk to work with the OIC staff to develop a summary of the policies, organized by standard, similar to the format of the Task Force report.

Next, in the fall of 2008, Senior Vice President Frank Cerra convened a committee to explore the development of a revised administrative conflict of interest policy for the University that has since become the draft titled Individual Business or Financial Conflict of Interest policy (draft policy). As the committee began its work, members recognized that the standards they would ultimately recommend should have University-wide application while at the same time allowing for some level of flexibility.

Besides the best practice policies identified by the IOM, the University looked to the policies of other institutions, e.g., Mayo Clinic, University of Kansas, Emory University, Stanford University, University of Alabama at Birmingham, and Duke University, to name a few. Additionally, the committee looked at business conduct codes that have been developed by the device and pharmaceutical industries. The committee also looked at a handful of other professional documents to

guide its work, the Task Force report, and later at the Medical School's Recommendations on the Oversight of External Relationships, which was issued in January 2009.

The current version of the University's conflict of interest policy, which has been in effect since the mid 1990s, focuses on financial interests. For example, if an individual has income from or an equity interest in a company, and there is an overlap between that financial interest and a person's University responsibilities, e.g., teaching or research, there is the potential that a conflict of interest exists. The University has a process for reviewing these circumstances to determine if a conflict of interest actually exists, and, if so, a management plan is developed to govern the conduct of the individual's University-related activities and responsibilities as long as the conflict of interest continues to exist.

It is also important to note that in 2005, the University established an institutional conflict of interest policy, which addressed conflicts of interest that occur at the institutional level (e.g., the University has a right to receive royalties from the sale of a product that resulted from a University-developed technology and the University is currently conducting research on the effectiveness of the product). The University developed its institutional conflict of interest policy long before many other institutions. In fact, many institutions still do not have institutional conflict of interest policies.

The difference between the University's current individual and institutional conflict of interest policies and the draft policy is that many of the standards set forth in the draft policy govern the activities that University employees engage in with "businesses" as that term is defined in the draft policy (e.g., consulting relationships, speaking engagements at business sponsored sales and marketing events, product endorsements, etc.). The draft policy looks not only at whether a financial interest exists, but also addresses the interactions that are occurring between a business entity and University employees. The draft policy covers gifts, industry-sponsored educational activities, conferences, speaking engagements, ghostwriting events, and the presence of industry representatives on campus. The "relationships with industry" aspect of the draft policy make it quite different from the University's current administrative conflict of interest policy.

The draft policy was disseminated to all faculty, academic professional and administrative staff, and graduate students on November 13<sup>th</sup> for a six-week comment period. In addition to collecting comments on a website, members of the committee have consulted with a variety of faculty governance committees, leadership groups, and administrative groups concerning the policy. Comments have also been received via e-mail.

With respect to the policy's guiding principle statement, noted Ms. Zentner, the goal was to convey the message that collaborative relationships with industry are a vital aspect of University work. Those relationships advance science and technology and have the potential to significantly benefit the greater society. At the same time, the University is keenly of the public's concern that bias and improper influence can also result from these relationships. The draft policy is intended to address and balance these perceived competing issues so that the public does not question the integrity of the work that is done here.

Next, Ms. Zentner highlighted the significant provisions within the draft policy and the rationale for each:

- Reporting and Evaluating a Covered Individual's Relationships with External Entities – This provision requires all covered individuals to complete a Report of External Professional Activities (REPA) on an annual basis. Covered individuals are required to report income and equity interests to the extent such interests are related to or overlap with their University expertise and responsibilities. Unlike the current policy that asks people to report only on amounts in excess of \$10,000, the draft policy requires individuals to report all income and to report that income in specified increments. This provision also asks questions about conflict of commitment, which looks at whether an individual's time commitment to an external entity is taking away from his/her responsibilities at the University. The current draft policy stipulates that a conflict of commitment review, as distinguished from a conflict of interest review, will be conducted for anyone who reports income from outside activities in excess of \$100,000 on his or her REPA.
- Determining Whether of Conflict of Interest Exists.
- Managing Conflicts of Interest.
- Disclosures of a Covered Individual's Conflict of Interest as Required by a Conflict Management Plan.
- Disclosures Made Outside of the Conflict Management Plan Context.
- Prohibited External Relationships or Activities – For example, noted Ms. Zentner, ghostwriting and product endorsement are prohibited activities.
- Consulting Relationships with Business Entities – Currently, the University does not review individual consulting agreements. That is true under the draft policy as well. However, the draft policy requires that all consulting relationships be described in a written consulting agreement and specifies some of the contents of such agreements. The draft policy, under this section, also requires that compensation received for the services provided not exceed fair market value. While some individuals are of the view that they should be able to earn whatever someone is willing to pay them, the flip side of this argument is that when payments are excessive, one might question whether the company is buying a person's loyalty in order to benefit its business.
- Speaking Engagements Sponsored by Business Entities – While the draft policy does not prohibit a University employee from making a presentation at a business sponsored event, it requires the employee to meet certain criteria if the event is a sales and marketing event, and the subject matter of the presentation overlaps with that person's University-related expertise and/or responsibilities.

- Presence of Business Entities on Campus – Representatives of businesses are welcome on campus so long as the purpose of being here is to further the University’s teaching, research and outreach missions and not for commercial purposes.
- Education and Training Sponsored by Business Entities – The draft policy stipulates that anyone can attend education and training events sponsored by business entities, but they cannot accept payment for expenses associated with attending these events.
- Using Educational Materials Developed and Provided by Business Entities – Under the draft policy, educational materials developed and provided by a business can be used in the classroom as long as they have educational value and not simply promotional value. Also, when non-branded educational materials developed by a business are used, students should be advised about who developed these materials so they can make their own judgments about the value of the information contained in these materials.
- Samples and Demonstration Items Provided by a Business for Use in a Health Care Setting – Samples can be accepted under the draft policy, but they should come in through a central administrative office rather than to an individual. In the clinical context, using a branded product with a patient may be acceptable as long as it is for educational and demonstration purposes and the product has been prescribed for a patient.
- Gifts, Food, and Entertainment – The draft policy proposes a “no gifts” approach. However, individuals may accept products provided by business entities during off-site educational activities if acceptance is optional and these materials are extended to all attendees, e.g., tote bags at a conference. Similarly, in the absence of departmental approval, individuals may not accept meals, refreshments, etc. from a business either on or off-site with the exception of meals offered to all attendees at a conference.

In closing, Ms. Zentner welcomed members’ comments and questions. A member asked about when the draft policy would be implemented. Ms. Zentner stated that given there is still work to be done related to reviewing the comments that have been submitted on the draft policy and the draft Regental-level conflict of interest policy has not yet been approved, she anticipates the final administrative policy will be implemented sometime this summer.

Who determines if a conflict of interest exists, asked a member? Ms. Zentner explained that the University has two conflict of interest committees that address individual conflicts of interest. One addresses matters involving faculty and staff with appointments in the AHC (the AHC Conflict of Interest Review and Management Committee) and the other addresses conflict of interest matters involving faculty and staff with appointments outside the AHC (the Provost Conflict of Interest Review and Management Committee).

What happens if a faculty member refuses to disclose information, asked a member? Ms. Zentner explained that in the interest of transparency is a very important element of the conflict of interest review process. Withholding information that is required to be disclosed by University Board of Regents policy and by University policy could lead to discipline. Once disclosed, the information provided by individuals is held in confidence and is used only for the purpose of evaluating whether a conflict of interest exists, and, if one exists, to develop an effective conflict management plan.

How does the policy impact students, asked a member? The policy will only apply to students who have responsibility for the design, conduct or reporting of research, noted Ms. Zentner. The University’s funding from federal agencies may be at risk if it fails to adequately identify and manage conflicts of interest.

A member asked whether students who receive scholarship money need to report it. To the best of her knowledge, Ms. Zentner stated that she does not believe scholarship money needs to be reported.

In response to a couple questions about whether it is acceptable for industry to speak to a group of students, and provide food, Ms. Zentner stated that with the exception of “conference meals,” the draft policy does not permit those covered by the policy to accept meals, food and refreshments from a business either on or off-site unless authorized by a department approver. If a department believes food should be provided then the department should be supplying the food, not industry. The rationale for prohibiting food is that it is viewed as an attempt by industry to buy student loyalty.

Several members had a difficult time accepting that simply eating pizza provided by industry, for example, could buy loyalty. These members were of the opinion that students have the wisdom, integrity and objectivity to make decisions about the quality of a product or service, irrespective if they were given food. Oaths students take upon graduation should also come into play as it relates to this issue. Ms. Zentner stated that a significant amount of research has been conducted, which demonstrates that gifts influence behavior and even small gifts may have as much or greater influence on people than larger gifts. She encouraged members to think about the purpose behind industry providing food/gifts if it is not to influence, and recommended that members look at the research of Dr. Eric G. Campbell and others who have done extensive research in this area. Ms. Zentner read from the Gifts, Food, and Entertainment section of the draft policy, which stipulates “Unless authorized by a Departmental Approver, covered individuals may not accept meals, food, refreshments, entertainment, or similar benefits from a business either on or off-site with the exception of modest meals offered to all attendees at educational events (“conference meals”), whether or not the costs associated with attendance at the educational event are reimbursed by the University.” She suggested members think about why they would only attend a sponsored event if food is provided, and would not go if food is not, irrespective of the educational value of the event. In addition, she asked members to think about the role that influence plays.

In light of time, Mr. Stein stated that this is an important topic and that the committee should continue this discussion at its next meeting. He proposed the committee think about crafting a position statement. Dr. Brandt suggested inviting Dr. Mac Baird to a future meeting to discuss this issue further.

In response to a question regarding whether all the AHC schools are represented on the AHC Conflict Review Committee, Ms. Zentner stated that at this time the committee has representatives from every school except the School of Nursing, unfortunately.

Mr. Stein thanked Ms. Zentner for attending, and providing information on the policy.

**III).** Mr. Stein reported attending the February 11 AHC-FCC meeting where he shared information on the topics that the AHC-SCC has taken up this year, e.g., conflict of interest, interprofessional education, etc. He also noted that an outcome of this meeting was that the AHC-FCC passed a motion to revise their charge to align it with the section of the AHC-SCC charge that stipulates that the chairs of the AHC-FCC and AHC-SCC should meet each semester to discuss issues of concern to both faculty and students.

**IV).** Before adjourning, Mr. Stein asked members for any additional comments and/or ideas for future agenda items. Hearing none, Mr. Stein thanked members for attending and adjourned the meeting.

Renee Dempsey  
University Senate