August 21, 2009

Memo

To: Senate Council

From: Daniel Wermeling, Pharm.D.

Senator, College of Pharmacy

Re: Code of Conduct Addendum

First I wish to thank the Senate Council for giving me, as a College of Pharmacy representative, an opportunity to voice concerns from the Practice Plan Committee in our College regarding the Code of Conduct Addendum. The Practice Plan Committee is a College of Pharmacy faculty governance committee that oversees faculty activity in pharmaceutical external education, service and scientific and legal consulting that generates supplemental income that is run through the University and the Plan. I hope that my presentation will be informative and allow the Council to determine if the full Senate should be aware of, discuss, and perhaps recommend helpful ways to make the policy of benefit and understanding to all 14 UK Colleges.

Secondly, I wish to present this to you through our eyes and perspective. We have concerns that relate to principles, process and content of the new policy. My purpose in coming to the Senate relates to the faculty and academic elements of the policy since this is our purview. Our College is also having conversations with the administration in parallel to the Senate presentation that relates to overlap of the Code of Conduct with our Practice Plan and the new University-based Practice Plan Administrative Regulation.

Lastly, we are committed to contributing in a positive way to the dialogue regarding the new Code of Conduct Addendum that is to be discussed below. We are hopeful that our offer to make contributions to the document will allow everyone to be comfortable with its purpose and operation when formally enacted.

<u>Principles Related Concerns</u>

The document is far-reaching and we are unclear as to how this document will affect our professional, and even personal, lives. More specifically, regular faculty do not understand how what appears to be a UK Healthcare Policy and operation fits into our overall governance system that usually is documented in administrative or governing regulation. How does a policy like this become enacted? How does it relate to what regular faculty would typically understand in our governance? How does such a policy related to the UK Healthcare enterprise have full reach into our faculty and academic enterprise and in some cases faculty self-governance?

An additional principle concern of this document relates to what it is trying to accomplish. We have been informed that motivations for such a policy have many different drivers. Some elements we are told are driven to prevent Stark violations (improper relations with vendors that can affect purchasing or medical decision making). Other elements relate to what the American Association of Medical Colleges (AAMC) is urging medical schools to enact. Some elements have unclear origins and purposes. Clearly, we can agree that we do not wish to violate laws. However, we also wish to be clear as to what applies to us as a faculty and what may apply strictly to other entities, and that we are clear on our responsibilities.

There is the potential for jeopardy for the faculty given the nature of the policy. Is it fundamentally fair to have a policy enacted that affects them without input? Is it fair to have the policy enacted when the enabling administrative mechanisms are not in place? Is it fair to have confusing and complicated oversight in which multiple university offices and functions appear to have some role in governance, rules and reporting? Faculty throughout the various colleges will not necessarily have the same specific concerns as the College of Pharmacy. However, I think we would all have overlapping concern related to the public trust and the roles and responsibilities of faculty in the academy.

Process Related Concerns

We as faculty and members of our various governance committees (Practice Plan, Curriculum, etc.) first became aware of the new policy through unofficial channels in early June of this year. In part this lack of notice may have been related to the evolving College of Pharmacy administration. However, we were very surprised to hear that the new policy was to become effective in less than one month, July 1, 2009. We then engaged in considerable research to read the policy and understand its multiple layered implications. I inquired with Senate Chair Randall for example, and he informed me he was not provided this document formally to determine if there would be Senate or faculty concerns. Through our research we learned that we were actually subject to a similar policy since 2004, yet, we were totally unaware of the policy. It is hard to imagine we had the policy without our input or knowledge. No regular College of Pharmacy faculty were appointed by the Dean to the new committee that was dealing with interactions with the pharmaceutical industry at all levels (research, education, continuing education, faculty status, consulting, etc.). Perhaps it was unclear what the new committee was being charged to do that affected his decisions. A report from the committee was issued along with the new policy. Given the nature of the policy one might imagine significant regular pharmacy faculty engagement, at least to some degree in proportion to medical faculty and administrators. We were informed of different drivers to have the policy, which in many senses reads like a AAMC document. Moreover, there are elements related to Stark law and inappropriate relationships and conflicts. This is all well and good, but, College of Pharmacy regular faculty did not have any input into the draft. The Director of Pharmacy at UK Healthcare did draft a section, but this relates only to the sampling of medications. This matter is not germane to College of Pharmacy faculty or governance

Initially there appeared to be barriers to consider changes to the Code of Conduct Addendum. We have recently been invited to provide a written report of our concerns through our Dean to Mr. Harry Dadds, a Medical Center attorney. We have had positive interactions with Mr. Dadds but wish to make sure that our voices are heard directly by the administration. We seek a more comprehensive examination of this compliance policy, how it relates to those already in force and a mechanism for input and change from the affected parties.

There is an intention to roll this policy out campus-wide. The Senate should consider the processes to date as it relates to how Colleges outside the UK Medical Center will be affected. Please recall the Senate was not consulted on this policy previously.

Content Concerns

As with generation of any policy, and as it attempts to be compliant with law, one has a balance of harms to consider. In the case of this policy, there are elements we do not agree with that were generated by the AAMC policy. With regard to Stark law, the question comes to how far down, into how much detail, does one wish to go to write a policy. The College of Medicine had

very specific requirements for policies (Stark, AAMC, etc.). Pharmacy and other healthcare colleges have some overlapping interests, but, also have distinct differences from the College of Medicine and the UK Healthcare enterprise. Most of our faculty are not engaged in patient care or vendor and purchasing decisions.

There can be an attempt to write an absolutely perfect policy, yet, such actions usually go so far as to infringe on rights or privileges of those who do no harm. Compliance is a problem when policies become too onerous. Below are highlighted areas of concern.

- There is considerable overlap with other university and college policies and what one could interpret as conflict, or that there are now multiple offices in charge of similar things. The Senate, Office of Research Integrity, Corporate Compliance, Conflict of Interest, Pharmacy and Therapeutics, our own College administrations, all have some governance or say over many things here. The problem is that when so many are in charge that in effect no one is in charge. Moreover, the reporting to all these different entities will be onerous on the faculty. The policies will be in effect without the implementing mechanisms. This creates a risk of jeopardy for the faculty.
- All faculty, including voluntary and adjunct faculty, are affected by the policy. We employ about 300 voluntary faculty state-wide to supervise clerkship rotations for fourth and final year of student training. We do not pay them for this service. Prohibitions in the Code of Conduct directly affect their personal finances and would cause them to leave our relationship. The implications for us at the College are in the millions of dollars and a lessening of our relations with the profession statewide.
- Faculty have spouses and family members in the medical field who are not restricted by the policy but could be considered at great risk of non-compliance. Penalties for non-compliance are severe.
- Page 6 does not allow faculty to attend professional meetings in which industry, <u>even indirectly,</u> subsidizes the conference. This is not appropriate in the sense that many of our faculty are leaders in professional organizations that have functions subsidized, including continuing education, venues, and meals for leadership meetings. Page 6 item 6 is not a policy and should be stricken. We should be able as highly educated professionals to hear whatever we want to hear.
- Page 7 deals with publications. Although there may be good policy intentions, it seems these matters are governed by our faculty and administration systems.
- Page 7 also deals with attending conferences. We need to be able to attend trade conferences to learn about newly released technology. The sponsors are governed by FDA as to what they can tell us.
- Although not necessarily related to Senate academics, Page 8 deals with consulting, which is the way our faculty generate supplemental income outside our UK salary. The policy grossly deviates from our current practices at the College of Pharmacy. Some elements are inappropriate, impractical, etc. We certainly would not agree to having prior approval of consulting since we do not do that now. Disclosure is one thing, which we can agree to if a proper method is available, but not approval. Almost everything we do in consulting has nothing to do with UK healthcare delivery or vendors.
- The reporting section on page 10 is not viable. When you consider this policy in light of all our other policies, it is likely a faculty member could report the same matter through 4 channels!! Such an administrative burden is frustrating and counterproductive. A thoughtful examination of the overlap and redundancies of the reporting needs to be addressed.

In summary, I hope I have been able to convey legitimate concerns that have faculty and academic origins. Faculty governance systems appear to be affected by the origination and implementation of the new policy. Elements within the policy directly relate to typical faculty roles and responsibilities including instruction, continuing education, attendance at conferences as a speaker or as a listener, ability to serve as a leader in professional organizations where industry is involved, publication and manuscript generation, administrative reporting and accountability, and mechanisms and sources of supplemental income.

Lastly, I think I can speak for the faculty in saying that we realize the health of the Medical Center and the University at large is in part dependent upon being compliant with laws and/ or having good policies even if laws are not involved. We do not object to doing some things differently, but want fair and equitable participation in the development and implementation of policies that directly relate to our professional and personal lives. We are quite willing and able to engage when approached. We hope to make a positive contribution to continued dialogue regarding the policy and perhaps make edits or find clarifications. Lastly, we hope that this report could be considered within the context of all 14 University Colleges and how all might best be served.

Thank you again for giving me the opportunity to present to the Senate Council.