Approval of Minutes
The minutes from the February 8, 2011, meeting were unanimously approved.

Dean’s Comments
Dean Krugman stated that the Denver Health and Hospital Authority (DHHA) Affiliation Agreement has now been approved. The agreement now explicitly states that all faculty at DHHA will have full-time appointments with the School of Medicine (SOM). In addition, the agreement more clearly outlines the roles and responsibilities of administration at both institutions.

The affiliation agreement between the School of Medicine and National Jewish Hospital is still in process. With regard to the Veterans Affairs Medical Center, we are still working under the same agreement, with the “Dean’s Committee,” meeting approximately 2-4 times per year. The “Dean’s Committee” includes the chairs of clinical departments at the SOM and directors of service at the VA.

The Surgery chair search is underway, with CVs now being received and considered. The Emergency Medicine chair search is also continuing, with one more candidate to visit on March 22nd. After that, the committee will most likely recommend its top candidates for further consideration. The Colorado School of Public Health dean search is also ongoing, with 14-15 CVs being received and visits expected in late spring.

The clinical enterprises of SOM, University Physicians, Inc. (UPI), and University of Colorado Hospital (UCH) are collaborating to coordinate clinical access, safety and quality. This effort is being led by Dr. Douglas Jones and Dr. Tom Henthorn. It was suggested that they provide a progress report to the Faculty Senate in April or May.

The Dean announced that the Regents are expected to approve the sale of the Given Institute this evening, which will net significant funds, of which 80% ($10-15 million) will be put into an SOM unrestricted endowment.

The Dean announced that Angela Wishon, Assistant Vice Chancellor for Regulatory Compliance, will be leaving this institution for a position at the University of Texas, Southwestern. Dean Krugman thanked Angela for her hard work over the past five and a half years.

CCTSI Research Navigator Resource Presentation – Molly P. Van Rheen
Molly Van Rheen, Research Navigator for the CCTSI, provided information regarding the CCTSI Research Navigator Resource, which is available to all members of CCTSI, with membership in CCTSI being open to everyone. The Research Navigator Resource was developed because of a need that was
identified from a 2005 needs assessment whereby three areas were identified as needing improvement: 1) biostatistical consultation; 2) data management and informatics infrastructure; and 3) experienced administrative personnel available to help navigate regulatory compliance essential to assure consistent standards of human research protection.

The Research Navigators are able to provide consultative services to investigators, including assisting with CTRC protocol submissions, IRB submission pre-review, and IRB submission consultation. In addition, they provide services to researchers which assist them in connecting to CCTSI resources that are necessary to implement their clinical and translational research. Currently, Sarah Stallings and Molly Van Rheen are Research Navigators, with the anticipation that an additional navigator will be hired soon.

Molly then discussed the benefits of using this resource, which include finding collaborators, addressing regulatory concerns, and finding and connecting to research resources. In addition, they have the ability to provide guidance with IRB and other regulatory applications, including providing step-by-step guidance and pre-screening of COMIRB applications. Molly added that she has developed an expertise in this process by attending panel meetings and asking questions regarding specific situations in order to be better able to provide accurate information.

Molly concluded by offering to come to departmental meetings to provide a similar presentation.

Resolution Regarding “Speakers’ Bureau” Activities by SOM Faculty Members – President Chesney Thompson

President Thompson opened the discussion of the Resolution Regarding Speakers’ Bureau Activities by addressing the fact that at the last Faculty Senate meeting, the principles that are contained in the resolution were agreed to by the Senate. Discussion surrounding this topic has elicited impassioned responses as this issue is extremely important. The resolution that was sent to all Faculty Senators last week was drafted by President Thompson, Associate Dean Steven Lowenstein, Dr. Andy Meacham, and Steve Zweck-Bronner, Managing Sr. Associate University Counsel. The resolution was drafted with careful wording to include all points that have been addressed over the last weeks of discussion, but there will be grey areas.

President Thompson then read the entire resolution, and commented that the last paragraph of the resolution addressed forming a faculty committee, which should address the grey areas of the resolution where the appropriateness of activities might be in doubt. He added that the intent of the resolution is not to limit collaboration with industry or to make this difficult for the faculty members to continue their obligations and responsibilities.

There was lengthy discussion regarding the definition of “exempt honoraria,” which was included in the resolution. Several senators commented that it was unclear which activities would be included as exempt honoraria, and whether all other activities outside of the definition would be taxed. Dean Krugman commented that the exempt honoraria definition had been debated and approved and placed in the Member Practice Agreement two years ago, but it has now become clear that many faculty may not understand what that actually means. Dean Krugman added that there is an important reason to bring all industry consulting through UPI, including research consulting, clinical trials, or data management, so that the liability for your activities with that company will be covered by the University. It was also clarified that the definition of “exempt honoraria” that was included in the resolution was
meant to be educational. There was a suggestion that, if there is a legitimate concern regarding which types of activities would be considered exempt honoraria, the solution might be to have a dollar threshold whereby anything under the threshold would not be taxed.

There was discussion regarding the guidance committee that is mentioned in the resolution. The purpose of the committee would be to engage a group of faculty who understand the rules and policies to review activities that may be in question. The Sites of Practice Committee is a similar committee to what is being proposed here. One senator commented that the policy is too restrictive and that initial determination of the appropriateness of activities should happen at the department chair or division head level, with the committee reviewing activities that fall in a grey area. It was suggested that the committee that is formed could be an extension of the current Conflict of Interest Committee, and that if there is a gap in time before this committee is formed, additional time could be allowed before the policy is put into effect.

There was discussion regarding the prohibition of speakers’ bureaus, as well as the definition of speakers’ bureaus that was included in the resolution. It was the general consensus of the senators that speakers’ bureaus should be banned, but there were comments made indicating that consulting activities with non-speakers’ bureaus is unclear in the policy; it is open to interpretation and would need to be defined. Another senator added that there are consumer-level speakers’ bureaus that are using language borrowed from industry to create rosters of speakers. By not defining speakers’ bureaus as pertaining to industry, we might inadvertently be including these consumer organizations as well. It was suggested that it is very important to clarify what is and what is not a speakers’ bureau, but it may not be possible to provide clarity to those specifics without passing the proposal so the details can be worked out.

There was also a question regarding what penalties would be imposed for violating this policy, and whether those penalties would be the same from department to department. One senator expressed concern that at the last Senate meeting, there was consensus that the policy should reflect that we don’t want to be a “mouthpiece for a marketer,” but that sentiment was not clearly expressed in this document. It was suggested that the following wording be added to the definition of “speakers’ bureaus”: “. . . where the effort is part of marketing and where they control the content.”

There was discussion regarding dividing the resolution into two sections so that each resolution could be voted on separately. While the Senate was generally in agreement with that strategy, there was concern raised by several senators that approval of this resolution should go to the general faculty, not just the Faculty Senate. Several senators outlined their efforts to engage their faculty in the review of this resolution. A few senators shared that they had received some negative feedback, while others were not able to reach all of their faculty in time for the meeting.

Dean Krugman commented that this resolution will be presented to the Executive Committee next week, at which time President Thompson will provide a summary of today’s discussion. He emphasized that leaving things the way they are is not acceptable in this environment anymore. He will
be instructing the Executive Committee and department chairs that every faculty member needs to have, as part of their annual review this year, a conversation about this issue.

The meeting concluded at 6:00 p.m.

Respectfully submitted,

Cheryl Welch

Faculty Affairs Administrator (for Debra Bislip, Faculty Senate Secretary)