

Present: Drs. Born, Bourdeaux, Da Silva, Daley, del Carmen, Donoff, Ferran, Galaburda, Khoshbin, King, Lovejoy, Nagler, Nour, Padwa, Podolsky, Poussaint, Richardson, Rose, Sieberg, Stone, Taqueti, Vleugels, Wagers

Guests: Drs. Bates, Dienstag, Golan, Mayer, Muto, Ryan; Ms. Day; Mr. Groteboer

Staff: Ms. Hecht; Dr. Lensch

Dean Daley called the meeting to order at approximately 4:05pm. He asked for and received approval for the February 6, 2019 minutes, as presented.

Dean Daley then turned the meeting over to Dr. Nawal Nour, Faculty Council Vice Chair, to make a few comments about the Council's subcommittee to look at Arts and Cultural Representations around HMS.

As has been mentioned a few times during previous Council meetings as well as in other sessions across the campus, HMS is taking a hard look at campus-wide artwork, primarily through a lens that considers how to better represent the diversity of our current faculty, student, and staff populations relative to our history. At this year's kick-off dinner at the Harvard Club, Dr. Nour mentioned the formation of a subcommittee of the Faculty Council that would evaluate current ideas for how to make changes around the campus along with putting new ideas on the table.

The dean's office has already made some strides in this area and the timing seems right to pull our subcommittee together to consider the subject in a more overarching manner. Dr. Nour hoped that some members of the Faculty Council would be willing to join the subcommittee. The current plan is to convene a couple of times before the end of the current academic year, either in person or via teleconference in order to discuss the topic and offer a recommendation to the dean.

The subcommittee is co-chaired by Dr. Nour as well as Dr. Fidencio Saldana, HMS's Dean of Students. It will be staffed by Dr. Willy Lensch, the dean's chief of staff, along with folks from HMS's Office for Diversity Inclusion and Community Partnership.

The subcommittee will not be starting from scratch as one or two proposals will be provided that have previously been made in this area along with hearing some updates on new projects that might be possible in the near term. Dr. Nour also looks forward to hearing from members of the Council regarding their own views.

The subcommittee will be joined by others who have volunteered to consider this subject from across the ranks of students and staff members at HMS. It will no doubt prove to be a rewarding experience.

The goal of this year's effort is to come back to the Council to provide an update and, hopefully, a recommendation to the dean regarding some changes that might be made in the near term along with what ideally would be a set of guiding principles as the school grapples with this subject going forward.

Dr. Nour then asked for a show of hands of those interested in participating in the subcommittee. The following members volunteered: Marcela del Carmen, Al Galaburda, Scott Podolsky, Gene Richardson, Christine Sieberg, Viviany Taqueti.

Next Dean Daley reviewed the agenda.

The Docket Committee expressed an interest in hearing what is going on in Washington DC and how it relates to HMS and the university in general. Two members from Harvard's Federal Relations office will be speaking to that. Then, HMS's Conflict of Interest Policy is an important part of how HMS operates. When it is in need of revision, the Faculty Council is required to consider that need and to vote on whether any proposed changes should be made. We have such a requirement today, that will not take much time but that is important for you to hear and weigh in on.

Dean Daley welcome Suzanne Day, Senior Director of Federal Relations and Jon Groteboer, Director of Federal Relations for Harvard University. To shed a bit of light into how their office works, Ms. Day and Mr. Groteboer are based primarily in Washington, DC but make frequent trips by traveling between DC and Boston. Their office reports to Paul Andrew, Harvard's Vice President for Public Affairs and Communications.

In her role, Ms. Day focuses on higher education and student aid related issues. Mr. Groteboer focuses is on the federal budget and appropriations, as well as issues related to science and research, international education and immigration policy.

Ms. Day gave a snapshot of national politics and looking ahead to the next election. She highlighted Harvard in the 116th Congress, 55 members and senators with a Harvard degree. These Harvard alumni and other Massachusetts delegates may provide new voices in Congress. She spoke about the divided government bringing mixed priorities on the Hill and at the White House, but said a vast majority of time is spent on Budget and Funding Issues because of research and student aid.

Harvard's Federal Relations Office represents the Harvard University, including all Schools. They pay attention to what is going on in Washington as there are usually short windows of opportunity. They work with peer institutions and build partnerships. The Federal fiscal calendar shapes the rhythm of the rest of the year. This year they are very constrained by politics.

Ms. Day discussed classic higher education issues and four major buckets where they spend their time enduring focus for research universities:

- Federal Funding
 - Defense vs. Non-Defense in FY20 and beyond
 - Proposed Cuts to Research and Education
 - Budget Control Act, Sequester, and Caps
- Immigration Policy
 - Future of DACA, TPS
 - International Scholars and Students
 - Visa limits from Administration
- Tax Reform
 - Student and Institutional Impacts
 - Impact on Charitable Giving Incentives
- Student Aid and Higher Education Policy
 - HEA Reauthorization
 - Regulatory Initiatives
 - Affirmative Action
 - Science policy

Next, Mr. Groteboer discussed the budget appropriations as the fiscal situation drives agenda. Currently, they are in the heart of budget season. With the partial government shutdown, the budget has been delayed. It is also a busy time of year for advocacy. The big question is can Congress agree on a budget as October 1, 2019 they are facing sequester to come back in which would mean decrease in funding. He spoke briefly on the NIH growth. When NIH and other funding agencies do well, so does Harvard when it comes to federal sponsorship.

Besides funding, they also keep an eye on research policy issues. Research policy issues at times become inserted into appropriation bills and various interested groups try to get them out. Mr. Groteboer reviewed a few research policy issues:

- Fetal Tissue Research- working with AAMC on discussing with policy makers
 - Appropriations rider blocked in FY18 and FY19
 - Administration action
- “Secret” Science- use of science in rule making (HSPH)
- Quantum Science- (SEAS and FAS)
 - Implementation of new legislation
- Threats to US science and labs- intense focus in DC
 - National Security – defense, economic and intellectual
 - New Rules from NDAA
- Sexual Harassment

Immigration is another issue they watch as Harvard depends on foreign talent.

- Linked to Border Security and Funding for Southern Boarder Wall
- Significant Institutional Interest
 - Dreamers on campus (some with, some without DACA status)

- International Students and Scholars
- Dozens of workers with Temporary Protected Status
- Graduates convert to high skilled worker categories
- Broad Advocacy Efforts
 - Capitol Hill
 - Administration
 - Courts
 - Case work

Mr. Groteboer highlighted Administration changes to policy:

- F (student) and J (exchange) visas:
 - Accrual of Unlawful Presence
 - Duration of Status
 - J-1 Visa extensions
 - Rising fees
 - China
- H-1B – critical tool for attracting tenure-track faculty and researchers:
 - Increase in Requests for Evidence – documentation to support application.
- Optional Practical Training / STEM OPT
 - New program limits coming?

Mr. Groteboer spoke briefly on the changing landscape of Tax Cuts and Jobs Act. This was a big accomplishment in the last Congress. There are changes buried in the Tax bill and the Federal Relations team is quite engaged with other educational institution teams. There's a high level of engagement needed to force changes with regards to tax issues.

Lastly, Mr. Groteboer touched briefly on the Higher Education Act Reauthorization which failed in 2018. It's a big bill which may have some window for this to get through due to significant bipartisan common ground:

- Concerns about student debt, college cost, outcomes
- Consolidation of aid programs
- Improved repayment, counseling and servicing of student loans
- New Accountability systems and changes to accreditation
- Support for “innovative programs” and alternatives to degrees
- Strengthening campus requirements on sexual assault

Harvard students receive \$a large number of federal loans and there are concerns with preserving benefits for graduate education and graduated students.

Ms. Day and Mr. Groteboer took questions.

Dean Daley thanked both Ms. Day and Mr. Groteboer before moving on to the next agenda topic.

HMS's Conflict of Interest Policy is occasionally subject to revision and when changes are sought, it is the responsibility of the Faculty Council to hear and then vote on the proposal. We have such a proposal today regarding the definitions of nominal risk in Human Subjects Research. The proposal will be offered by Dr. Robert J. Mayer, Faculty Associate Dean for Admissions and Dr. Jennifer M. Ryan, Executive Director for Academic and Research Integrity

Dr. Mayer reviewed the current definition of Nominal Risk Clinical Research and the Standing Committee on Conflicts of Interest and Commitment's recommendation that the definition of Nominal Risk Clinical Research be modified such that the definition of Nominal Risk Clinical Research is all research determined to be Minimal Risk Research by an IRB. The Committee has talked with other Conflict of Interest (COI) Committees at affiliates and they agree that the change would be beneficial. Dr. Mayer discussed some anticipated benefits:

- Increase clarity of the policy
- Harmonization with the Institutional Review Board
- To have easier application of the policy
- A policy that is more fair
- Less administrative effort to prepare materials for exception requests to the policy
- Increased discretion for the primary institution (where this is happening) to review and assess for management.

Discussion took place. Dean Daley mentioned that any changes HMS makes gets enormous attention because HMS has one of most stringent COI policies. This change is an attempt to try making a current area of the policy less complicated and allow the IRB to judge.

Faculty Council, being advisory in its recommendations of policy changes to the Dean, substantive changes to the Faculty of Medicine Policy on Conflicts of Interest and Commitment are recommended by the Standing Committee on Conflict of Interest and Commitment to the Faculty Council and Dean for review and approval. A formal motion was called to accept the Standing Committee's recommendation to change the definition of Nominal Risk Clinical Research such that the exclusion from the Clinical Research Rule will apply to all research that meets the definition of Minimal Risk as determined by the IRB. A formal vote was taken and the Faculty Council unanimously voted to recommend to the dean to approve the motion. The Policy will no longer refer to Nominal Risk Clinical Research and will instead refer to Minimal Risk Clinical Research. Minimal Risk Clinical Research will be defined as:

Clinical Research that is determined by the Institutional Review Board as minimal risk (as that term is defined in 45 CFR Part 4610) which means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those

ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Vote Tally:

21 in favor

0 opposed

After discussion, Dean Daley invited the Council to stay to socialize and adjourned the meeting at 5:33pm.