Harvard Medical School

Faculty of Medicine Committee on Conflicts of Interest and Commitment

2009-2010 Review

Report

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I. PREAMBLE

In January 2009, Jeffrey S. Flier, MD, Caroline Shields Walker Professor of Medicine and Dean of the Faculty of Medicine of Harvard University, appointed an advisory committee to review, supplement and clarify the existing Faculty of Medicine Policy on Conflicts of Interest and Commitment (COI Policy). Joseph Loscalzo, MD, PhD, Hersey Professor of the Theory and Practice of Physic; Robert J. Mayer, MD, Stephen B. Kay Family Professor of Medicine; Thomas Michel, MD, PhD, Professor of Medicine; and Christopher T. Walsh, PhD, Hamilton Kuhn Professor of Biological Chemistry and Molecular Pharmacology, co-chaired the Committee. We worked in cooperation with, and as a subcommittee to, a University-wide committee led by David Korn, MD, Harvard University Vice Provost for Research. Drs. Loscalzo, Mayer and Walsh have served as representatives of the Faculty of Medicine to the University-wide committee. The Harvard University committee developed a Policy on Individual Financial Conflicts of Interest for Persons Holding Faculty and Teaching Appointments, setting forth University-wide principles and guidelines for conflicts of interest policies, with which this Committee's recommendations are aligned.

The COI Policy was first adopted in 1990 and has guided faculty interactions with industry for over two decades. The original version of the COI Policy and all subsequent revisions have reinforced an essential principle: interactions between academia and industry are crucial to science and to facilitating the translation of knowledge from the research bench to the hospital bedside. The recommendations of this Committee strongly support and reinforce that principle while also providing guidance in structuring relationships between academia and industry to ensure transparency and continued public confidence in the integrity of the scientific enterprise.

Neither the COI Policy nor the recommendations in this report prohibit a faculty member from interacting with industry in support of this objective. In fact, we encourage faculty to engage in a wide variety of activities with industry, including, but not limited to:

- Conducting research sponsored and supported by industry;
- Collaborating with industry on research protocols and co-authoring publications derived from these collaborations;
- Consulting for industry;
- Founding biotechnology companies;
- Licensing technology to or from pharmaceutical, medical device and biotechnology companies;

- Serving on the scientific advisory boards of pharmaceutical, device and biotechnology companies; and

- Holding equity in pharmaceutical, device and biotechnology companies.

The Faculty of Medicine has long valued faculty collaboration with industry as a fundamental part of its mission to facilitate scientific discoveries and clinical translation that will alleviate human suffering caused by disease. At the same time, certain collaborations may lead to conflicts of interest, and it is necessary to provide standards for our faculty members to guide their interactions. As the COI Policy states, "with clear guidelines and principles, in conjunction with appropriate mechanisms for supervision and monitoring, cooperation between industry and academic medicine is consistent with the highest traditions of the medical profession and can energize scientific creativity."

In the years since the COI Policy was last revised, in 2004, there has been increased interest in and scrutiny of faculty financial interests and interactions, and the topic of conflicts of interest has become an important matter of national debate.[1] As stated in the current policy, "The complexity of the subject matter is such that the current guidelines and their ensuing interpretations should be formally reviewed on a periodic basis." Therefore, this Committee was convened to review, update and clarify the COI Policy and its associated implementation processes for all members of the Faculty of Medicine.

As members of this Committee, we undertook Dean Flier's charge in an atmosphere of intense public scrutiny. The issue of individual financial conflicts of interest in academic medicine has been the subject of debate from Capitol Hill to the classrooms of our own institution. We have endeavored to educate ourselves on the views of all constituencies through (1) expert witness testimony; (2) review of COI policies developed by national academic organizations, by other medical schools and by our affiliated institutions; and (3) input from our more junior faculty colleagues and administrative colleagues at our affiliated institutions. We have strived to reach thoughtful conclusions and recommendations, relying upon evidence-based research where available, and, where unavailable, upon the vast experience of our members and those of our colleagues within the Faculty of Medicine. We have attempted to resist the natural tendency for immediate reaction to public pressure to appease critics, endeavoring instead to give each complex issue the thoughtful and deliberate analysis it deserves and to carefully consider the realities within which our recommendations are issued.

[1] This Committee acknowledges that as used in this report, the term "conflicts of interest" may include an actual conflict of interest or a perceived conflict of interest. While our members have strived to refrain from making policy based on perceptions alone, we do not discount the importance of acknowledging, as appropriate, the harms that may result from the public's diminished trust in our work because of the perception of an individual conflict.

In crafting the following recommendations, our members have not always agreed. When consensus could not be reached, we have noted this within our report. Similar to our faculty, our committee members come from differing backgrounds and have varying areas of interest and expertise. Our members have PhDs, MDs, DMDs and other advanced degrees. The members of our large and diverse faculty are based at affiliated teaching hospitals, research institutions, the School of Dental Medicine, and on the HMS Quadrangle. Our members are engaged in education and training, patient care and a large range of research activities, from theoretical research to multi-site clinical trials involving human participants. Our experiences and relationships with industry over the years have differed, and we have come to this Committee with the personal biases that such varying experiences inevitably carry.

As a result, we have endeavored to carry out our charge in a manner that respects the principles upon which the Faculty of Medicine stands. The mission of Harvard Medical School is to "create and nurture a diverse community of the best people committed to leadership in ending human suffering caused by disease." This Committee's recommendations are submitted in the spirit of being one inclusive Faculty of Medicine. We celebrate the rich academic and professional experience that comes with such a large network of highly trained individuals and the innovation for which they are widely recognized. We affirm our belief in the inherent integrity of this faculty and our trust in them to act ethically in conducting activities, both at this institution and beyond. We hope and expect that, while we may disagree on some of the details, as one Faculty of Medicine, we can together support the underlying principles and goals of these recommendations.

We are:

Eugene Braunwald, MD, Hersey Distinguished Professor of the Theory and Practice of Physic (Brigham & Women's Hospital);

Julia Carnevale, HMS medical student;

Jules Dienstag, MD, Carl W. Walter Professor of Medicine (Massachusetts General Hospital) and HMS Dean for Medical Education;

Patricia Donahoe, MD, Marshall K. Bartlett Professor of Surgery (MGH);

R. Bruce Donoff, MD, DMD, Walter C. Guralnick Distinguished Professor of Oral and Maxillofacial Surgery (Harvard School of Dental Medicine);

Gary Fleisher, MD, Egan Family Foundation Professor of Pediatrics (Children's Hospital Boston);

Michael Gimbrone Jr., MD, Ramzi S. Cotran Professor of Pathology (BWH);

David Golan, MD, PhD, Professor of Biological Chemistry and Molecular Pharmacology (HMS) and HMS Dean for Graduate Education;

Shelly Greenfield, MD, Associate Professor of Psychiatry (McLean Hospital);

Elizabeth Hohmann, MD, Associate Professor of Medicine (MGH);
Isaac Kohlberg, Senior Associate Provost and Chief Technology Development Officer at Harvard University;

Ellice Lieberman, DrPH, MD, Professor of Obstetrics, Gynecology and Reproductive Biology (BWH);

Joseph Loscalzo, MD, PhD, Hersey Professor of the Theory and Practice of Physic (BWH);

Robert J. Mayer, MD, Stephen B. Kay Family Professor of Medicine (Dana-Farber Cancer Institute);

Barbara J. McNeil, MD, PhD, Ridley Watts Professor of Health Care Policy (HMS);

Thomas Michel, MD, PhD, Professor of Medicine (BWH);

Joan W. Miller, MD, Henry Willard Williams Professor of Ophthalmology (Massachusetts Eye and Ear Infirmary);

Richard Mills, JD, HMS Dean for Operations and Business Affairs;

Lee Nadler, MD, Virginia and D.K. Ludwig Professor of Medicine (DFCI) and HMS Dean for Clinical and Translational Research;

Marjorie A. Oettinger, PhD, Professor of Genetics (MGH);

Nancy Oriol, MD, Associate Professor of Anaesthesia (Beth Israel Deaconess Medical Center) and HMS Dean for Students;

Barrett J. Rollins, MD, PhD, Linde Family Professor of Medicine (DCFI);

Paul S. Russell, MD, John Homans Distinguished Professor of Surgery (MGH);

Richard M. Schwartzstein, MD, Ellen and Melvin Gordon Professor of Medical Education (BIDMC) and Director of the HMS Academy;

Ganesh Shankar, HMS MD-PhD student;

Peter Sorger, PhD, Professor of Systems Biology (HMS);

Nancy Tarbell, MD, C.C. Wang Professor of Radiation Oncology (MGH) and HMS Dean for Academic and Clinical Affairs;

Patrick L. Taylor, JD, Assistant Clinical Professor of Pediatrics (CHB);

Todd Theman, MD, former HMS medical student;

Christopher T. Walsh, PhD, Hamilton Kuhn Professor of Biological Chemistry and Molecular Pharmacology (HMS);

Mark Zeidel, MD, Herrman Ludwig Blumgart Professor of Medicine (BIDMC).

Drs. Loscalzo, Mayer, Michel and Walsh acted as co-chairs of this Committee. Dean Flier attended each meeting as a non-voting witness to the comprehensive and

lively deliberations. Gretchen Brodnicki, JD, HMS Dean for Faculty and Research Integrity, and Kristin Bittinger, JD, HMS Director of Scientific Integrity, served as staff to the Committee.

II. STRUCTURE OF REVIEW AND REPORT

Early in its deliberations, this Committee subdivided into separate subcommittees to focus on three core areas:

- Research;
- Education; and
- Implementation and Compliance.

Each subcommittee submitted recommendations for full Committee review and approval pertaining to the particular subject area for which it was charged. The subcommittees met a total of 16 times and the full Committee met an additional 14 times to meet its charge. The Faculty Reaction Group[2] met an additional four times and the Affiliate Operations Reaction Group[3] met an additional four times, for a total of 38 meetings dedicated to this task.

We have attempted to respond to the concerns of our colleagues that we simplify the COI Policy document and streamline the procedures required for compliance with these policies. We make our recommendations and draft this report with this overall aim in mind, while at the same time acknowledging that complex issues may require complex solutions. We understand that a policy is only as strong as its effective implementation, and that effective implementation requires widespread understanding. Accordingly, we have included within each section a bullet point summary highlighting the key conclusions and, when appropriate, an example of how a particular recommendation would be enacted in practice. We have made a number of recommendations for ease and clarity of implementation and understanding of the policy, including the resources necessary to implement them. We acknowledge that our work, and this report, is the beginning of what will be needed for comprehensive and sustained efforts to ensure our faculty are well informed and well equipped with the tools necessary to understand and comply with the new requirements.

The following report is subdivided into four sections. The first three sections principally discuss the recommendations of each subcommittee, as approved by the full Committee. As noted, in any situation where consensus could not be reached, we

[2] The Faculty Reaction Group comprised nine faculty members across the HMS community, who provided input on behalf of their more junior colleagues regarding how pending recommendations may impact the junior faculty's professional experience. As applicable, the views of this group on certain issues were provided to the larger committee. The Faculty Reaction Group also met with the co-chairs of the full committee and with Deans Flier, Tarbell and Brodnicki.

[3] The Affiliate Operations Reaction Group comprised administrative professionals who are responsible for managing conflicts of interest policies of the affiliated institutions.

have included an alternative recommendation and minority report for Dean Flier's consideration. The final section sets forth additional recommendations of the full Committee.

III. EDUCATION SUBCOMMITTEE

The Education Subcommittee was asked to examine issues related to potential conflicts of interest affecting the education, training and experiences of medical students, graduate students, postdoctoral fellows and faculty (with special emphasis on the training of junior faculty), and to revise and/or draft additional provisions to ensure all educational activities, including those within HMS and HSDM programs in continuing medical education (CME), are appropriately balanced, unbiased and free of influences unrelated to the HMS and HSDM educational missions. This subcommittee consisted of Eugene Braunwald, MD; Julia Carnevale; Jules Dienstag, MD; R. Bruce Donoff, MD, DMD; David E. Golan, MD, PhD; Shelly Greenfield, MD; Thomas Michel, MD, PhD; Richard G. Mills, JD; Nancy Oriol, MD; Ganesh Shankar; Richard Schwartzstein, MD and Todd Theman, MD. Dr. Michel served as chair.

A. SUMMARY OF RECOMMENDATIONS

- Increase the scope of COI education and integrate COI curricula throughout the continuum of education and training at HMS and its affiliated institutions.
- Continue to prohibit access by pharmaceutical, medical/dental device and supply company sales/marketing representatives to medical/dental students on campus.
- Restrict campus access by all biomedical company representatives to "invitation only" and require identifying badges.
- Prohibit sponsorship of HMS/HSDM-accredited CME by a single healthcare corporation. Multiple company sponsorship is allowed if support is relatively equitable (with no one company accounting for more than 50% of budget).
- Establish a Dean's Fund at each of HMS and HSDM to support strategic CME objectives.
- Delegate responsibility for evaluating CME funding structure and potential conflicts to the HMS/HSDM CME Review Committees.
- Require additional separation of industry exhibits and CME educational content.
- Prohibit simultaneous and/or co-localized industry-sponsored educational programs with HMS/HSDM-accredited CME. Eliminate industry co-promotion with HMS/HSDM content.
- Modify HMS's Current Clinical Issues in Primary Care (Pri-Med) conferences to minimize marketing presence.

- Mandate CME speaker disclosure slides that highlight and estimate the value of relevant financial interests.

- Apply Accreditation Council for Continuing Medical Education Standards for Commercial Support to non-accredited events.

B. STUDENT AND TRAINEE EDUCATION AND CAMPUS ACCESS

Guiding Principle I: Balanced and Consistent Education

HMS/HSDM curricula must offer balanced and consistent education in critical thinking and decision-making in the art and science of medicine. Education must be provided both at HMS and HSDM and at the HMS teaching hospitals throughout the training and career continuum of each student and trainee, and of each member of the Faculty of Medicine. Educational offerings should not only focus on recognizing and managing conflicts of interest and commitment, but should also provide guidance on how to incorporate potential conflicts into the critical evaluation of scientific and clinical evidence. The essential nature of the academic-industry partnership in developing new therapies and in transferring discoveries from the bench to the patient should also be recognized and sustained within these guidelines.

The Education Subcommittee systematically examined the concerns and experiences of various HMS and HSDM student and trainee cohorts with respect to their education and training. Specifically, the Subcommittee evaluated what educational content the Faculty of Medicine and the affiliated institutions currently offer with respect to managing industry interactions in the medical and research profession and what each should offer in view of the experiences and needs of the following groups: (a) medical/dental students; (b) graduate students; (c) postdoctoral research fellows; (d) clinical trainees (residents and clinical fellows); and (e) faculty members. The Subcommittee concluded that a more systematic incorporation of educational content covering the identification, critical evaluation, and inevitability of potential conflicts was warranted throughout the HMS/HSDM professional training continuum. They also found that additional institutional resources are necessary to address individual concerns of educational integrity. Thus, the following recommendations are made:

Recommendation 1: Additional Curricula

HMS/HSDM must continue to develop and implement curricula covering conflicts of interest throughout the educational trajectory and training of its students, trainees and faculty. Particular attention should be paid to enhancing the COI curriculum for

medical students during their transition from pre-clinical classroom studies to the clinical setting.[4] Online educational modules could also be developed for completion in connection with the resident orientation process and in connection with faculty completion of the annual financial reporting form.[5]

Recommendation 2: Ombudsperson's Role

The services of the HMS/HSDM/HSPH Ombudsperson Program and the HMS Academic Societies should be optimized as resources for addressing student, trainee and faculty concerns related to educational integrity and conflicts of interest and commitment. Additional resources should be provided, as needed, to achieve these goals.[6]

Guiding Principle II: Transparency in Financial Interests of Faculty

HMS/HSDM policy must mandate transparency regarding potentially conflicting personal financial interests of faculty, lecturers and investigators who are involved in the education and training of members of the HMS/HSDM community. Students and trainees must be provided with specific, relevant and timely information regarding potential conflicts to enable an informed evaluation of education content. HMS and HSDM should endeavor to prevent marketing influence over the academic environment, while also preparing their students for those beneficial and necessary interactions with industry in the profession.

In 2008, the HMS Faculty of Medicine became the first to mandate disclosure by educators of potential conflicts of interest as related to the content of a classroom lecture. This rule was codified in Section 4.14 of the Student Handbook and has since been expanded by the HMS Curriculum Committee to implement additional procedural safeguards and to increase adherence to the rule.[7] We support increased

[4] Specific courses identified as providing useful opportunities for additional conflicts of interest and commitment content include: (i) Introduction to the Profession; (ii) Molecular and Cellular Basis of Medicine; (iii) Medical Ethics and Professionalism; (iv) Principal Clinical Experience; (v) Patient-Doctor III; (vi) Pharmacology and Clinical Therapeutics; (vii) Clinical Epidemiology and Population Health and (viii) Introduction to Social Medicine and Global Health.

[5] Online education in connection with faculty members' completion of the annual financial reporting form is recommended with additional detail within Recommendation 32.

[6] We similarly recommend that the role of the HMS Ombudsperson be expanded in order to provide a resource to members of the faculty in addressing individual concerns of supervisor influence. See Recommendation 16. Such influence may include potential misuse of the teacher-student and mentor-mentee role and, therefore, is consistent with the expanded Ombudsperson role set forth in this recommendation.

[7] Section 4.14 states, in part, "Faculty and students must disclose any financial interests they may have in a pharmaceutical, biotechnology or medical instrument company, or any other business that owns or has a contractual relationship to the subject matter being reported or discussed in a presentation, lecture, tutorial,

disclosure in this area and the School's high standards for transparency within student lectures. In connection with this increased disclosure, the Subcommittee recommended expanding the restriction prohibiting pharmaceutical marketing/sales representatives from interacting with students on the HMS/HSDM campus to medical/dental device and supply company sales personnel. Marketing personnel from such companies provide no direct educational benefit to our students on campus and are not necessary to the academic environment. We do acknowledge that students conducting basic research on this campus may benefit from limited interactions with biotechnology vendor sales personnel, who are often best situated to counsel researchers on new laboratory techniques and related products. We anticipate, however, that such individuals need only be present on campus when requested or invited by a faculty member, and that the presence and purpose of such visits should be transparent. With this in mind, the following recommendation is submitted.

Recommendation 3: Access of Industry Representatives to HMS Campus

The policy on "Access of Pharmaceutical Representatives to HMS Campus" should be modified to (i) restrict access by medical/dental device and supply company sales and marketing representatives to medical/dental students on the HMS campus, (ii) require biomedical company representative(s) to wear an identifying badge setting forth the individual's company affiliation while on the HMS/HSDM campus, and (iii) restrict access of all biomedical personnel on campus to "invitation only" from a member of the HMS/HSDM faculty or designated staff.

Policy in action. A sales representative from Medical Device Manufacturer X is not allowed to give a lunchtime presentation to interested students in the Tosteson Medical Education Center (TMEC) on the latest advancements in a drug-eluting stent's development. However, a sales representative from Biotech Company Y is allowed to visit a graduate student researcher in a TMEC laboratory to demonstrate a new PCR machine if (i) the representative receives a formal invitation from a faculty member or fellow and his/her arrival is expected by HMS Security, and (ii) Biotech Company Y sales representative obtains an identifying badge with company affiliation from Security upon his/her arrival and wears the badge at all times while on the HMS Quadrangle.

In the spirit of eliminating marketing influence on students' educational experience, the Subcommittee also examined industrial funding of scholarships and education funds for students and trainees, and of HMS professorships. Based on this review, we have concluded that such support does not automatically give rise to concerns of

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paper or other teaching exercise or assignment." The Curriculum Committee now mandates the use of template slides by lecturers, completion of conflicts of interest disclosure forms by presenters and compliance oversight by course managers.

industry influence and, in fact, can be an important resource for advancing our educational mission by providing academic and professional opportunities that may not otherwise be available without such funding. Nonetheless, our conclusions are dependent upon the imposition of appropriate safeguards to ensure no industry influence on, or input into, the identity of recipients. We therefore recommend:

Recommendation 4: Scholarships/Educational Funds for Trainees

Industry support for scholarships and education funds for students/trainees and for professorships remains an important resource for advancing our educational mission. HMS and HSDM must continue to apply rigorous safeguards to ensure that the selection of the recipient of funding is free of industry influence or input. Scholarship recipient selection shall be at the exclusive discretion of the educational institution, an institutional committee or a third-party academic committee that is not influenced by industry input. The composition of any such third-party committee shall be reviewed from time to time by the Office of the Dean, or its designee, to ensure appropriate safeguards. It is the expectation of HMS and HSDM that fellowships awarded through HMS-affiliated institutions be managed in a manner that protects against fellowships established for marketing rather than academic purposes.

While the Education Subcommittee considered whether to mandate additional formal financial reporting by HMS students and fellows, we concluded that the current requirements adequately gather relevant information at the most sensitive junctures. Specifically, we already require disclosure of student and fellow financial interests relevant to one's role as a researcher[8] and as an educator.[9] Additional disclosure is therefore unnecessary.

Recommendation 5: Additional Student/Trainee Disclosure

HMS and HSDM shall continue to require medical and dental students, graduate students and postdoctoral research and clinical fellows to report outside financial interests that relate to an individual's role in clinical or sponsored research to the same extent as such transactional disclosures are required of members of the Faculty of Medicine.

C. CONTINUING MEDICAL EDUCATION (CME)

[8] All individuals responsible for the design, conduct and report of research, including students and fellows, whose research funding is through HMS and or HSDM must comply with the Harvard University Government, Foundation and Industry-sponsored Activity Financial Disclosure Process at the time of grant submission. Investigators applying for federal Public Health Service or National Science Foundation Awards must comply with the provisions of federal regulations governing conflicts of interest in research (42 CFR § 50 Subpart F, 45 CFR §§ 94 and 60, and Fed. Reg. 35820).

[9] As noted, Section 4.1.4 of the student handbook requires this. See footnote 7.

Guiding Principle: Rigorous Standards in CME

The Faculty of Medicine reaffirms its commitment to providing lifelong learning opportunities to providers of medical and dental care. The institution has an obligation to lead high quality, evidence-based continuing medical education. The same rigorous and superior standards applied by HMS/HSDM to educational content delivered in its classrooms must also apply to content delivered through programs approved for credit by the HMS/HSDM Offices of Continuing Education.

The Education Subcommittee spent considerable time contemplating the role of industry funding in HMS/HSDM accredited medical and dental continuing education. Its members considered past industry support for HMS/HSDM accredited CME and the procedures traditionally imposed to ensure that educational content is not influenced by a commercial entity. At HMS, industry funding historically accounts for only a small fraction of the overall accredited CME program budget. It has helped, however, to support specific programs.

This Committee acknowledges the complicated history of industry support for educational activities in this country. Some companies have clearly used sponsorship of educational sessions inappropriately, namely, to attempt to increase market demand for company products and, at times, to promote uses beyond a product's Food and Drug Administration indication. Such scenarios can result from a failure on the part of an accredited provider to appropriately safeguard against industry influence in compliance with the Accreditation Council for Continuing Medical Education's (ACCME) Standards for Commercial Support.[10] This failure of compliance, should not, however, necessarily be interpreted to mean that all industry sponsorship of CME is biased and inappropriate. In fact, we have found little research or definitive data from the HMS, HSDM or elsewhere proving one way or the other that industry supported CME is generally more biased when required safeguards are imposed. Yet even the idea that some in industry may have advanced their marketing goals through the use of CME programs has tarnished academia's trust in commercial support for CME. Some of our peer institutions have banned all industrial sponsorship of educational programs. However, the Education

[10] All accredited CME providers must comply with the ACCME Standards for Commercial Support. Standard 1.1 mandates the following:
A CME provider must ensure that the following decisions were made free of the control of a commercial interest.

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

Subcommittee concluded, and this Committee agrees, that when appropriately managed, industry remains an important resource for funding of high quality CME. While we collectively support and endorse the formation of a focus group aimed at developing alternative funding models for exceptional, cost-effective CME, we believe at this time that continuing to accept industry support does not pose an unacceptable risk of compromising quality.

Nonetheless, we have concluded that funding for programming that is provided by a single company gives rise to an increased risk that such company's unique marketing objectives will influence the program's content, or appear to do so, and diminish attendee trust in its content. The Education Subcommittee therefore recommended, and we concur, that HMS/HSDM prohibit sponsorship by a single healthcare corporation, but allow for funding by more than one company if the allocation of such support is reasonably equitable. In connection with this, the HMS/HSDM CME Programs should also establish a general account, entitled the "Dean's Fund," to accept undesignated funds from industry and individuals. This Dean's Fund can, from time to time, be utilized by the HMS/HSDM CME programs to fund strategic objectives in medical education.

In view of the foregoing conclusions, the following recommendations are submitted:

Recommendation 6: Industry Funding of CME

Following a transition period, sponsorship by a single healthcare corporation (pharmaceutical, medical/dental device or supply or other biomedical company) of any HMS/HSDM accredited CME shall be prohibited. However, industry support shall be acceptable if:

(1) Funding is provided for a specific course/program in conjunction with one or more other industry sponsors in a relatively equitable way, with no one sponsor accounting for more than 50% of a particular course budget; or

(2)Money is contributed to a Dean's Fund for Continuing Medical Education, which shall be established by HMS/HSDM to support programs aimed at advancing strategic objectives in CME as determined by the HMS/HSDM Departments of Continuing Medical Education.

Rigorous safeguards must be imposed on all industry sponsored events to separate curriculum design and content development decisions from commercial support. At the discretion of the CME Review Committee, additional monitoring and peer review mechanisms may also be imposed to assess for and eliminate bias in such programs. Programs supported by the Dean's Fund will cite the Dean's Fund support in disclosure slides. Individual sponsors of the Dean's Fund will be listed on the HMS/HSDM CME websites.

Policy in action. A course director for an HMS-accredited CME course on the latest treatments for reducing high blood pressure may fund the program's expenses by accepting the following distribution of educational grants:

50% of budget from Pharma X
30% of budget from Medical Device Company Y
20% of budget from Foundation Z

However, the course director may not fund the program's expenses with the following distribution of educational grants:

51% of budget from Pharma X
49% of budget from Medical Device Company Y

Pharma X and Medical Device Company Y may contribute any amount to the Dean's Fund but shall have no control of or input into the specific course*/program to which the funds are directed.*

Recommendation 7: CME Review Committees

The HMS/HSDM CME Review Committees shall be delegated responsibility for reviewing proposed programs prior to approval to assess:

(1) Whether the proportion of industry funding for a particular program is appropriate in view of the policy's requirements as to funding equity among the multiple sponsors, and

(2) Conflict of interest risk by reason of the financial relationships of the organizers/speakers.

The HMS/HSDM CME Review Committees may determine that a particular program is sufficiently high risk to require additional safeguards and independent evaluation for potential bias. Such additional limitations shall be imposed at the discretion of the relevant CME Review Committee in consultation with the Standing Committee on Conflicts of Interest and Commitment. The Standing Committee on Conflicts of Interest and Commitment will periodically review the assessments of, and provide guidance to, the HMS/HSDM CME Review Committees.

Policy in action. Prior to approval for accreditation, the HMS/HSDM CME Review Committee will review a proposed course using the ACCME and/or American Dental Association content standards historically imposed. The financial disclosures of course developers and speakers will also be evaluated, consistent with prior practice, to identify potential individual conflicts of interest that may require additional management. In addition, the CME Review Committee will now evaluate (i) the proposed program budget for compliance with the rules for distribution of industry support; (ii) any proposed industry exhibitor support and marketing materials for compliance with the rules set forth below in Recommendation 8).

In connection with its discussion of direct commercial support for HMS/HSDM accredited CME courses, the Education Subcommittee also considered other mechanisms commonly used to support programming, including advertising and exhibitor income. On this subject, both the Subcommittee and this Committee specifically considered the HMS CME-accredited Current Clinical Issues in Primary Care course offered at Pri-Med conferences. Pri-Med is "a communication and education platform owned by M/C Communications, LLC,"[11] a for-profit medical education company that principally utilizes funding from exhibitors and advertisers to support its conferences. The HMS CME-accredited program provided during the Pri-Med conferences represents one of the most popular and acclaimed primary care continuing medical educational forums nationwide. Because tuition is kept very low and the quality of the HMS CME-accredited faculty presentations is quite high, primary care physicians, nurses and other health providers from across the country consistently attend this HMS-accredited CME program during the Pri-Med conferences. While the development and delivery of HMS CME-accredited content at the Current Clinical Issues in Primary Care courses is independent from and uninfluenced by any Pri-Med conference exhibitor or advertiser, there is significant commercial presence in the exhibitor halls of the conferences, the appearance of which may, to members of this Committee, distract and detract some attendees from the meeting's HMS CME-accredited educational objectives.

We were informed in our review of HMS's relationship with M/C Communications by an external assessment of the Pri-Med Conferences previously performed by experts unaffiliated with HMS, as well as by an informal review of the relationship by the HMS CME Review Committee. Both reviews concluded that the educational content of the HMS CME-accredited Current Issues in Primary Care courses offered during the Pri-Med Conference is excellent and of the highest quality, without any apparent bias or influence by industry. We agree with this conclusion based upon the experiences of members of this Committee. However, we also concur, as recommended by both the previous external panel and the HMS CME Review Committee, that the relationship with M/C Communications requires clarification to ensure that the academic independence and integrity of the HMS CME-accredited course content is equally matched by integrity in appearance by distinction of those events from other non-HMS-accredited offerings at the Pri-Med conferences.

This Committee affirms that every effort should be made to continue providing the Current Clinical Issues in Primary Care course, and any other courses as deemed appropriate by the HMS CME Review Committee, in a manner accessible to a wide audience, while also taking all appropriate steps to eliminate any confusion about industry's involvement, or lack thereof, in the design and delivery of the HMS CME-accredited sessions.

To accomplish these goals, the following recommendations are made:

[11] http://www.mc-comm.com/live/mc/

Recommendation 8: Industry Exhibits and Advertising

The following rules are recommended in connection with any HMS/HSDM CME program that includes industry exhibits (including the Pri-Med conferences):

- An industry-sponsored educational program/course must occur (i) in a distinct location[12], as approved in advance by the HMS/HSDM CME Review Committee, and (ii) at a distinct time[13] as a CME program approved for credit through HMS/HSDM.

- All industry exhibits[14] must be located in a separate room from HMS/HSDM CME content so that participants do not have to interact with industry exhibitors unless they choose to do so.

- As appropriate, HMS/HSDM CME programs must provide for reasonable and convenient access to food.

- All industry programs and/or exhibits must be marketed separately from the Harvard program. In other words, no co-promotion of HMS/HSDM content and industry content should be permitted.

- Gifts from industry should be prohibited in conjunction with HMS/HSDM CME programs.[15]

Recommendation 9: Pri-Med Relationship

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[12] A "distinct location" may include a separate wing or floor of a conference center or may, as circumstances dictate, require an entirely separate address from the location of a particular HMS CME event. Such proposed locations are to be evaluated by the CME Review Committee with an aim to eliminate participant confusion as to HMS content versus industry content, and to eliminate any implicit co-promotion by HMS of industry content by reason of its co-location.

[13] A "distinct time" may include an event occurring on a different day or an event occurring on the same day, but finishing and/or commencing at a time period to be approved by the CME Review Committee, that is sufficiently prior to or following an HMS CME program as to avoid any confusion concerning the support of the non-HMS CME content. At no time shall the industry-sponsored educational program occur within a time period that the HMS CME event is ongoing. An industry-sponsored event may not occur during breaks for meals or other open time planned in connection with an HMS CME event and shall be allowable only following completion (or prior to commencement) of all HMS program content planned during a particular day.

[14] In accordance with the previous bullet, such exhibits should not include a formal educational program/course.

[15] While Massachusetts state law currently prohibits gifts to health care providers registered in Massachusetts, residents of other states can still receive gifts from pharmaceutical and medical device companies in connection with HMS programs. The Committee believes that the gift ban imposed by Massachusetts law should apply to all participants of HMS CME programming.

The following specific recommendations are made with regard to the Pri-Med conferences and the relationship between HMS CME and M/C Communications:

- Review the present contractual arrangement with M/C Communications to ensure that it fully complies with the letter and spirit of this Committee's recommendations.

- Adopt a plan to distinguish further between the Pri-Med conferences and the HMS-accredited Current Issues in Clinical Care CME courses. At a minimum, require participants of the HMS CME course to execute an "opt-in" prior to their inclusion on any Pri-Med advertising distribution list. This opt-in must also clarify that participants understand that the Pri-Med online course offerings are not affiliated with Harvard or the HMS CME program.

- Mandate speaker financial disclosure slides with each presentation (and any advertising in connection therewith [*See Recommendation 10*]).

- Members of the HMS Standing Committee on Conflicts of Interest should attend a Pri-Med conference during the transition period and shall be delegated with authority to recommend to the Dean additional guidance about industrial advertising/exhibits in connection with its members' experiences.

Policy in action. The Pri-Med conference may continue to offer an industry exhibit hall if the exhibits are confined to a conference room separate from the conference room hosting the HMS-accredited CME. A participant may not be required to walk through an exhibitor hall to obtain access to any HMS-accredited course. In addition, the Pri-Med conference may not permit industry exhibitors to offer educational programs or courses on the same day or in the same general location (on any day) of the conference center hosting the HMS-accredited CME. Advertising for the Pri-Med conference may not commingle information about the HMS CME-accredited content with information about industry or other third party-supported CME content within the same brochure, pamphlet web site or other method of distribution. Following a conference, M/C Communications may not send advertising for non-HMS content to a participant unless the participant has affirmatively agreed that he/she would like to receive such mailings or has responded proactively (opt-in) to an email participation request.

While considering the previous recommendation's mandate for conflicts of interest disclosure slides, this Committee also considered whether, and in what manner, Faculty of Medicine speakers should be required to disclose personal financial interests in connection with a particular CME presentation. Following discussion and some dissent, a majority of this Committee recommended that faculty members include within a financial disclosure slide the estimated value (set forth as a range)

for relevant interests. Such detailed disclosure information encourages transparency and provides audience members with information most relevant to their individual assessment of the material presented.

Accordingly, a majority of this Committee recommends as follows:

Recommendation 10: HMS/HSDM CME Speaker Disclosures

Any speaker at an HMS/HSDM CME event shall disclose all financial interests relevant to the content of his/her presentation at the beginning of a presentation. Such disclosure shall highlight the financial interests that are most significant either in value or in relevance, including, in ranges, the value of such relevant financial interests. The HMS public disclosure website (See Recommendation 32) shall also be provided and referenced within any presentation, with audience members explicitly directed to such website for additional information with respect to the type and value of any particular interest.

Policy in action. An HMS speaker must include a disclosure slide at the beginning of her accredited presentation on breast cancer stating that (i) she receives royalties in an amount of approximately $50,000–$60,000/year on a genetic test for BRCA-X; (ii)she receives consulting income of $10,000–$20,0000 from Pharma X, which is active in this field; and (iii) other financial disclosures not relevant to her presentation can be found on the HMS public disclosure website at the URL presented in the slide.

A minority of this Committee recommends as follows:

Minority Recommendation 1: HMS/HSDM CME Speaker Disclosures

Any speaker at an HMS/HSDM CME event shall disclose all financial interests relevant to the content of his/her presentation at the beginning of a presentation. Such disclosure shall highlight the financial interests that are the most significant either in value or in relevance. The HMS public disclosure website (See Recommendation 32) shall be provided and referenced within any presentation, with audience members explicitly directed to such website for additional information with respect to the type and value of any particular interest.

Finally, this Committee considered and endorsed the Education Subcommittee's recommendations for non-accredited and non-HMS educational events. The following recommendations were approved:

Recommendation 11: Compliance with ACCME Standards for Speakers

Faculty members should, at a minimum, abide by the ACCME Standards for Commercial Support when participating in non-accredited educational events.

Recommendation 12: Standards for Non-HMS Events

The policy should strongly encourage a faculty member with a curriculum leadership role in a CME program, including a program accredited through another institution or society and/or occurring at another location, to conduct the program in compliance with HMS/HSDM rules for CME to the greatest extent possible. This includes, but is not limited to, the recommended restrictions over industry funding, the required public disclosures and the required separation (in time and space) of commercial industry exhibits.

Policy in action. Under certain circumstances, the HMS rules may be inconsistent with the rules of an institution hosting and/or accrediting a CME program for which an HMS faculty member has a curriculum leadership role. In such situations, it may be appropriate for the HMS faculty member to abide by the host institution's rules and not comply with the HMS recommendations for non-HMS accredited events (which are requirements for HMS events).

IV. RESEARCH SUBCOMMITTEE

The Research Subcommittee was asked to examine the current policy with a focus on issues relating to basic and clinical research. In many ways, the task of the Research Subcommittee was the most complicated because the existing policy is principally designed to address conflicts arising in the context of research. This Subcommittee, therefore, had to consider the effectiveness of the existing provisions and its history of implementation challenges. The Research Subcommittee was comprised of Patricia Donahoe, MD; Michael Gimbrone, MD; David E. Golan, MD; Elizabeth Hohmann, MD; Isaac Kohlberg; Ellice Lieberman, DrPH, MD; Joseph Loscalzo, MD, PhD; Lee Nadler, MD; Barbara McNeil, MD, PhD; Barrett Rollins, MD, PhD; Peter Sorger, PhD; Patrick Taylor, JD and Christopher Walsh, PhD. Drs. Loscalzo and Walsh served as chairs.

SUMMARY OF RECOMMENDATIONS

- Retain rule-based approach and generally prohibit exceptions.
    - Allow limited exception by petition for prohibitions arising solely by reason of spouse's career pursuits.
    - Allow for limited exception to I(b) rules for grants and subgrants under a Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) award.
- Clarify that improper use of the supervisory role for personal financial gain is misconduct and subject to sanction. Provide resources to faculty and trainees who feel inappropriately influenced by a supervisor.
- Clinical Research (Category I(a) rule)
    - Reduce income de minimis to $10,000/yr and require that the local Institutional Review Board/COI committee review any income less than de minimis.
    - Narrow definition of clinical research to exclude certain defined categories of research posing a lower risk to human participants.
    - Mandate faculty members be free of impermissible financial interest (other than equity) for at least six months prior to commencing relevant clinical research.
    - Clearly define duration of one's "participation" in clinical research as the later of (i) twelve months following the last day a human participant completes trial or (ii) the first publication of data derived

from study or a decision being made not to publish. All investigators are subject to the I(a) restrictions for this entire time period.

- Clarify what is clinical research "on a technology" vs. research that uses a technology for purposes of the I(a) restriction.

- For Phase IV Clinical Research, include any post-market royalties earned from Technology under study through institutional royalty sharing agreements in calculating income earned for purpose of de minimis.

- Basic Research (Category I(b) rule)

  - Allow for limited exception to I(b) for grants and subgrants under an SBIR or STTR award.

  - Require prior review and approval of income from Business sponsoring one's research.

- Modify definition of "Sponsored Research" to include any research requiring resources (money, personnel, intellectual property, proprietary materials or equipment) from a Business, but excluding certain categories of Material Transfer Agreements (MTAs).

B. GENERAL APPROACH

Guiding Principle: Preserving the Integrity of Research

To protect and preserve the integrity of scientific discovery, faculty members engaged in the design, conduct, and reporting of research must be free of individual conflicts of interest in conducting, analyzing and reporting on the results of their research.

The Research Subcommittee, asked to take a fresh look at the COI Policy, began by examining the policy's underlying framework, which promulgates prohibitive rules for specific activities under Category I rather than presumptions that may be overcome by exceptional explanations and circumstances in individual cases.[16] Following discussion, the Subcommittee recommended, and this Committee agrees, that retaining the rule-based approach is advisable. Moving to an "exception

[16] In its February 2008 report entitled, "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research," the Association of American Medical Colleges and the Association of American Universities recommend a "rebuttable presumption" approach to conflicts management. Under this approach, the institution presumes that an investigator may not perform clinical research in the presence of a competing financial interest. However, the presumption may be overcome in "exceptional circumstances."

required" model would, in our opinion, weaken the COI Policy. It would allow for potentially disparate treatment among our large faculty and would be inconsistent with our belief that no one faculty member is so exceptional as to justify relaxing certain principled rules to allow for the potential pursuit of individual financial gain.

Finally, this Committee was asked to consider whether the strictness of the rules creates obstacles to faculty members' pursuit of potentially innovative technologies. Specifically, for certain technologies, can we be confident that a scientist, other than the individual who has developed a particular technology and/or has a financial interest in its success, will be interested in pursuing necessary, and at times arduous, research absent the potential for personal financial gain? The hypothesis is that if a faculty member is prohibited from retaining personal financial interests related to the research, the policy restriction may block the development of tools that will alleviate human suffering and cure disease.

This Committee notes that there are little data to support such hypothesis. We further note that, while our faculty members make extraordinary contributions to research across the world, it is highly unlikely that the decision of any one individual to retain a personal financial interest rather than pursue research would result in research not being conducted. In fact, if a technology is truly valued by an individual's colleagues and by the scientific community as a whole, there will be interest beyond the relevant individual in conducting further research on the technology. Moreover, the technology must be capable of being utilized by more than one scientist in order to be successful. In the limited circumstances where our COI Policy might prohibit a faculty member from holding a potential financial interest in the technology he or she is interested in continuing to develop, he or she may continue to do so by foregoing his/her interests or by pursuing development outside the auspices of a faculty appointment at HMS.

We therefore recommend as follows:

Recommendation 13: Rule-based Approach

To retain the rule-based model instead of adopting an exception required ("exception required") approach to conflicts of interest.

This Committee expects that the application of the prohibitions of the COI Policy will be sensible and reasonably designed to address the true potential harm of particular financial interests. The full Committee identified one circumstance that may, in limited situations, require flexibility to prevent the unintended consequences of an unreasonably stringent rule-based approach. This arises in the context of dual career families, which have increased dramatically since the COI Policy was first adopted in 1990. Consistent with all similar legal and policy frameworks, the COI Policy applies to the same extent to the financial interests of one's immediate family (in the same household) as it does to the financial interests of the individual faculty

member. Financial interests of one's immediate family clearly also benefit the individual and must be disclosed and assessed to understand whether they give rise to potential conflicts. In addition, however, the financial interests of a faculty member's spouse and other family members have also triggered the prohibitions of Category I of the COI Policy in the same manner as if the faculty member directly held the financial interest. As the number of dual career families increases, it has become increasingly difficult for individual spouses/partners to arrange outside activities in a manner that does not hinder the academic career pursuits of the spouse/partner. At HMS, we wish to support and encourage the dual career family by recognizing the unique potential impact of the prohibitions of the COI Policy, especially where the nexus between the impact upon one family member's academic research and the other family member's financial interest is so remote as to be negligible. Accordingly, we recommend allowing for very limited exceptions, by formal petition to and review by the Standing Committee, as follows:

Recommendation 14: Dual Career Families

Faculty Members shall continue to disclose all financial interests, including the financial interests of family members (as defined by the policy). However, the Standing Committee on Conflicts of Interest and Commitment shall have the authority to grant limited exceptions to the Category I(a) and I(b) rules if:

(1) A faculty member is subject to the rule(s) solely by reason of the activities and/or Financial Interests of his/her spouse or domestic partner;

(2) The Standing Committee determines, in its discretion, that strict application of the rule under the circumstances presented unduly inhibits scientific progress; and

(3) The potential conflict arising by reason of the spouse/domestic partner's financial interest can be managed through a formal management plan.

Such exceptions should be subject to case-by-case assessment by the Standing Committee following a formal petition by the individual faculty member. Following an initial trial period not to exceed two years, the Standing Committee may review and recommend to the Dean of the Faculty of Medicine specific changes and/or clarifications to this limited exception.

Policy in action. A faculty member has a spouse who is employed as a senior scientist with Pharma X. His spouse conducts basic research on potential targets for preventing and treating type 2 diabetes. The faculty member is a clinician and conducts clinical research on Alzheimer's disease. He would like to study a particular inhibitor developed by Pharma X that targets a genetic promoter believed to increase the disease's progression. The division of Pharma X that developed the inhibitor is not connected to the division for which the faculty member's spouse works. The faculty member may petition the Standing Committee for an exception to

Category I(a), which would otherwise prohibit the faculty member from conducting the clinical study by reason of his spouse's salaried employment.

The Research Subcommittee also recognized and addressed the concern raised in every university and academic health center that the most troublesome conflicts may arise not by reason of an individual's financial interests, but rather by those of the influence of his/her supervisor or mentor. Consistent with the Education Subcommittee's recommendation that the institution provide additional resources to students and trainees who feel their educational integrity is compromised by an instructor's competing interests (See Recommendation 2), the Research Subcommittee recommended additional resources for researchers who feel the integrity of their studies is being compromised by a supervisor's competing interests. The Subcommittee also recommended, and we agree, that, as an institution, we must make clear that any improper use of one's supervisory role for personal gain is misconduct and subject to sanction. Consistent with this principle, we submit the following additional recommendations:

Recommendation 15: Supervisor Responsibility

The Faculty of Medicine should explicitly affirm its expectation that each faculty member maintain the highest level of ethical integrity in carrying out his/her responsibilities to HMS. Regardless of one's home institution, a Faculty Member shall not behave in a manner that exploits the influence he/she may at any time have over another HMS faculty member by reason of his/her appointment with/obligations to HMS for personal advantage, including a personal financial interest. The Standing Committee on Conflicts of Interest shall be delegated with authority to review any claims of inappropriate conduct by faculty members in influencing subordinates and/or colleagues for personal gain. Such identified ethical breaches shall be deemed misconduct and subject to sanction.

Recommendation 16: Expanded Role of Ombudsperson

The HMS Ombudsperson shall have expanded authority to review confidentially and advise individuals on claims of ethical misconduct by faculty members who utilize institutional influence for personal advantage. The HMS Ombudsperson shall attempt to resolve claims informally when appropriate. However, if unable or if it is inappropriate to resolve a claim informally, the Ombudsperson shall encourage individuals to take the claim to the Standing Committee on Conflicts of Interest for institutional faculty misconduct review.

Policy in action. A junior faculty member is eligible for promotion at HMS. Accordingly, she is feeling intense pressure to impress her department chair. Her chair is a founder and major shareholder in Biotech Startup X, which wants to initiate a public offering in the coming year. Junior faculty member has just accepted research support from Biotech Startup X to conduct a proof of concept study in

humans examining the company's drug Y, which, to date, has been studied only in mice. Junior faculty member has been told by her supervisor that she was selected by Biotech Startup X at supervisor's suggestion because supervisor was aware that the additional funding to faculty member would help faculty member's laboratory during this "critical evaluation period." In her weekly meetings with supervisor, supervisor consistently asks faculty member about the status of the study and its preliminary results. More than once, her supervisor has mentioned what a successful study would mean to supervisor's company. The supervisor is engaged in misconduct and should be reported to Standing Committee for review and possible sanction.

C. CLINICAL RESEARCH (CATEGORY I(A) RULE)

Guiding Principle: Financial Interests of Clinical Investigators Demand Scrutiny

Financial interests of investigators engaged in clinical research demand heightened scrutiny to ensure the integrity of the science and the protection of:

(1) Human participants in research studies;

(2) Subsequent patients, because biased data may be incorporated into an FDA application for approval of drug/device;

(3) The research community, because biased data may be published; and

(4) The reputation of the individual, his/her laboratory, the department and the institution, because of the perception of biased data.

Certain categories of clinical research pose a lower risk to human participants and subsequent patients and therefore require less scrutiny. Nonetheless, the institution must remain committed to eliminating potential bias in research, and it must do so by appropriately balancing the benefits of increased academic–industry collaboration in efficiently advancing scientific discovery with the identifiable risks of potential conflicts.

The existing rule for clinical research set forth under Category I(a) prohibits:

> A Faculty Member Participating in Clinical Research on a Technology owned by or contractually obligated to a Business in which the Faculty Member, a member of his/her Family, or an Associated Entity has a consulting relationship, holds a stock or similar ownership interest, or has any other Financial Interest, other than receipt of University- or Hospital-supervised Sponsored Research support or post-market royalties under institutional royalty-sharing policies.

The rule includes a *de minimis* exception, whereby a faculty member may continue to hold equity if in a publicly held, widely traded Business with a value of $30,000 or less[17] and may continue to earn income from a Business if the amount of money received does not exceed $20,000 per year.

[17] There must be no relationship between the acquisition of the stock or similar ownership interest and the research to be conducted.

The Research Subcommittee began by evaluating whether the *de minimis* limits were appropriate. Some Subcommittee members felt that a faculty member should never be engaged in clinical research on a technology of a company if the individual receives income or holds equity from that company. The trust placed in researchers by human participants is simply too sacrosanct to potentially undermine with a competing personal interest. Nonetheless, the Subcommittee acknowledged that, at a certain level, income or equity may represent nominal payments in connection with evaluating the feasibility of, and preparing for, the research effort. In addition, because companies are increasingly utilizing third-party entities to organize events, a researcher could receive payment for engagements while having no prior knowledge of company sponsorship. Therefore, the Research Subcommittee recommended, and we agree, that some *de minimis* remains appropriate. We do recognize, however, that any *de minimis* value inevitably appears arbitrary and that potential conflicts may still persist at levels below the *de minimis*. We therefore accept the Research Subcommittee's compromise and recommend as follows:

Recommendation 17: Reduce I(a) De Minimis *Limits*

The following changes shall be incorporated into the Category I(a) analysis:

- Category I(a) shall prohibit any member of the Faculty of Medicine from earning outside income in an amount greater than or equal to $10,000 from a Business while simultaneously Participating in Clinical Research on a Technology owned or contractually obligated to such Business.

- Category I(a) shall require a member of the Faculty of Medicine who earns outside income in an amount less than $10,000 from a Business while simultaneously Participating in Clinical Research on a Technology owned or contractually obligated to such Business to have the Participation reviewed and approved by the HMS or affiliated institution's conflicts of interest committee and/or the Institutional Review Board, and be subject to such restrictions as are imposed for the protection of human subjects and the maintenance of scientific integrity.

Policy in action. A faculty member receives $9,575 from Dental Device Company X for consulting on behalf of the company as to the optimal specifications for a new dental implant. Dental Device Company X now wants the faculty member to test the dental implant in patients. The faculty member may perform the proposed research if (i) he discloses potentially competing interests to institutional IRB/COI committee for assessment, and receives approval, with or without additional requirements to manage the potential conflict, to conduct research; and (ii) he discloses in any

publication or presentation of data his financial interests from Dental Device Company X.

The plain wording of Category I(a) carves out post-market royalties (e.g., royalties received from sales following FDA approval of a drug or device) received through institutional royalty sharing policies from application under the Category I(a) *de minimis*. The full Committee considered this exclusion at its final meeting. Specifically, we contemplated the divergent views expressed on this topic by members of the Research Subcommittee, which submitted the issue for full Committee debate. The Bayh-Dole Act requires that institutions that commercialize inventions discovered through federally sponsored research share royalties with inventors to reward innovation and further incentivize discovery. If we eliminate the exclusion, some members of the Subcommittee felt that we would undermine this goal and punish faculty members for achieving the same research success that the institution must encourage in order to accomplish its mission of alleviating human suffering. On the other hand, it is difficult to argue that the results of Phase IV studies will not affect the public marketplace for a particular drug/device or that a researcher who receives royalties on such drug/device would not be inherently conflicted. Accordingly, in an effort to address the particular concern raised, while not undercutting the spirit of the original carve-out, the full Committee recommends as follows:

Recommendation 18: Revision to Post-market Institutional Royalty Exclusion

Category I(a) shall be revised as follows: For any Phase IV Clinical Research study, post-market royalties received by a Faculty Member as a result of the Technology subject to the proposed study shall be included in the definition of relevant Financial Interests. All other post-market royalties received by a Faculty Member, however, shall continue to be excluded from the definition of relevant Financial Interests. Following an initial trial period, the Standing Committee shall review faculty financial reporting data and the application of this exclusion to determine whether additional restrictions are advisable. Following its review, the Standing Committee shall have discretion to submit additional recommendations to the Dean on this topic.

Policy in action. Affiliated Hospital owns a patent on a biodegradable surgical implant invented by an HMS professor. The implant is currently approved by FDA for use in adults ages 18–65. Affiliated Hospital has exclusively licensed the patent to Medical Device Company X and receives post-market royalties on the sales of this device. The HMS professor receives a share of these royalties through Affiliated Hospital's royalty sharing policy; she receives approximately $40,000/yr. Medical Device Company X is conducting a Phase IV study on the implant and would like the HMS professor to participate in the studies on the device. The proposed studies

would be covered by Affiliated Hospital's patent. However, HMS professor may not participate in the proposed study unless she forgoes receipt of her share of the royalties on the device.

The Research Subcommittee also recommended changes to the equity *de minimis* exception, applicable to both the current Category I(a) and I(b) rules. We agree with the Subcommittee's conclusions that, while a *de minimis* remains appropriate for publicly traded equity, additional guidance would be helpful to faculty regarding how one may manage such equity so as to prevent inadvertent rule violations in light of the constantly changing stock market. Accordingly, we recommend the following:

Recommendation 19: Reduce and Clarify Equity De Minimis

The *de minimis* equity limits for the purpose of applying the Category I(a) and Category I(b) rules should be modified as follows:

- Eliminate "widely traded" modifier for purpose of public equity *de minimis*.
- A faculty member who holds public equity valued at less than $30,000 in a relevant Business may choose to execute a broker sell order directing the broker to sell relevant equity if, at any time, the value of such equity exceeds $30,000.

Consistent with the guiding principle that certain types of clinical research carry a lower risk to participants and, therefore, should be excluded from Category I(a)'s heightened scrutiny, the Research Subcommittee proposed a revised definition for clinical research. This definition carves out of the Category I(a) prohibitions specific categories of lower-risk research. We agree that such exclusion is appropriate and, therefore, submit the following recommendation:

Recommendation 20: Narrow Definition of Clinical Research

(1) Category I(a) shall be revised as follows (additions are underlined) to prohibit:

A Faculty Member Participating in Clinical Research (other than Nominal Risk Clinical Research) on a Technology owned by or contractually obligated to a Business in which the Faculty Member, a member of his/her Family or an Associated Entity has a consulting relationship, holds a stock or similar ownership interest or has any other Financial Interest, other than receipt of University- or Hospital-supervised Sponsored Research support.

A new section to Category I(a) shall be added as follows:

A Faculty Member may not Participate in Nominal Risk Clinical Research on a Technology owned by or contractually obligated to a Business in which the Faculty Member, a member of his/her Family, or an Associated Entity has a consulting relationship, holds a stock or similar ownership interest or has any other Financial Interest unless such Participation is reviewed and approved by the institution's conflicts of interest committee and/or the institution's Institutional Review Board, and subject to such restrictions as are imposed for the protection of human subjects and the maintenance of scientific integrity.

(2) The definition of "Clinical Research" shall be revised as follows:

"Clinical Research" is defined as any research or procedure involving human subjects in vivo or the use of human samples for the development and evaluation of patient therapies, such as diagnostic tests, drug therapies or medical devices. It includes early clinical studies, evaluative research, epidemiological studies and clinical trials. It excludes research using commercially obtained, de-identified human cell lines, as well as commercially obtained, de-identified human tissue. It also excludes research that uses human tissue obtained from institutional tissue banks where the individual identifiers are unknown to the researcher. In general, the term includes all research required to be reviewed and approved by an institution's Institutional Review Board.

(3) The following new definition shall be added to the policy:

"Nominal Risk Clinical Research" is defined as any Clinical Research that

(a) Meets the federal definition of minimal risk (45 CFR 46; http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)

(b) Fits into one or more of the following categories:

(i) Use of bodily fluids, secretions or other biospecimens, excluding blood and discarded tissues that are obtained through non-invasive, routine and established operating procedures; from a healthy, non-pregnant individual who is not a member of a vulnerable population as defined by 45 CFR Part 46; and any such materials retained in a way that ensures that the samples cannot be linked to any individual identified patient;

(ii) Use of excess blood or discarded tissue, where the tissue is otherwise obtained for clinical care purposes through routine and established operating procedures by an individual who is not (1) Participating in the Nominal Risk Clinical Research; (2) under the direction or control of any individual Participating in the Nominal Risk Clinical Research; and (3) supervising any individual Participating in the Nominal Risk Clinical Research;

(iii) Medical records review, including collection of coded identifiable data, provided, however, that the protocol ensures that, after collection of the data, the faculty member cannot link it to an identifiable subject;

(iv) Non-sensitive survey research on individuals or group characteristics or behavior, provided that if the subjects are considered members of a vulnerable population as defined by 45 CFR Part 46, the institution's conflicts of interest committee and/or Institutional Review Board may, on a case by case basis, conclude that the research is not Minimal Risk Clinical Research; or

(v) Such other minimal risk research as may from time to time be designated by the Faculty of Medicine Standing Committee on Conflicts of Interest.

Policy in action. HMS professor proposes a study that tests Startup X's (a privately held company) new drug's effect in human liver tissue samples obtained from Affiliated Hospital's pathology department. HMS professor holds equity in Startup X. The liver samples he wishes to use are not linked to identifiable individuals and have been obtained in the course of routine diagnostic procedures. HMS professor, his supervisors and his trainees were not involved in collecting the tissue. The proposed research requires certain approval under the policies of the Affiliated Hospital's Institutional Review Board. However, HMS professor may participate in this research if approved by Affiliated Hospital's IRB because it is not Clinical Research under the revised definition and not subject to Category I(a).

To ensure that the spirit of the Category I(a) rule is not undermined by consulting relationships that remain active until the moment an individual commences participation in a clinical research protocol, the Research Subcommittee recommended, and we endorse, establishing a "washout period." This requires a faculty member to be free of impermissible financial interests for some period of time before commencing the relevant research. Accordingly, we recommend as follows:

Recommendation 21: Washout Period

Faculty members should be free of impermissible Financial Interests[18] for at least six months prior to commencing Participation in Clinical Research on a Technology owned or contractually obligated to the Business with which the faculty member

[18] A Financial Interest shall be deemed active: (i) in the case of consulting agreements or other service agreements, for the duration of the written contract and (ii) in the case of honoraria or other fees, until the date of the particular engagement.

has a Financial Interest.[19] A faculty member's disassociation from a Business for purpose of this rule is not intended to be transient. Any agreement to re-engage services following a faculty member's Participation in the Clinical Research at issue is inconsistent with the spirit of this rule.

Policy in action. A faculty member is a party to a consulting agreement with Pharma X that terminates on July 1, 2010. The faculty member receives $50,000 annually under this agreement. Faculty member wishes to participate in a clinical research project of her colleague that examines drug Y, which is exclusively licensed to Pharma X. The faculty member may not participate in the clinical research if it commences prior to January 1, 2011.

In connection with the previous recommendation, the Research Subcommittee also considered and submitted recommendations clarifying what it means "To Participate" in Clinical Research under the HMS Policy. The current policy defines "Participation" as:

> To be part of the described activity in any capacity, including but not limited to serving as the principal investigator, co-investigator, study designer, research collaborator, provider of direct patient care or author on a publication of the research study. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis), unless they are in a position to influence the study results or have privileged information as to the outcome.

However, faculty members have often found it difficult to determine (i) when one's participation ends; (ii) whether certain researchers may terminate their participation prior to others by virtue of actual roles on the project and (iii) in an atmosphere of increasing cross-disciplinary work, whether all researchers must be deemed to be "Participating" in all aspects of the study. This Committee reaffirms the critical importance of holding our faculty to a high standard in academic authorship and the expectation that each author listed on a publication of data stands behind its integrity. For theses reasons, we clarify the duration and coverage of "Participation" as follows:

Recommendation 22: Refine What It Means "To Participate"

[19] For the avoidance of confusion, equity and other ownership interests are not subject to this six-month washout and may be divested immediately preceding a faculty member's participation in Clinical Research.

All individuals "Participating" in a Clinical Research project shall be subject to the Category I(a) prohibition until the date that is the later of (i) twelve months following the last day that a human subject participant completes the clinical trial (e.g., data lock plus 12 months), or (ii) the first publication of data derived from the clinical study or a decision not to publish the data derived from the clinical study. For the avoidance of doubt, a "publication" includes an abstract, poster or public presentation given to others, or a paper published in a peer-reviewed journal.

Recommendation 23: Duration of Participation

An individual whose activities with respect to a particular research protocol meet the HMS definition of "Participation," as modified herein, shall be deemed to be Participating in the Clinical Research for the entire duration of the protocol (as set forth in Recommendation 22). A Faculty Member cannot assert that he/she "Participates" in only one aspect of the study (i.e., there are no zones of Participation). Similarly, a Faculty Member cannot assert that his/her "Participation" ends prior to that of another Faculty Member who Participates in the same research study (i.e., there is no premature termination of Participation).

Policy in action. An HMS clinical researcher and a basic researcher are engaged in a cross-disciplinary study that examines the clinical effects of Protein X in treating symptoms of multiple sclerosis. The basic researcher is responsible for isolating Protein X from a mammalian cell line in sufficient quantities for clinical investigation. The clinical investigator is responsible for testing the protein on adult MS patients. Protein X is patented by Pharma Y. The basic researcher wishes to execute a consulting agreement with Pharma Y for work unrelated to Protein X or the proposed study, under which the basic researcher will receive $30,000/yr. Basic researcher may not execute the consulting agreement until the later of (i) twelve months following the last day that a human subject participant completes the clinical trial or (ii) the first publication of data derived from the study or a decision not to publish the data derived from the clinical study.

Finally, the Subcommittee submitted recommendations clarifying what it means to conduct clinical research "on a Technology." As an initial matter, the Research Subcommittee considered the existing definition of "Technology," which includes "any compound, drug, device, diagnostic, medical or surgical procedure intended for use in human health or health care delivery," and deemed such definition appropriate in light of the policy's aims. We agree that expanding this definition is simply not necessary in addressing potential issues of concern.

Next, the Subcommittee recommended clarifying when a particular protocol is "on a Business's Technology" rather than one that incidentally uses the particular Business's Technology (thereby not requiring Category I(a) scrutiny). We agree that a clarification is helpful and submit the following recommendation:

Recommendation 24: Definition of Research on a Technology

For purposes of Category I(a), a faculty member will not be deemed to be Participating in Clinical Research on a Technology (as opposed to *with* a Technology) provided that:

(1) Research will not assess the safety or effectiveness of the Technology in question, either directly or indirectly, as a control or comparison arm to the study of another Technology;

(2) The use of the Technology in the research study will not materially affect the outcome of the study by leading to the conclusion that a treatment paradigm derived from such study depends upon the use of the particular Technology in the study protocol;

(3) The Technology has been approved by the FDA; and

(4) No alternative Technology is available for use in the particular study protocol.

Policy in action. A clinical research protocol proposes using a new mass spectrometer developed by Company X in analyzing patient samples obtained during a clinical trial to examine the levels of biomarkers for a particular disease. Company X's spectrometer is new and increases the rate of analysis 10x. However, other spectrometers could be utilized to evaluate the samples in the study, albeit at a reduced rate. This is not clinical research on Company X's Technology. However, if the clinical research instead evaluated the emotional impact on patients of more rapid diagnosis of disease state and compared the speed by which Company X's spectrometer allows for definitive diagnosis versus Company Y's spectrometer, the protocol would be clinical research on Company X's technology for purpose of applying I(a).

D. BASIC RESEARCH (CATEGORY I(B) RULE)

Guiding Principle: Commitment to Elimination of Potential Bias

The institution must remain committed to eliminating potential bias in research data, and it must do so by appropriately balancing the risks of bias with the benefits of increased academic-industry collaboration in efficiently advancing scientific discovery.

The existing rule for basic (and clinical) research set forth under Category I(b) prohibits:

> A Faculty Member receiving University- or Hospital-supervised Sponsored Research support (whether in dollars or in kind) for Clinical Research or research which does not involve human subjects, from a Business in which he/she, a member of his/her Family or an Associated Entity holds a stock or similar ownership interest. Sponsored Research (and the prohibition of equity ownership) is considered to have ended when the term of the Sponsored Research agreement has ended and publications reporting on the research are completed (or the decision is made not to publish). It is the Faculty Member's responsibility to determine when that time has been reached.

As noted, the *de minimis* exception for equity, as revised herein, also applies under this rule (e.g., a faculty member may continue to hold publicly traded equity in a Business if value of equity at any given time does not exceed $30,000).

The Research Subcommittee first contemplated whether the scope of the rule is appropriate. In other words, should HMS automatically prohibit a faculty member from receiving sponsored research support from a Business in which he/she holds equity, or can such risks be managed?

As to this question, neither the Subcommittee nor this Committee is uniform in its views. All of our members agree that industry is essential to advancing medical science and transferring discoveries from the bench to patients and otherwise bringing useful products to the public. We all agree that certain personal financial relationships between a faculty member and industry pose a risk of harm to the integrity of the faculty member's collaborative research by undermining either the actual integrity of such research or the public's and/or scientific community's trust in the integrity of such research. However, a majority of us believe that when a faculty member holds equity or other ownership interest in a company that sponsors research he conducts, the risk of actual bias in and/or diminished trust in the data derived from such research is unacceptably high. Consequently, limits on those relationships are necessary. Accordingly, a majority recommend as follows:

Recommendation 25: Retain Absolute Prohibition of Category I(b)

Category I(b) shall remain an absolute prohibition on a faculty member receiving University- or Hospital-supervised Sponsored Research support for <u>any</u> research

from a Business in which he/she, a member of his/her Family, or an Associated Entity holds a stock or similar ownership interest.

In the minority's view, this rule is too stringent in view of the comparatively attenuated risks. Whether the activities that give rise to such potential conflicts of interest should be subject to absolute prohibition, or, rather, permitted in certain instances and then carefully managed, should depend on whether the proposed research is clinical or basic in nature. Specifically, if a faculty member holds equity or other ownership interest in a company that sponsors clinical research in which he or she participates, the prohibition should be absolute in view of the additional risk to human participants. For basic research that does not include human subjects, the risks should be managed by HMS as follows:

Minority Recommendation 2: Apply "Exception Required" Approach to Basic Research under Category I(b)

Requests to perform basic research under the sponsorship of a company in which a faculty member holds equity should be open to review on a case-by-case basis and allowance in rare instances, subject to appropriate institutional oversight and management. Although such an arrangement might require the exclusion of students and trainees from the sponsored research program, the research would, nonetheless, remain within the scope of the University's and Medical School's respective missions as regards the creation and dissemination of new knowledge, delivery of benefit to the public, and, where applicable, the alleviation of human suffering.

The majority recommendation notwithstanding, a majority of the Subcommittee and this Committee are willing to submit that certain limited categories of commercial sponsorship may have characteristics that distinguish them from traditional industrial sponsorship in a manner that lowers corresponding risks. Specifically, subcontracts to Harvard (or its affiliated institutions) from Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) government grants could be excluded from application under the Category I(b) rule. A majority of this Committee believes that SBIR and STTR subgrants are different because they are subject to stringent governmental review through an impartial peer review process. In addition, the institution's competing interest in encouraging small business collaboration is sufficiently high to outweigh the reduced risk. Accordingly, the majority recommends testing the SBIR/STTR exemption in the following manner:

Recommendation 26: Exemption for SBIR/STTR Grants and Subgrants

A faculty member shall be allowed to participate in research funded through an SBIR and STTR grant/subgrant from an applicant business in which the faculty member holds equity. This exemption shall be subject to periodic review by the Standing Committee on Conflicts of Interest to determine whether additional management and/or recommendations are necessary in view of additional HMS experience with the exclusion.

Policy in action. A faculty member may not accept visiting scientists from private Startup X to train a faculty member and his postdoctoral fellow on Startup X's proprietary method for isolating an unstable glycopeptide because the faculty member holds 3 percent of the outstanding equity in Startup X. However, the faculty member may receive funds from Startup X in any amount if the funds are awarded through a subgrant of an SBIR grant awarded to Startup X.

A minority of the Subcommittee, and of this Committee, believes that SBIR/STTR subgrants are not sufficiently unique as to warrant disparate treatment under the Category I(b) rules. These individuals believe that the same principles that hold for the Category I(b) prohibition apply to government subgrants, i.e., ownership of equity in a business sponsoring one's research creates an impermissible risk of research bias/perception of bias.

Minority Recommendation 3: No Exemption for SBIR/STTR Grants

SBIR/STTR grants and subgrants from an applicant business in which a faculty member holds equity should not be exempt from Category I(b) prohibitions.

Having concluded that exceptions to the Category I(b) rule must be limited, the Research Subcommittee then took a step back and considered broadly whether the rule is sufficiently stringent in its application. If risks arise by reason of an investigator receiving sponsored research support from a Business in which he/she holds equity, do similar risks arise if the investigator earns income from the Business in excess of some threshold level? A majority of the Subcommittee believed they do, as does a majority of this Committee. The Research Subcommittee concluded, however, that absolute prohibitions are not appropriate in this context and that case-by-case review may be necessary. In the Subcommittee's view, the risks arising in such scenarios for basic research do not require the same stringency of absolute prohibition as required for clinical research. Income earned from a company sponsoring one's basic research certainly requires review to identify potential conflicts that may demand a prohibition. Yet the Subcommittee recognized that, in an atmosphere of increasing consolidation among biomedical companies, it was plausible to envision income in excess of the established *de minimis* being earned from one division of a company completely unrelated to the division sponsoring one's research. Without the additional sensitivity of protecting human participants and safeguarding their trust, the Subcommittee concluded that the fundamental importance of industry collaboration to the success of basic research

made an absolute prohibition in this case overreaching and not warranted by potential risks. In addition, public disclosure of such income as mandated by Recommendation 32 addressed the transparency issues of concern. A majority of this Committee agrees.

Recommendation 27: Review of Income from Sponsor under Category I(b)

Category I(b) shall require prior review and approval by HMS or an affiliated institution of any outside income received from a Business that provides University- or Hospital-supervised Sponsored Research support (whether in dollars or in kind) for any research in which the faculty member Participates. Following an initial trial period, the Standing Committee shall review data regarding the extent and frequency of outside income being paid to faculty from Businesses that provide the faculty Sponsored Research support, including the sufficiency of public disclosure in addressing potential risks. The Standing Committee shall have the authority to make recommendations to the Dean regarding additional potential restrictions following its review of data.

Policy in action. Company X wishes to provide a grant to a faculty member to conduct a study exploring the effects on phenotype of knocking out specific genes in mice thought to increase tumor growth. Three months earlier, the faculty member consulted for a separate division of Company X on an unrelated project that was abandoned as a result of their intensive, but fruitful, collaboration. Faculty member earned $33,000 cumulatively from this work. Faculty member must disclose his prior income from Company X to HMS for review and approval prior to accepting the proposed grant from Company X. If approved, faculty member may immediately participate in the proposed study.

A minority of this Committee disagreed with the Research Subcommittee's majority recommendation. In the minority's view, the Category I(b) rule should be expanded to include income earned from the sponsoring Business in excess of an appropriate *de minimis* and that exceptions are neither necessary nor desirable. The minority notes that this Committee has affirmed the policy's rule-based approach in other contexts. For the minority, the clarity and equity provided under a rule-based approach applies equally in the case of basic research as it does for clinical research. A minority of this Committee see no reason to alter this approach for the proposed expansion of Category I(b) and, therefore, make the following recommendation.

Minority Recommendation 4: Expansion of Category I(b)

Category I(b) should be expanded to prohibit the receipt of University- or Hospital-supervised Sponsored Research support for any research, from a Business in which he/she, a member of his/her Family, or an Associated Entity has a consulting

relationship, holds a stock or similar ownership interest, or has any other Financial Interest with a cumulative value exceeding $30,000 per year. The duration of the Sponsored Research for purpose of this rule shall be the term set forth in the relevant University- or Hospital-supervised research agreement.

The entire Committee agreed, however, that if the Dean chooses to accept Minority Recommendation 4 and the Category I(b) rule is expanded, a wash-out period identical to that proposed for the application of Category I(a) should similarly apply to the new Category I(b) limitation.

Minority Recommendation 4-A: Washout Period for Category I(b)

Faculty members must be free of impermissible Financial Interests for at least six months prior to executing an agreement with the relevant Business for University- or Hospital-supervised Sponsored Research support (whether in dollars or in kind) for all research in which the faculty member will Participate.

Finally, both this Committee and the Subcommittee struggled with clearly defining "Sponsored Research" so as not to inadvertently incorporate materials obtained through routine materials transfer agreements, but to appropriately include research supported with significant resources from a Business, including proprietary information, proprietary materials, personnel, equipment and funds. The precise definition was not resolved by the Committee, but a subgroup of the Committee is currently working together to draft a definition that achieves the goals set forth in the following recommendation:

Recommendation 28: Definition of Sponsored Research

The definition of Sponsored Research shall be revised to clarify that Sponsored Research includes any research, training or instructional project involving resources (funds, proprietary compounds, equipment, personnel, etc.) from a third party under an agreement between the third party and the university or an affiliated institution, under which the third party is granted defined rights to data and/or information derived from the study. A detailed definition shall be drafted by subject experts. However, HMS should provide simplified guidance and instruction to faculty members on applying the drafted definition.

Policy in action. Faculty Member holds equity in Pharma X valued at approximately $50,000. Pharma X has offered to supply faculty member with access to Pharma X's high throughput screening capabilities to identify compounds with particular structural characteristics that the faculty member believes are likely to provide attractive disease targets. Pharma X will provide such capabilities in exchange for a right of first negotiation in licensing any discoveries generated from faculty member's discoveries. Faculty member may not utilize the capabilities of Pharma X

unless she divests a portion of her equity so that her total holdings are valued at less than $30,000.

V. IMPLEMENTATION AND COMPLIANCE SUBCOMMITTEE

The Implementation and Compliance Subcommittee was asked to examine the current procedures followed by Harvard Medical School to implement and enforce the COI Policy. This Subcommittee was asked to identify areas of ambiguity within the policy and to make recommendations that simplify and strengthen the process of faculty reporting and disclosure, as well as institutional enforcement. This Subcommittee was comprised of Gary Fleisher, MD; Elizabeth Hohmann, MD; Ellice Lieberman, DrPH, MD; Robert J. Mayer, MD; Joan Miller, MD; Paul S. Russell, MD; Nancy Tarbell, MD and Mark Zeidel, MD. Dr. Mayer served as chair.

A. SUMMARY OF RECOMMENDATIONS

- Clarify requirement that faculty annually report all outside professional income.
- Consolidate annual reporting requirements between HMS and its affiliates.
- Increase policy educational outreach. Incorporate mandated electronic training into annual reporting process.
- Require disclosure of relevant faculty financial interests on public website.
- Mandate review and sign off of annual financial reporting forms by local supervisors/department chairs.
- Initiate random institutional monitoring program to test faculty compliance.
- Reconstitute Standing Committee on Conflicts of Interest and delegate it with the authority to advise, interpret and review alleged violations.
- Prohibit part-time faculty member with executive positions from engaging in clinical research on his/her company's technology or receiving sponsored research support from his/her company.
- Clarify that faculty may serve on the fiduciary board of non-profit and simultaneously participate in clinical research on a technology of non-profit/ receive sponsored research support from non-profit.

B. SIMPLIFICATION AND CLARIFICATION OF POLICY AND REPORTING OBLIGATIONS

Guiding Principle: The Policy Should Be Clear and Unambiguous

The parameters of the policy must be clearly understood by each individual to whom the policy applies. The policy should not contain ambiguities regarding which activities are allowable and which are not. Unnecessarily complicated or elaborate procedures must be simplified and/or eliminated to maximize compliance.

Recognizing that the policy is effective only if it is widely understood, respected and followed by faculty members, the Implementation Subcommittee endeavored to identify ways to clarify and simplify the policy's compliance requirements. Academic success inevitably translates into competing demands on faculty time from numerous sources. While we demand that our faculty act with integrity, in part, through compliance with numerous regulatory and policy requirements, both the Implementation Subcommittee and this Committee acknowledge that it is the institution's responsibility to reduce administrative burden when possible. Accordingly, this Committee resolved early in its deliberations to make efforts in this direction by recommending as follows:

Recommendation 29: Consolidated Reporting

Develop a consolidated reporting mechanism among all affiliated institutions so faculty members are required to complete only one annual financial reporting form. From a single entry point, a faculty member may enter relevant financial/activity information, which will be fed, as necessary, to HMS and the faculty member's affiliated institution(s). Other financial reporting required on a transactional basis, including through each institution's sponsored programs office, technology transfer office and institutional review board, may be phased into this central system. Following this phase-in, a faculty member should be able to pre-populate his/her transactional reporting form with information previously disclosed to any institution in the course of the annual reporting process.

Policy in action. A faculty member holds a faculty appointment with HMS and a dual clinical appointment with MGH and BIDMC. Once developed, the consolidated reporting system will allow this faculty member to log in from his desktop and enter information at one time that responds to all of HMS's, Partners', and BIDMC's reporting requirements. As new financial interests arise, the faculty member may log in and update all institutions' information with a single entry.

In the spirit of the previous recommendation, the Implementation Subcommittee noted that misunderstanding regarding HMS's reporting requirements is simply not acceptable, and HMS must increase its educational outreach to assist faculty in understanding and meeting their obligations. This Committee agrees. In addition, because the HMS reporting cycle spans a time period of approximately two to three years (the time it takes to track down all faculty members, obtain reports and resolve any conflicts identified), it has become increasingly difficult for faculty members to gather all relevant information required for accurate reporting. The system must be revised so that faculty members submit reports on an annual basis,

coinciding with tax filings for ease of compliance. Accordingly, this Committee affirms the following recommendations of the Implementation Subcommittee:

Recommendation 30: Reporting/Disclosure

All outside professional income relevant to an individual's role as an HMS faculty member[20] must continue to be periodically reported to HMS. The institution must move to an annual process for faculty financial reporting. Such reports should cover outside activities and income earned by a faculty member during the previous calendar year (January through December). For consistency, application of the Category I(a) and Category I(b) rules must also be based on calendar-year income and not a rolling twelve-month period.

Policy in action. In early January, HMS sends an email to all members of the faculty asking them to submit their annual financial reports through the new consolidated system before April 15. Faculty member has received the following five W-2s and 1099s for income earned during the previous calendar year:

- From Harvard University:
    - Salary earnings from prior calendar year; and
    - Royalties paid to the faculty member under Harvard's institutional royalty sharing policy. The royalties represent a portion of a milestone payment paid by Biotech Company X to Harvard under its license to three University-owned patents invented by the faculty member.
- From Pharma Y:
    - Honoraria for three speaking events discussing the latest advances in preventing cardiac disease in adult men over the age of 50.
- From Law Firm Z:
    - Expert witness testimony during three days in July of the previous year. Faculty member was asked to discuss typical side effects of a commonly used drug for hypertension.
- From Art Museum A

[20] This may include consulting income (including expert witness testimony), royalties, honoraria or equity from pharmaceutical, device, software, biotechnology, publishing, medical education, marketing/promotional, insurance, government, foundation or other relevant for-profit or non-profit entity.

    - For modest income earned as a member of the company's fiduciary board of directors.

- From Journal B

    - For income earned as editor of scientific manuscripts submitted.

Faculty member also holds equity in a start-up medical device company, a doll manufacturer and multiple large mutual funds.

Regardless of the amount received or held, the faculty member must report to HMS all of the following: (1) royalty income from Harvard from license to Biotech Company X; (2) honoraria from Pharma Y; (3) consulting income from Law Firm Z; (4) income from Journal B; and (5) equity in the start-up medical device company. The faculty member will not have to report the income received from Art Museum A.

Recommendation 31: Training and Education

Training and education for Faculty Members regarding their obligations under the COI Policy must be coupled with the obligation of each faculty member to fill out the annual reporting form. Prior to completing and submitting the form, faculty should be required to complete, at least once, a web-based test that evaluates the individual's knowledge and understanding of the policy. This test should utilize a case-based approach. Its successful completion will be a requirement for satisfactory completion of the annual process the first year that the new policy is implemented or the first year that a faculty member completes his/her financial report for HMS. In addition, HMS should conduct live seminars on a periodic basis at and in cooperation with the staff of the affiliated institutions covering the HMS policy and process.

C. PREVENTING UNMANAGED CONFLICTS

Guiding Principle: The Policy Should Prevent, not Punish, Conflicts

The policy must identify and resolve/manage potential conflicts of interest prior to an individual being criticized for making an academic, clinical or research decision while subject to a previously unknown competing personal financial interest. Put differently, the policy should aim to prevent potentially biased decision-making or the appearance thereof, rather than punishing insufficient disclosure or improper behavior after it has occurred.

Our Committee uniformly endorses additional transparency regarding the outside professional activities of our faculty. As faculty members, we should be proud of the contributions we make to a variety of professional areas. To advance our academic mission effectively, we must interact with businesses, professional societies, journals and publishers. Our knowledge and expertise add value to these sectors, and we must not be ashamed of the fair compensation we may receive for the work we do and the unique contributions we make. Accordingly, this Committee recommends adoption of a public disclosure website by HMS for faculty and supports the Implementation Subcommittee's recommendations on the content of the disclosures as follows:

Recommendation 32: Web-based Disclosure System

Public disclosure of faculty financial interests/activities reported to HMS should occur through a web-based interface. All of the following categories that equal or exceed $5,000[21] (excluding reimbursement for travel, lodging and other reasonable expenses) should be disclosed[22]:

[21] The value may be measured based upon the cumulative amount a faculty member receives directly or indirectly in exchange for the services described or may be measured based on the fair market value of the

(1) Consulting arrangements, including legal consulting as expert witness;

(2) Memberships on scientific advisory boards;

(3) Service on Boards of Directors of pharmaceutical, device, software or biomedical companies;

(4) Equity or other ownership interest in privately held companies;

(5) Equity or other ownership interest in publicly traded pharmaceutical, device, software and biomedical companies; and

(6) Honoraria payments from for-profit pharmaceutical, device, software and biomedical companies, non-profit foundations, medical education companies, promotional or marketing firms, and any other relevant for-profit organizations (e.g., publishers and journals). This shall include payments anticipated under any deferred payment plan.

Policy in action. A faculty member reports annually to HMS and Children's Hospital Boston the relevant financial interests and activities with which she engaged in the previous calendar year. From such entries, her profile on the Harvard Catalyst website is updated to include a listing of outside professional activities and estimated income/value. This information is available to the public, including the faculty member's patients and potential patients.

This Committee also supports the Implementation Subcommittee's recommendations regarding additional procedural safeguards that reinforce a culture of academic integrity regarding the activities in which our faculty members engage. This Committee agrees that a system that provides for both local review of each disclosure form as well as random monitoring for faculty member compliance is required. We therefore recommend as follows:

Recommendation 33: Review by Local Supervisors

In addition to review by HMS and/or hospital conflicts of interest liaisons, each department chair/supervisor will designate one or more individuals to be responsible for reviewing the annual financial disclosure forms of faculty members

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ownership interest described. The $5,000 threshold may be exceeded by multiple smaller payments from the same Business, which together exceed $5,000.

[22] Such disclosure must clarify that information provided is (i) effective as of "X" date and (ii) disclosed "to the best of the faculty member's knowledge."

over whom such designee has supervisory authority.[23] He/she will certify to HMS in writing that he/she has completed the review following each annual disclosure cycle. Supervisors responsible for reviewing annual financial disclosure forms will be trained by HMS regarding appropriate standards for review, factors that automatically trigger heightened review and specific scenarios giving rise to recusal from the review process. Reviewing supervisors will not be administrators. They will be identified in a systematic way by HMS prior to the first disclosure cycle. Division chiefs will ultimately be responsible for local review and for individually reviewing any form triggering a "heightened review." All division chiefs will also be trained by HMS. Division chiefs shall consult with HMS regarding individual cases, as needed. On a periodic basis, each division chief will provide a report to HMS summarizing the individual cases he/she reviewed and the outcome of such review. This information will be brought, on an anonymized basis, to the Standing Committee on Conflicts of Interest (*See Recommendation 36)*. The Standing Committee will utilize this information to develop a "case law" for conflicts resolution/monitoring. Additional resources will be necessary to fully implement this recommendation.

Policy in action. A faculty member submits his annual financial report through the new centralized disclosure system. Shortly thereafter, his division chief at an Affiliated Hospital logs into the same system and accesses the financial reports for all personnel under his supervision, including faculty member. The division chief notices that faculty member has not disclosed a major consulting agreement with Pharma X that just came to the attention of the division chief. In light of this inconsistency, the division chief meets with faculty member to better understand his disclosures. Faculty member simply forgot to include the consulting arrangement. The error is fixed. Following division chief's review of all financial reports, he reports any unresolved discrepancies to HMS and the Affiliated Hospital's COI liaison and provides a brief anonymous summary to the Standing Committee regarding the data and trends he uncovered in the course of his review.

Recommendation 34: Monitoring Program

Develop a monitoring program to be conducted following each annual HMS reporting cycle. Under such program, the following process will be followed: A random sample of the faculty will be selected. HMS will examine each identified faculty member's financial reporting form and compare this form to available financial payment information disclosed by: (i) biomedical companies, (ii) Massachusetts Department of Public Health (DPH) and (iii) other publicly or

[23] As noted, the subcommittee anticipates that financial reporting forms will continue to be simultaneously reviewed by the Office of Professional Standards and Integrity and the hospital liaisons following each disclosure cycle consistent with the current procedures.

internally available sources. Any significant discrepancies will be highlighted.[24] HMS will work with department heads and hospital liaisons to understand discrepancies.

HMS should also issue a general report to faculty members following completion of its evaluations. The report will not identify individuals reviewed (nor will individuals be informed that they are the subject of a review unless a significant discrepancy is discovered that requires clarification), but will report on general findings and trends identified through the review.

Policy in action. Following HMS's deadline for faculty completion of the annual financials, the Office of Integrity and Professional Standards randomly selects x number of faculty members from across affiliated institutions and departments to review. HMS examines publicly available information to identify discrepancies. Faculty member is selected. She is not aware of this review and is never notified because no significant discrepancies are uncovered. The Office of Professional Standards and Integrity publishes annually an anonymized report setting forth the overall results of the monitoring program.

Recommendation 35: Office of Professional Standards and Integrity

The Office for Research Issues should be renamed the Office of Professional Standards and Integrity to reflect appropriately the expanded purview of the office under a revised policy.

D. EQUITABLE APPLICATION OF POLICY

Guiding Principle: Efficient, Transparent, Consistent and Equitable Application of Policy

Application and enforcement of the policy must be efficient, transparent, consistent and equitable with regard to each discipline, department, and member of the Faculty, regardless of rank or institutional affiliation.

As noted in various places in this report, effective implementation requires consistent and equitable application of policy provisions. Historically, the Standing Committee on Conflicts of Interest, appointed by the Dean, was delegated with responsibility for oversight of policy compliance; however, in recent years, the committee has not routinely met. The Subcommittee and this Committee agree that its role could be structured as a resource for centralized administration, oversight and policy interpretation. The following recommendation is, therefore, submitted:

[24] It is the expectation that, until a single central reporting structure and policy can be developed nationally, many discrepancies may be uncovered. The monitoring program will operate with this understanding during its initial years.

Recommendation 36: Standing Committee on Conflicts of Interest

The Standing Committee on Conflicts of Interest should be reconstituted and its authority expanded. This Standing Committee will be supported by HMS staff and delegated with responsibility for reviewing alleged violations, recommending and overseeing additional fact-finding (as necessary in any particular case) and recommending sanctions to the Dean for identified violations. The Standing Committee shall consider the following principles in making recommendations for appropriate sanctions: (a) gradient of faculty member knowingness/intentionality (vs. inadvertent); (b) if applicable, level of risk involved in research and whether it includes human subjects; (c) magnitude of violation; and (d) any mitigating factors. The Standing Committee shall also receive and review division chiefs' (or designees') periodic anonymous reports. The Standing Committee will utilize this information to develop a "case law" for conflicts resolution/monitoring. The Standing Committee shall have authority to issue additional guidance to the HMS community from time to time as it deems necessary in view of developing case law.

In the context of its discussion of consistencies and inconsistencies within the policy, the Implementation Subcommittee was also asked to consider the Category I(c) rule. Category I(c) states that:

> A full-time Faculty Member is not permitted to take an Executive Position (responsible for a material part of the operations of a Business such as Chief Executive Officer, Chief Operations Officer, Scientific Director or Medical Director) in a for-profit Business engaged in commercial or research activities of a biomedical nature.

Specifically, the Subcommittee considered whether and how this provision might apply to part-time faculty members. While this Committee recognizes that part-time faculty must be granted additional leeway to hold simultaneous roles, we agree with the Implementation's Subcommittee's recommendation that allowing for such dual roles must not inadvertently compromise the integrity of research. Accordingly, we recommend as follows:

Recommendation 37: Application to Part-Time Faculty

Category I(c) should also prohibit any part-time Faculty Member[25] who holds an Executive Position (responsible for a material part of the operations of a Business such as Chief Executive Officer, Chief Operations Officer, Scientific Director or

[25] A "part-time Faculty Member" shall include any member of the HMS Faculty whose official appointment with the Faculty of Medicine is less than full-time.

Medical Director) in a for-profit Business engaged in commercial or research activities of a biomedical nature from:
(1) Participating in Clinical Research on a Technology owned by or obligated to the Business (regardless of whether he/she has a Financial Interest in the Business) and/or

(2) Receiving Sponsored Research from that Business (regardless of whether he/she has an equity interest in the Business).

Policy in action. Faculty member has elected to reduce his full-time appointment with HMS to part-time, so that he may accept an executive position with Startup X. He wishes to continue his HMS-based research sponsored by Startup X examining a specific RNase inhibitor. He <u>may not</u> continue this work if he accepts the executive position with Startup X.

Finally, the Implementation Subcommittee was also asked to consider the role of a member of a fiduciary board of directors and whether application of the Category I(d) rule was equitable. Category I(d) currently states:

> A Faculty Member who serves on the Board of Directors of a Business is not permitted to Participate in Clinical Research on a Technology owned by or obligated to the Business, regardless of whether he/she has a Financial Interest in the Business, and is not permitted to receive Sponsored Research from that Business, regardless of whether he/she has an equity interest in the Business. This provision does not apply to a Faculty Member who is a member of a Scientific Advisory Board and who does not either hold an Executive Position or serve on the Board of Directors.

The Subcommittee explored whether the rule's application to non-profit philanthropic organizations protected against an identifiable harm. The Subcommittee concluded and we agree that it does not. We, therefore, recommend as follows:

Recommendation 38: Category I(d) Application to Non-Profits

Category I(d) should be modified to allow a faculty member who serves on the Board of Directors of a *non-profit* Business to Participate in Clinical Research on a Technology owned by or obligated to the Business and to receive Sponsored Research from that Business. For the purpose of this rule, a *non-profit* Business shall include any Business legally organized for charitable purposes (e.g., 501(c)(3) and

equivalents), but shall exclude any non-profit entity that is principally organized, funded and/or managed by one or more for-profit Business(es) engaged in commercial or research activities of a biomedical nature.

VI. ADDITIONAL RECOMMENDATIONS OF FULL COMMITTEE

A. SUMMARY OF RECOMMENDATIONS

- Prohibit solicitation or receipt of gifts from pharmaceutical, medical device or biotechnology manufacturing/supply companies.

- Prohibit receipt of meals from pharmaceutical, medical device or biotechnology manufacturing/supply companies, except pursuant to bona fide consulting arrangement.

- Prohibit receipt of travel expenses/registration fees for attendance at professional meeting or conference, unless attendee is a speaker or panelist at event.

- Explicitly prohibit ghostwriting/honorary authorship.

- Prohibit receiving compensation for presenting educational materials developed by industrial sponsor.

- For initial trial period, gather data regarding income earned directly or indirectly from commercial biomedical companies for speaking events. Standing Committee shall have authority to recommend additional restrictions following review of gathered data.

- Require HMS and affiliated institution review and approval of participation on for-profit boards of directors for biomedical companies.

Several additional topics were independently considered by the full Committee. Specifically, this Committee examined as a group (1) the conflict of commitment provisions of the COI Policy, (2) the necessity of a faculty gifting policy, (3) ghostwriting and honorary authorship, (4) faculty participation in industry-funded speaking events and (5) participation on fiduciary boards.

B. CONFLICT OF COMMITMENT

Guiding Principle: Faculty Obligations to HMS are Primary

<u>Faculty members must arrange outside activities so as to emphasize the primacy of one's academic, clinical and research obligations to HMS and its affiliated institutions</u>.

The COI Policy currently provides:

> The Faculty of Medicine recognizes that its members may engage in outside professional work, and to the extent these activities serve the Faculty's interests, as well as those of the participant, the Faculty of Medicine approves of such involvement. However, no more than twenty percent (20%) of a full-time faculty member's total professional effort may be directed to outside work, not to exceed the equivalent of one working day per week.

The Committee continues to endorse the conflict of commitment provision, but our members feel that there should be increased emphasis in the policy that our faculty's involvement in outside activities is a privilege and not a right. Our members acknowledge that faculty engaged in outside professional work often gain experience, knowledge, and involvement consistent with one's role as a faculty member. The Committee reaffirms, however, that such activities must remain secondary to one's primary obligations to HMS and its affiliated institutions. Accordingly, prior notification to and approval by one's chair/designated supervisor is required before a faculty member can accept such obligations. We therefore submit the following recommendation:

Recommendation 39: Conflict of Commitment

It is the expectation of HMS that a faculty member's principal professional loyalty shall remain, at all times, with HMS and the faculty member's affiliate institution(s). However, with the permission of a faculty member's chair and/or designated supervisor, he or she may devote up to 20 percent of his/her professional time to outside activities. It is expected that such outside activities will not compromise the faculty member's normal workweek in excess of one day per week. Traditional scholarly ventures, including academic communications/publications and professional or advisory service for other universities, nonprofits or governmental entities, shall be subject to review and approval by chiefs and/or designated supervisors, but may be excluded from the 20 percent limitation.

Policy in action. Faculty member typically works 14 hours/day Monday through Wednesday lecturing, conducting research, and overseeing her laboratory on the HMS quadrangle. On Thursday, she spends her day at StartupX, a company she founded, consulting on day-to-day research issues. She typically spends about eight hours on Thursdays at the company and is well compensated for her time. On Friday, faculty member spends her mornings volunteering at a local school, where she advises on a government-run program designed to improve early childhood education in the sciences. On Friday afternoon, she is back in her office at HMS, responding to emails, reviewing manuscripts and addressing her various administrative responsibilities. On weekends, she may work on and off preparing

her lectures for the coming week, reviewing data generated in her lab the previous week and advising her trainees via e-mail on proposed experiments. Faculty member's department chair is aware of her responsibilities to StartupX and the local school, has reviewed them and has approved of faculty member's involvement. Faculty member is not in violation of the conflict of commitment provision.

C. INDUSTRY-SPONSORED GIFTS, TRAVEL AND MEALS

Guiding Principle: A Marketing-free Culture

The Faculty of Medicine must establish a culture free of unnecessary marketing paraphernalia, which do not advance the shared goal of academia and industry in collaborating to advance scientific discovery but rather create an appearance of inappropriate industry influence that undermines public trust in these critical collaborations.

Consistent with the new Massachusetts state law applicable to all faculty members that are healthcare providers[26], this Committee recommends that as one Faculty of Medicine, all of our members should reject gifts, travel expenses and meals from industry if not pursuant to a bona fide agreement for services. In addition, we must guard against indirect gifting through third parties that essentially act as an agent for a biomedical company in violation of the spirit of these recommendations. We, therefore, submit as follows:

Recommendation 40: Prohibition on Solicitation or Receipt of Individual Gifts

HMS shall prohibit:

- Solicitation by any member of the HMS community, including students, fellows or faculty members, of any personal gift. A personal gift shall be defined as anything of any value that is received by an individual for which the recipient has not paid fair market value.

- Acceptance by any student, fellow or faculty member of any personal gift from a pharmaceutical, medical device or biotechnology manufacturing/supply company (or its representatives). By way of example, such gifts may include but are not limited to the following:

    - Entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting

[26] The Massachusetts Manufacturer Conduct Law restricts the provision of meals and gifts by pharmaceutical and medical device manufacturers to Massachusetts healthcare practitioners. See Mass. Gen. L. c. 111N.

equipment or leisure or vacation trips to any of the listed individuals who is not a salaried employee of the pharmaceutical, medical device or biotechnology manufacturing/supply company;

- Payments of any kind, including cash or cash equivalents, equity, "in kind" or tangible items, including any "complimentary" items such as pens, coffee mugs, T-shirts and gift cards to the above individuals either directly or indirectly, except as no more than reasonable compensation for bona fide services;

- Any grants, scholarships, subsidies, supports, consulting contracts or educational- or practice-related items in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices;

- Any other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or "kickback" that is prohibited under applicable federal or state "fraud and abuse" laws or regulations, including the federal "Anti-Kickback Statute" (42 U.S.C. 1320a-7b) and equivalent Massachusetts laws.

- Token gifts (such as key chains, T-shirts and pens) given as part of an institutional (HMS, HSDM or affiliated institution) sponsored public awareness campaign or event, even when donated by a participating corporate partner, are allowed as they are designed to increase awareness of a community need and fit within the mission of the organization.

- Donations to individual institutions and gifts of data, reagents, equipment or other laboratory materials provided by vendors to lab personnel for use in the scope of institutional and HMS academic work are considered institutional gifts for purposes of this policy. Such institutional gifts shall not be prohibited by this policy; however, it is expected that HMS, HSDM and each affiliated institution shall have individual policies related to gifts to the institution and it is the expectation that each faculty member, student and fellow will strictly adhere to the requirements of the policy of his/her institution.

Policy in action. Pharma X representative has been selling a faculty member surgical supplies for years. The prices offered by Pharma X are at or below market price and faculty member has never experienced any problems with the quality of Pharma's products. Over the years, faculty member and Pharma X representative have become friends. As avid football fans, they often spend time discussing highlights from the previous weekend's game. One day, Pharma X representative offers to take faculty member to an upcoming Patriots game "on the company's dime." Faculty

member may not accept the tickets. He may, however, go to the game with the Pharma X representative, provided that the faculty member pays for his own ticket.

Recommendation 41: Prohibition on Industry-sponsored Meals/Travel

HMS/HSDM shall prohibit:

- Acceptance by any student, fellow or faculty member of any meal from a pharmaceutical, medical device and biotechnology manufacturing/supply company, except as follows:
    - The ban upon acceptance of meals shall not include meals that may be provided to a faculty member while attending meetings of a scientific advisory board or board of directors of a pharmaceutical, medical device or biotechnology manufacturing/supply company, where attending such meetings is required as part of a bona fide consulting agreement with the faculty member, provided that meals served during those meetings are modest in nature.
        - For the avoidance of doubt, in accordance with state law, in no event shall a faculty member accept a meal (a) offered as part of an entertainment or recreational event; (b) offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present; (c) offered, consumed or provided outside of the health care practitioner's office or hospital setting; or (d) provided to a healthcare practitioner's spouse or other guest.
- Acceptance by any student, fellow or faculty member of registration or travel fees for attendance at any professional or trade meeting or conference, unless the attendee is a speaker or panelist at the meeting.
    - "Users Group" meetings or training sessions to learn how to use a technical device already purchased by the institution, where attendance at the meeting or training was included as a part of the written contract, shall not be prohibited by this policy. In all cases, the payment should be for reasonable travel and lodging expenses and a fair market value (FMV) for the person's time (if compensation is indicated). The primary purpose of the meeting must be training or education related to the product and its upgrades and/or enhancements.

Policy in action, Medical Supply Company X contacts faculty member and notifies her of an upcoming international meeting on the latest advancements in neuroimaging technology. The meeting is sponsored by a prominent professional

society. Faculty member is active in this field, having just completed a clinical trial testing a new product of Medical Supply Company X. Medical Supply Company X has offered to pay the travel expenses and registration fees for a specific fellow in her lab whose work has been highly complimentary to the use of Company X's product. The fellow may not accept the offered expenses from Medical Supply Company X.

Recommendation 42: Prohibition on Indirect Industry Gifts, Meal and Travel Sponsorship

Acceptance by any HMS/HSDM student, fellow or faculty member of any gifts, meals or travel expenses sponsored by a pharmaceutical, medical device, or biotechnology manufacturing/supply company through one or more third-party entities or individuals shall also be prohibited if such student, fellow, or faculty member is made aware that his or her expenses are being paid by industry.

Policy in action. Foundation X invites faculty member, an expert on bacterial meningitis, to dinner to discuss its public outreach campaign for increasing awareness of available treatments and preventive measures. Faculty member is aware that Foundation X is affiliated with and funded entirely by Pharma X, a company which has just announced a new vaccine for preventing a specific strain of meningitis. Faculty member may attend the dinner meeting with Foundation X, but must pay his own expenses in connection with the meal.

D. GHOSTWRITING AND HONORARY AUTHORSHIP

Guiding Principle: Authorship Guidelines Prohibit Ghostwriting

Honorary or guest authorship is unacceptable.

The HMS Authorship Guidelines set forth detailed requirements for being an author on a biomedical publication. These standards are consistent with the recommendations of the International Committee of Medical Journal Editors and clarify that honorary or guest authorship is not acceptable. However, the institution's expectations around this important issue should be included in the COI Policy to clarify that faculty participation in industry ghostwriting or honorary authorship violates the COI Policy and could be subject to review and possible sanction by the Standing Committee.

Recommendation 43: Ghostwriting and Honorary Authorship

A HMS/HSDM student, fellow or faculty member shall be prohibited from representing his/herself as an author of any publication[27] for which the individual has not satisfied either: (i) HMS Authorship Guidelines or (ii) the authorship guidelines of the International Committee of Medical Journal Editors as set forth in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals (Updated October 2007). Any use of a third party medical writer or editor must be disclosed to journals in connection with a manuscript submission process.

Policy in action. Faculty member is a world expert on pre-term labor in pregnant women. Pharma X is studying the root cause of pre-term labor for some women and has discovered a new and improved method to test pregnant women for risk of the condition, which may represent a target for preventing onset. Faculty member has worked with Pharma X previously on other research collaborations, but was not involved in the current study. However, Pharma X sends their manuscript to faculty member, asking her to review the draft and inviting her to be an author on the paper. Faculty member does not meet the requirements for authorship and violates HMS policy if she accepts Pharma X's offer.

E. PARTICIPATION IN INDUSTRY-SPONSORED SPEAKING EVENTS

Guiding Principle: Intellectual Independence in Speaking Engagements

As members and representatives of the HMS/HSDM community, faculty members must retain intellectual independence over the content of any educational material they present. Tacit participation in industry's use of academic reputation to achieve marketing aims must be discouraged.

This Committee discussed for several meetings the questions of whether, when and to what extent the COI Policy should limit faculty independence in choosing the kinds of activities with which one participates outside of his/her responsibilities to HMS and its affiliated institutions. As noted, we trust our colleagues and believe that inappropriate behavior is a rarity. The vast majority of our faculty conduct their affairs with the highest of integrity. Nonetheless, certain industry-sponsored educational events, while not per se unethical on the part of a participating faculty member, clearly represent a comingling of marketing and education in a manner that tarnishes the institution's reputation as a steward of independent academic thought. While this Committee is reluctant to limit our colleagues' autonomy and ability to legitimately supplement income in a time of economic difficulty, we cannot endorse industry's use of a hard-earned HMS/HSDM title to cloak a company's promotional message in the guise of academia. We therefore recommend as follows:

[27] A "publication" includes an abstract, poster or presentation given to others, a paper published in a peer-reviewed journal or a review paper appearing in an industry-supported periodical.

Recommendation 44: Prohibition on Receipt of Income for Presenting Industry-developed Slides

Faculty members shall be prohibited from receiving compensation in exchange for presenting slides and/or educational content developed by and/or provided by a commercial biomedical company. Faculty members shall not accept a speaking engagement for compensation that limits the faculty member's intellectual independence with regard to presentation content. No HMS faculty member shall knowingly permit a commercial biomedical company from listing such faculty member on the company's list of industry-sponsored educational speakers or as a member of the company's "speaker's bureau."

Policy in action. Faculty member is asked by Medical Device Company X to travel for two weeks in Europe speaking at various medical practices and other organized events on Medical Device Company X's new cardiac implant. Faculty member uses the implant often in his practice and believes it represents a tremendous breakthrough in alleviating the often painful side effects that are common with other comparable devices. He is told that he will be compensated for each of the 15 presentations scheduled. Medical Device Company X has a prepared slide deck for faculty member's use. He is not opposed to any of the material in the slide deck, but had no role in preparing the content or in conducting its underlying research, nor is he permitted by Medical Device Company X to change any part of the slide deck. Faculty member may not accept this opportunity from Medical Device Company X unless he forgoes all compensation and refrains from using his HMS affiliation in connection with the presentations.

Recommendation 45: Allow Sponsorship of Lectures through Non-profits

Faculty Members shall be allowed to receive compensation for presenting educational content developed independently by the faculty member, but supported indirectly by a commercial biomedical company through a third party non-profit organization (e.g., professional society, university or hospital/medical provider). The third party non-profit organization shall exercise full control over the selection of topics and speakers for such educational event and shall impose firewalls to ensure that the commercial biomedical company does not influence the content or conduct of such event.

Policy in action. Faculty member is asked by Hospital X to present at the next psychiatric grand rounds on faculty member's research into schizophrenia. Faculty member is told that the event will be sponsored by multiple companies through grants to the University. Faculty member may participate in this event.

In this context, the full Committee also considered when a faculty member engaging in repeated speaking events funded by industry, but presenting one's own independently developed content, is nonetheless engaged in a commercial rather than educational activity. A majority of the members of this Committee did not believe a threshold could be appropriately defined by number of talks given or amount of money earned. To these members, there are insufficient data to draw any conclusions. Some topics may be of such general interest to practitioners that repeated delivery is consistent with our academic aims. In addition, these members did not feel it was appropriate for the institution to dictate how a faculty member is compensated for activities conducted during his/her free time absent the compelling institutional interest of ensuring academic independence. Accordingly, the following recommendation is submitted:

Recommendation 46: Review of Faculty Participation in Industry-sponsored Speaking Events

Faculty members shall continue to be allowed to receive compensation for presenting educational content developed independently by the faculty member, but supported either (i) directly by a commercial biomedical company, or (ii) indirectly through a third party medical education company or an entity controlled by a commercial biomedical company. The Standing Committee, however, shall gather data for the next one to two reporting cycles regarding the extent and frequency of faculty involvement in such industry sponsored events, including accredited medical education. Following a review of these data, the Standing Committee shall have the authority to make recommendations to the Dean regarding additional restrictions which it may conclude are warranted by the institution's interest in discouraging commercial use of the Faculty of Medicine reputation.

Policy in action. Faculty member is the lead author on a paper that has dramatically changed the prescribing paradigm for seasonal influenza. PharmaX and PharmaY have both invited her to present at several national meetings and smaller peer events to report on her results following this publication. Faculty member developed all of the content of her presentation, but was not invited or even contacted by any companies until after her talk was developed and delivered at a national meeting of her professional society. Faculty member may accept engagements to speak funded by either PharmaX or PharmaY, but must report her activities to HMS in connection with its annual financial reporting process, including the amount of income earned, the name of the pharmaceutical company that funded the presentations (even if a third party entity was utilized in organizing the events and/or as a paying agent of the particular pharmaceutical company) and the frequency of such engagements. The Standing Committee shall review these data to determine whether additional restrictions are advisable.

To a minority of this Committee, however, the patterns of activities that give rise to legitimate institutional questions are already identifiable. If a faculty member is spending substantial time engaging in such activities, he/she may not be appropriately meeting his/her professional commitments to HMS/HSDM. In addition, the institution has a responsibility to safeguard against commercial use of institutional reputation for marketing goals even if such use takes the form of capitalizing on an individual faculty member's experience-driven views. In the minority's opinion, we risk the public's trust if we don't take a hard line on such activities. Accordingly, the minority submitted the following recommendation:

Minority Recommendation 5: Limit Faculty Participation in Industry-sponsored Speaking Events

Faculty members shall be allowed to receive compensation for presenting educational content developed independently by the faculty member, but supported either (i) directly by a commercial biomedical company, or (ii) indirectly through a third party medical education company or an entity controlled by a commercial biomedical company *provided* the amount of compensation received for such services from all such companies does not cumulatively exceed $30,000 in any calendar year.

F. PARTICIPATION IN FIDUCIARY BOARDS

Guiding Principle: Vigilance When Participating on Fiduciary Boards

Senior personnel within HMS/HSDM must be especially vigilant to potential conflicts and the appearance of conflicts when engaging in outside relationships with biomedical companies.

Our Committee also discussed at length the appropriateness of senior officials within the Faculty of Medicine participating in fiduciary boards of for-profit biomedical companies. As a fiduciary of such companies, these officials are obligated to act in the company's best interests. Nonetheless, as a member of senior personnel within the HMS system, the faculty member may also be responsible for decisions related to business dealings with the relevant company. Inherent conflicts may exist. This Committee, however, does not wish to diminish the valuable insight that our most senior people can contribute to a company's operations. Such contributions are consistent with this institution's aim to remain a leader in biomedicine and shape the field in more ways than just academic discovery within the campus walls. Nonetheless, we think review of such relationships remains necessary.

A minority of the Committee also believes that the compensation for board service by senior officials should be structured in a manner that reduces the appearance of impropriety. A majority of the Committee disagreed and felt that such arbitrary

limitations did not address the actual conflict arising from fiduciary service, inappropriately rewarded companies and potentially cast academic board members in an inferior light when compared with compensated board colleagues and that such discrepancies may diminish the critical importance of academic voice in industry operations. In addition, such restrictions fail to recognize that, in some cases, more stringent restrictions are appropriate to address the potential conflict, including prohibiting participation altogether. The following recommendation is therefore submitted:

Recommendation 47: Review of Fiduciary Board Participation

The Subcommittee recommends that any individual serving on the Board of Directors of a for-profit business engaged in commercial or research activities of a biomedical nature shall subject such relationship to periodic review by HMS and the affiliated institution (as applicable) to evaluate whether the arrangement gives rise to actual or potential conflicts of interest. As applicable, all institutions with which an individual holds an appointment must approve of a faculty member's involvement for the arrangement to be permitted. As an individual's authority within HMS and/or the individual's affiliated institution (as applicable) increases, the scrutiny applied by HMS and the affiliated institutions shall similarly increase in light of the changing scope of authority of such individual. Any such arrangements may be subject to supervisory approval and written plans for oversight as necessary.

Minority Recommendation 6: Institutional Official Service on Boards of Directors

A senior institutional official within the Faculty of Medicine may continue to serve on Board of Directors of a commercial biomedical company provided that he/she does not accept equity as compensation, and receives no more than $5,000/day for actual service on the board of directors.

VII. CONCLUSION

We respectfully submit to the Dean of the Faculty of Medicine this report of the discussions and deliberations of the Committee on Conflicts of Interest and Commitment on the 16th day of March, 2010. Please do not hesitate to call upon us if we can be of any further assistance.