This week, Harvard Medical School (HMS) released its 2009-2010 report from the Faculty of Medicine Committee on Conflicts of Interest and Commitment, an advisory committee appointed by HMS Dean Jeffrey S. Flier, MD in January 2009.

The report reviewed the Harvard University COI Policy, which was first adopted in 1990, and how the original version and all subsequent revisions 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.”

Consequently, the report acknowledged that “the recommendations of the 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.” Despite their claim, the strict rules, as outlined below, will most likely make these relationships extremely difficult, and perhaps nonexistent, even though “neither the COI Policy nor the recommendations prohibit a faculty member from interacting with industry.” In fact, the Committee “encouraged faculty to engage in a wide variety of activities with industry, including, but not limited to:

- Consulting for industry and conducting research sponsored/supported by industry;
- Collaborating with industry on research protocols and co-authoring publications derived from these collaborations;
- Founding biotechnology companies and 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.

Structure of the Report

To accomplish their goal, the committee was divided into three subgroups: research, education, and implementation and compliance. In all, members of the panel in one form or another dedicated 38 meetings to this task. The report was then broken down into four sections to discuss full Committee and subcommittee recommendations.

In examining the issues related to potential COI affecting the education, training and experiences of medical students, graduate students, postdoctoral fellows and faculty, the education subcommittee recommended to:

- 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 copromotion 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.

CME

With regards to CME, the report noted that despite issues with sponsorship of educational sessions, “this failure of compliance, should not, however, necessarily be interpreted to mean that all industry sponsorship of CME is biased and inappropriate.” In fact, the report explicitly stated that the Committee:

“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
The research subcommittee introduced the following recommendations:

- 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
- Conflict of interest risk by reason of the financial relationships of the organizers/speakers.

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, as approved in advance by the HMS/HSDM CME Review Committee, and (ii) twelve months following the last day a human participant completes trial or (i) the first (i) new Board/COI committee review any income less than de minimis.
- At a distinct time as a CME program approved for credit through HMS/HSDM.
- All industry exhibits 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.
- CME accredited by Harvard will be multi supported with no supporter giving more than 50% of the budget.
- Gifts from industry should be prohibited in conjunction with HMS/HSDM CME programs.

Harvard Medical School receives approximately 2.5 million of commercial support for a program with revenues of $24.9 million.

Pri-Med

The Committee also reviewed Pri-Med, a communication and education platform owned by M/C Communications, LLC, a for-profit medical education company that principally utilizes funding from exhibitors and advertisers to support its conferences. Their evaluation of Pri-Med conferences revealed that “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.” They also found that “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.”

In fact, the Committee found 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.” Despite this finding, the Committee recommended that Pri-Med conferences:

- 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)
- 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.

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. 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.

Any speaker at an HMS/HSDM CME event must disclose all financial interests relevant to the content of his/her presentation at the beginning of a presentation. These disclosures must 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 will 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.

Clinical Research

The research subcommittee introduced the following recommendations:

- 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.
- 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.
- 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.

Implementation

- 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.

Another part of implementation will be training and educating Faculty Members regarding their obligations under the COI Policy, which will include a web-based test that evaluates the individual’s knowledge and understanding of the policy. In addition, the Committee recommended that HMS conduct live seminars on the policy.

**Disclosure**

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

- Consulting arrangements, including legal consulting as expert witness;
- Memberships on scientific advisory boards;
- Service on Boards of Directors of pharmaceutical, device, software or biomedical companies;
- Equity or other ownership interest in privately held companies;
- Equity or other ownership interest in publicly traded pharmaceutical, device, software and biomedical companies; and
- 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.

**Part Time Faculty**

The rules also prohibit any part-time faculty member 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 Medical Director) in a for-profit Business engaged in commercial or research activities of a biomedical nature from:

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

Accordingly, prior notification to and approval by one’s chair/designated supervisor is required before a faculty member can accept such outside work. The rules also establish that a faculty member may devote only up to 20 percent of his/her professional time to outside activities.

**FDA Mandated Education**

Faculty members under the new rules are also 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 must not accept a speaking engagement for compensation that limits the faculty member’s intellectual independence with regard to presentation content. No HMS faculty member can 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.”

Faculty members are 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.

**Conclusion**

What is problematic about this report is that in making their recommendations, the Committee members acknowledge their own “personal biases” and the “varying experiences they inevitably carry.” In other words, opinions, not evidence, are largely what drove this rule making process.

Such an outcome is particularly troublesome because “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.” Moreover, for specific programs, HMS has relied on industry funding to support the CME program budget.

As such, these new rules are concerning because of their burdensome nature, and the framing bias they appeal to, which suggests that such relationships are unethical. As the report notes, “when appropriately managed, industry remains an important resource for funding of high quality CME.” But with these new rules, it appears that industry will have few options to choose from when it comes to funding CME, and if they do so, companies will face significant administrative and compliance burdens.

Creating a “Conflict of Interest” standing bureaucracy is also a really bad idea as much like an inquisition committee, it will probably be staffed with faculty who are not on the cutting edge of research and product development, and will likely be ruled by those with no interests in the real world. Also unsettling about this is they will find problems, if one looks for problems in any relationship they will find some. Imagine if you had a “conflict of interest” committee looking daily into your marriage, how successful would that
Consequently, since the committee believes “at this time that continuing to accept industry support does not pose an unacceptable risk of compromising quality,” why do they find it necessary to adopt such restrictive rules? To date, no evidence has shown any harm to patients such relationships have created, so why restrict them now, because of the media? As the authors recognize, faculty members “should be proud of the contributions they make to a variety of professional areas,” and they should not be ashamed of the fair compensation they may receive for the work they do and the unique contributions they make.

With that in mind, we hope that HMS will heed their own words and always keep true to their essential principle that “interactions between academia and industry are crucial to science and to facilitating the translation of knowledge from the research bench to the hospital bedside.”

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