

Harvard Medical School Issues Revised Conflicts of Interest Policy for Faculty Relationships with Industry

The life science industry has had a long and mutually rewarding relationship with Harvard Medical School (HMS). Collaborations have sped the development of new products to treat serious illnesses and brought the world new scientific insights. HMS faculty members have founded life science companies, served as advisors and directors to life science companies and conducted crucial pre-clinical and clinical research in collaboration with life science companies. HMS has long maintained a policy to govern potential conflicts of interest between its faculty and the life science industry (the “Conflicts Policy”). Given the increasing spotlight recently on industry’s relationship with academic medicine, HMS revisited and substantially revised its Conflicts Policy.¹ These revisions will impact industry’s current and future relationships with HMS faculty. **The new Conflicts Policy will take effect on a rolling basis starting in January 2011.**

Information about the implementation schedule will be posted at (<http://hms.harvard.edu/public/Conflicts/policy/integritypolicy.html>) as it becomes available.

As the current Conflicts Policy does, the revised Conflicts Policy will classify relationships with industry into four categories:

- Category I – relationships that are generally not allowed, with minor exceptions
- Category II – relationships that are generally allowed only after disclosure, review and approval with oversight
- Category III – relationships that are ordinarily allowed following disclosure, and potentially, oversight procedures
- Category IV – relationships that are allowed because they are accepted practices and have minimal personal financial impact on faculty

A fuller description of the types of relationships that are covered by each category under the current Conflicts Policy is set forth on [Exhibit A](#).

Revisions to the Conflicts Policy

A number of revisions are planned for HMS’s Conflicts Policy. The changes that are relevant to life science companies include: (1) requiring public disclosure of financial interests between faculty and life science companies, (2) lowering the compensation a faculty member can earn from a life science company when participating in research related to that company’s interests, (3) introducing “wash-out” periods before (A) clinical research can be conducted following a consulting or similar arrangement and (B) a consulting or similar arrangement can be entered into following clinical research, and (4) prohibiting the participation in speaker bureaus or the provision of gifts and most travel and meals.

Public Financial Interest Disclosure

Annually, HMS will disclose on its HMS Catalyst Profiles website (<http://connects.catalyst.harvard.edu/PROFILES/search>) the following financial interests of each faculty

¹ This article focuses on the impact of the Conflicts Policy on faculty interaction with for-profit life science companies. The effect of the Conflicts Policy on interactions with non-profits, including foundations, or internal requirements for HMS faculty are not discussed. In addition, there are policies of the institution with which HMS faculty are affiliated in addition to the HMS policy that may impact a life science company’s relationship with HMS faculty. Such policies are not discussed in this article.

member in or with a life science company that, alone or in the aggregate, equal or exceed \$5,000 for such year:

- Consulting arrangements
- Scientific Advisory Board memberships
- Board of Director service
- Equity or other ownership interest in private and public companies
- Honoraria payments

Limits on Income from Life Science Companies

Under the revised Conflicts Policy, the annual limit of income an HMS faculty member may earn from a life science company for which he or she conducts clinical research will be reduced. Specifically, HMS faculty members will be restricted from earning² \$10,000 or more per year from a life science company that owns or exclusively licenses or markets a compound, drug, device, diagnostic or procedure (a “Therapy”) the subject of clinical research³ in which such faculty member participates, subject to certain de minimis exceptions. **This is a decrease from \$20,000 under the current Conflicts Policy.** In addition, the relevant institutional review board or conflicts committee will review faculty member participation in clinical research with a life science company that owns or exclusively licenses or markets the Therapy being studied where such faculty member earns less than \$10,000 from such company. If the review board or committee determines the faculty member’s earnings pose an unacceptable conflict of interest such faculty member will not be able to participate in the clinical research. **This board or committee review increases the level of conflict scrutiny from the current Conflicts Policy.**

Calculation of Annual Income. In calculating a faculty member’s income for the year, such faculty member’s share in equity, license fees or milestone or other licensing payments earned through institutional royalty-sharing programs will continue to count toward the calculation of the annual income limitation under the revised Conflicts Policy. Post-marketing royalties earned by a faculty member will continue not to count toward the calculation of the annual income limitation, unless such faculty member participates in a Phase IV study on the Therapy to which the royalty relates. **The inclusion of post-marketing royalties when a faculty member participates in such Phase IV studies is a change from the current Conflict Policy.**

Wash-out Periods

Wash-out Following Consulting Relationship. In addition to the limitation on annual income, there will be a six-month washout period on any consulting arrangement or other paid engagement with a life science company for purposes of determining whether a faculty member may participate in clinical research with such company (i.e., the consulting or other arrangement must be terminated or completed for at least six months before it is no longer taken into account for determining whether participation in clinical research violates the Conflicts Policy). Equity or other ownership interests in a company are not subject to this six month period and may be divested immediately preceding participating in clinical research. **This six-month washout period is a new requirement.**

Wash-out Following Clinical Research. For purposes of determining whether an HMS faculty member is participating in clinical research under the revised Conflicts Policy and is subject to income and equity

² Income earned from a life science company can include income indirectly earned, such as payments from a third party funded by such life science company.

³ Excluding certain nominal risk clinical research (e.g., certain research on de-identified bodily fluids or tissues).

limitations, such faculty member will be deemed to be participating in clinical research until the latter of (A) 12 months following the last day a human subject completes the clinical trial, or (B) the first publication of data from the clinical trial or a decision not to publish the data from such trial. This wash-out period applies regardless of what, or how long, the role such faculty member had in the clinical trial. **This twelve month wash out period is a new requirement.**

Restrictions on Speakers Bureaus, Gifts, Travel and Meals

Under the revised Conflict Policy faculty members will no longer be able to participate in industry-sponsored speakers bureaus. In addition, a faculty member will not be able to accept a speaking engagement sponsored by a for-profit life science company if the company limits the faculty member's intellectual independence regarding the educational content of his or her presentation. Faculty members will be able to accept industry sponsorship and support for CME programs, but no one sponsor should account for more than 50 percent of the budget of a particular course or program.

Faculty members will be prohibited from receiving any personal gifts (i.e., gifts of any value received by a faculty member for which such faculty member has not paid fair market value) from a life science company. Life science companies will not be able to provide meals to faculty members unless the meal is provided in connection with a bona fide consulting or services arrangements or compliant industry-funded educational events and conferences. In addition, life science companies will not be able to pay for travel expenses to meeting and conferences unless the faculty member is a speaker or panelist.⁴

What types of relationships may life science companies maintain with HMS faculty under the revised Conflicts Policy?

Under the revised Conflicts Policy, a life science company will still be able to have HMS faculty member:

- Participate on its Scientific Advisory Board, provided such faculty member complies with the limitations on income and equity holdings while conducting clinical research for or receiving sponsored research support from such company.
- Serve as a director, subject to periodic review by HMS for conflicts of interest requiring management or elimination (Note: as the faculty member's authority within HMS increases so will the scrutiny applied by HMS).
- Be a founder, provided such faculty member (A) complies with the limitations on income and equity holdings while conducting clinical research for or receiving sponsored research support from the company he or she has founded and (B) does not devote more than 20% of his or her time to the company.
- Hold a financial interest in such company provided the faculty member is not conducting research on the company's Therapy or does not have research sponsored by the company.
- Conduct clinical or pre-clinical research for such company, provided such faculty member complies with the limitations on income and equity holdings.

Takeaway for Life Science Companies

Applicable to Existing Relationships. Subject to potential transition periods for implementation, the revised Conflicts Policy will apply to relationships with HMS faculty in existence on January 1, 2011. Therefore, you should review your current relationships with HMS faculty to make sure that the relationship doesn't need

⁴ The PHRMA Code on Interactions with Healthcare Professionals (the "PHRMA Code"), the ADVAMED Code of Ethics on Interactions with Health Care Professionals (the "ADVAMED Code") and Massachusetts law (M.G.L. ch. 111N) (the "Massachusetts Gift Ban") also have similar prohibitions on gifts, meals and travel.

FABBRILAW^{LLC}

to be modified in light of the revisions to the Conflicts Policy. Don't assume that HMS faculty members will know whether a relationship complies with the revised Conflicts Policy.

Manage Public Disclosure. You should be aware that the amount you pay HMS faculty members (although not the specific and detailed nature of the research or services) will be publicly available. If you are paying different Scientific Advisory Board members, consultants or researchers different amounts for similar work, the disclosure of this information may raise issues among these SAB members, consultants or researchers who feel they are not being appropriately compensated. In addition, if a particular HMS faculty member is renown in a certain area of research, the mere disclosure of a relationship with such faculty member could signal to competitors or the market the direction of your research before you are ready to disclose it.

Broader Gift Ban. Although the PHRMA Code, the ADVAMED Code and the Massachusetts Gift Ban apply stringent restrictions and/or ban gifts, meals and travel to healthcare providers and practitioners, the revised Conflicts Policy will apply not only to healthcare providers and practitioners, but to all HMS faculty, including those that do not practice medicine, such as Ph.D.s and bench scientists. Therefore, you should consider whether to revise your policies and controls to reflect this broader applicability.

Plan and Regularly Review Relationships. Finally, you should consider the nature of the relationship you want to have with an HMS faculty member, short term and long term, prior to entering into a relationship. In particular, consider how the six and twelve month wash-out periods may affect your ability to conduct planned activities with HMS faculty. If the value of your relationship with an HMS faculty member is based on factors such as his or her (i) knowledge of a specific area of science or drug development, (ii) contacts within academia, industry or regulatory circles, or (iii) experience with advising life science companies, then service as a consulting, scientific advisory board member or board member may be most appropriate. If the value of your relationship with an HMS faculty member is based on factors such as his or her (A) ability to conduct testing with unique models or testing methods, or (B) strength as an enroller of subjects in a clinical trial or a thought leader for communicating the results of clinical trials in which he or she participates, then sponsoring research with such faculty member or engaging or involving such faculty member in clinical research may be most appropriate. It will be difficult to engage HMS faculty members in both a consulting-type relationship and a research (pre-clinical or clinical) relationship concurrently or within the applicable six or twelve month wash-out period. Even if a consulting relationship complies with the income and equity limitation, factors such as the changing value of equity held in a public company or potential payments under institutional royalty-sharing arrangements can endanger compliance. Therefore, significant planning and regular review of a relationship with HMS faculty may be necessary.

William Fabbri
617-875-7190
wfabbri@comcast.net

©2010 Fabbri Law, LLC

Because of the generality of this update, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on particular situations.

Exhibit A

Types of Relationships within Each Category under Current Conflicts Policy

Category I – Impermissible relationships

Relationships covered under Category I include:

- faculty participating in clinical research on a compound, drug, device, diagnostic or procedure (“Therapy”) owned by or licensed to a life science company from or in which the faculty member or his or her family (i) receives consulting fees, honoraria or similar fees of \$20,000 or more per year or (ii) holds any stock if such life science company is private or \$30,000 or more of stock if such life science company is public or (iii) has any other financial interest in such company (other than certain supervised sponsored research or post-market royalties under an institutional royalty-sharing policy).
- faculty receiving sponsored research support⁵ supervised by Harvard or an HMS affiliated hospital for clinical or non-clinical research from a life science company in which the faculty member or his or her family holds any stock if such life science company is private or \$30,000 or more stock if such life science company is public.⁶
- faculty holding an executive position with a for-profit life sciences company.
- faculty serving on the Board of Directors of a life science company and (i) participating in clinical research on a Therapy owned or exclusively licensed or marketed by such life science company, or (ii) receiving sponsored research from such life science company in which such faculty has an equity interest.

Category II – Relationships requiring disclosure, review and approval

Relationships covered under Category II include:

- Conducting research externally that would ordinarily be conducted within Harvard;
- Participating in an FDA or insurer committee to consider clinical research regarding a Therapy owned or licensed by a life science company in which the faculty member or his/her family has a financial interest;
- Making clinical referrals to a life science company in which the faculty member or his/her family has a financial interest;
- Having a financial interest in a life science company that competes with services provided by Harvard or the HMS affiliated hospital with which the faculty member is affiliated;
- Publishing or presenting research results or expert commentary on a subject without disclosing any financial interest in a life science company that owns or licenses the Therapy being reported or discussed or which sponsors the research; or
- Being an applicant for Public Health Service or National Science Foundation funding while having or a family member having a significant financial interest which could directly and significantly affect the design, conduct or reporting of the federally funded research.

⁵ Material transfer agreements must be reviewed to determine whether the provision of materials constitutes sponsorship.

⁶ A faculty member’s ability to hold up to \$30,000 in stock in a public life science company without the relationship being treated as an impermissible Category I relationship requires that there is no relationship between the acquisition of the stock and the relationship (i.e., the equity must be acquired in an arms-length transaction and the purchase or acquisition decision must be completely independent from the relevant research).

Category III – Relationships ordinarily allowable following disclosure and potential oversight

Relationships covered under Category III include:

- Participating in clinical research on a Therapy developed by that faculty member or a member of his/her family that does not fall under Category I
- Assigning students, post-docs or other trainees to a project sponsored by a for-profit life science company in which the faculty member or family member of the faculty has a financial interest, unless the project would fall under Category I
- Serving on the Scientific Advisory Board of a life science company from which that faculty member or a member of his/her family receives Harvard or HMS affiliated hospital supervised sponsored research support or with which Harvard has a substantial contractual relationship, unless the service would fall under Category I
- Assuming an executive position in a not-for-profit life science company.

Category IV – Relationships routinely allowable

Relationships covered under Category IV include:

- Receiving royalties for published scholarly work and other writings
- Receiving post-market royalties under institutional royalty sharing policies