

Appendix K

Commission Recommendations

Gifts

Recommendation #1:

- **Partners policy should prohibit all gifts (including meals and funding for meals) provided directly to staff members (physicians and non-physicians) by pharmaceutical companies, medical device companies, or other vendors.** Partners should also prohibit such companies and vendors from providing to the institution any items for the personal use of staff members, as well as meals and funding for meals for individual staff members, whether provided on a Partners site or off-site.

Drug Samples

Recommendation #2:

- **Partners should develop a mechanism for distributing free drug samples to patients only through the pharmacy or some other centralized system.**
- Once such mechanisms are in place, Partners policy should prohibit physicians from receiving free drug samples directly from pharmaceutical companies.

Industry Representative Access to Partners Sites

Recommendation #3:

- **The current Partners policy of prohibiting industry representatives from having access to Partners sites and Partners staff without prior appointment should be revised to require that all such appointments must be by prior written invitation, specifying the purpose and duration of the visit.** The Commission considered it important to continue to allow industry representatives on site in particular situations – for instance, in providing assistance in the use of devices, given their specialized knowledge of the proprietary technology involved. This access should be appropriately monitored and structured by the host institution.

Institutional Purchasing

Recommendation #4:

- **Partners should institute a more proactive system for managing conflicts in institutional purchasing transactions by making the following changes:**
 - **Significant transactions may not be entered into unless and until the decision-maker has determined from the Partners COI database (which is discussed in Recommendation #17) whether any relevant Partners individuals have a significant relationship with the company involved.**

- The COI Committee (also discussed in Recommendation #17) shall determine the criteria for “significant transactions,” “relevant individuals,” and “significant relationship,” guided by the principles that this system must not allow interested persons to be the final decision-makers, and may recognize de minimis exceptions for informational purposes or to make the system practical and amenable to implementation and compliance.
- If a conflict exists, the decision maker must document consideration of the conflict by using one of the two template memos attached as Appendix F.

Clinician-Level Decisions on Product Use

Recommendation #5:

- **Partners should institute a policy that identifies, and establishes a process for managing, significant financial interests held by physicians in companies that make products that they prescribe or use in their clinical practices.** The policy should include disclosure, including to patients, as well as additional management mechanisms for situations where physicians hold financial interests above a de minimis threshold of \$20,000 of income per year or \$30,000 in equity interest in publicly traded companies.¹

Institutional Royalties from Institutional Sales

Recommendation #6:

- **Partners should require that royalties derived from the sales of a particular drug or device at the institution be excluded from the royalty payments to the institution.** The Commission agreed to the principle that neither the institution, nor its employees, nor the individual physician should receive any benefit from sales to the institution granting the license, thereby reducing the appearance of a conflict. This recommendation could be implemented by ensuring that licensing agreements exclude royalties on sales to Partners institutions (and thus would be implemented by Partners Corporate Sponsored Research and Licensing) or by having these royalties donated to a specific approved charity.

Industry Support of CME

Recommendation #7

- **Partners institutions may not accept industry funding for educational programs except through the Educational Review Board or President’s Fund mechanisms described below.** (Industry funding for fellowship programs is addressed in Recommendation #8.)
 - Partners institutions may accept industry funding, either directly or indirectly through intermediaries, for a specific institutional educational program (whether

¹ De minimis values should be reviewed periodically to ensure the levels remain appropriate.

for CME credit or not), only if that program has been reviewed and approved by the Partners Educational Review Board (ERB).

- The ERB shall be created in accord with Recommendation #17, and shall be responsible for approving, monitoring, and reviewing industry-supported educational programs. The ERB shall have a status and authority similar to that of the Institutional Review Board for human subjects research², and it shall include prominent individuals who are unaffiliated with Partners. Partners should consider having the ERB assume the responsibilities of a CME-accredited provider.

- To approve industry support of a specific educational program, the ERB shall require compliance with at least the following conditions, as well as any others determined by the ERB:
 - Funding for a specific program must come from more than one company, with no single company being responsible for a specific topic area. The policy should define specific, extraordinary circumstances where the ERB shall have the authority to make exceptions to this rule, for instance, for a one-time gift that creates an endowment, the interest of which will fund ongoing programs.
 - Any gift of equipment for a specific educational program may be acceptable, but must be reviewed and approved by the ERB.
 - Any program that involves conferences or lectures, or other forms of presentations, must meet ACCME or comparable standards (as determined by the ERB), whether for CME credit or not.
 - The ERB will review the relevant financial relationships of all individuals providing content, including speakers from other institutions.
 - The ERB will conduct a more specific content review of presentations or programs that are deemed to present particular concerns about conflicts based on: 1) the monetary value of any faculty connections to industry sponsors of the program, with a de minimis threshold of \$20,000 of income per year or \$30,000 in equity interest in publicly-traded companies³; 2) the amount and/or source of industry funding for the presentation/program; 3) the accrediting body; and 4) any other factors determined by the ERB. In such instances, all materials for the presentation/program must be submitted to the ERB (or a subcommittee of the ERB) for prior review, to ensure the educational integrity and balance of the proposed program.

² The Commission recognizes that the IRB acquires its authority from regulatory sources external to the institution, and so, in that respect, the ERB, which would gain its existence solely by institutional mandate, technically cannot have the same stature. The intent, however, is to create the ERB with a stature as close to that of the IRB as possible, given the different circumstances of the underlying source of creation of the different Boards.

³ De minimis values should be reviewed periodically to ensure the levels remain appropriate.

- A “President’s Fund for Medical Education” should be established at each hospital to support institutionally-determined priorities in medical education. Industry partners will be encouraged to contribute to this fund; however, specific programs will not be identified with specific companies, and a company’s contribution to the President’s Fund must not be targeted or directed by the company to any specific educational program.
 - Educational programs funded by the President’s Fund need to be reviewed and approved by the ERB.
 - The President’s Fund may also include institutional funds and could be used, in part, to support existing educational programs deemed to be institutional priorities that lose industry support as a result of new Partners policies. (See below.)
- In recognition of the importance of industry funding for particular educational programs, the hospitals should work with departments, units, or divisions that will be substantially affected by the new policies to assist them, through the President’s Fund or other sources, during a transition period of up to five years, in maintaining programs that are currently supported by industry at a level of at least \$50,000 per year. To obtain this assistance, the department will need to demonstrate that, as a result of this new Partners policy, the program can no longer access industry funding that is available to other AMCs; that the loss of such funding jeopardizes the continuation of the program; that the institution’s educational mission would be detrimentally affected if the program were not to continue; and that the Partners Education Committee (PEC) and the ERB concur that continuation of the program is appropriate.
 - Existing contracts should be carried out until their termination, but should not be renewed, and no new contracts should be entered into, unless they are consistent with this recommendation.

Industry Support of Fellowships

Recommendation #8:

- **Partners institutions may not accept industry funding for fellowship programs with clinical components⁴ except through the Educational Review Board or President’s Fund mechanisms described below. The requirements of this recommendation shall not apply to merit-based fellowships that are determined by an external jury comprised primarily of academic peers.**
 - Partners institutions may not accept industry funding for a fellowship program unless the fellowship program itself has been approved by the Partners Education Committee. It is the responsibility of Partners institutions to determine how many fellowship slots to offer in various programs.

⁴ This recommendation is not intended to address industry support of fellowships that are solely focused on research and have no clinical component – i.e. no direct clinical care component and no clinical research component.

- In addition, any industry funding for the support of a specific fellowship program must be reviewed and approved by the ERB (as described in Recommendations #7 and #17).
- To approve industry support of a specific fellowship program, the ERB shall require compliance with at least the following conditions, as well as any others determined by the ERB:
 - The proposed funding must be consistent with institutional targets for fellowship slots to be offered in various programs.
 - Funding for a specific fellowship program must come from more than one company, each of which must provide a significant level of support. The sources of funding should not be known to specific trainee(s). Exceptions to the multiple funder requirement may be granted in the manner described in Recommendation #7.
- A “President’s Fund for Medical Education” (as described in Recommendation #7) may also be used as a vehicle to support institutionally-determined priorities for fellowship programs.
 - With respect to fellowship programs, the President’s fund shall operate in a manner similar to and with similar restrictions as described in Recommendation #7, except that individual fellowship programs will not need to be reviewed and approved by the ERB, as they will be reviewed and approved by other institutional mechanisms that over see fellowship programs.
- In recognition of the importance of industry funding for particular fellowship programs, there should be a similar transition period, with similar hospital support, for fellowship programs substantially affected by the new policies, as described in Recommendation #7 for non-fellowship educational programs. Existing contracts for fellowships should be handled similarly to existing contracts for non-fellowship educational programs, as is also described in Recommendation #7.
- **Partners should not accept industry funding to support observerships, preceptorships, or similar mechanisms which allow non-Partners physicians and company staff to receive training by observing and participating in Partners activities.** Exceptions may be granted by the ERB for such programs if they are deemed to be particularly supportive of exceptional charitable goals (for example, where the observers are physicians from foreign countries), provided that the program is appropriately insulated from industry influence. Under no circumstances shall the observers be accompanied by anyone associated with the sales or marketing department of a company. This recommendation is not meant to prohibit pharmaceutical or medical device company representatives from coming to our institutions to teach our physicians or other health professionals. (See Recommendation #3.)

Definition of Clinical Research

Recommendation #9:

- **Partners should work with HMS to modify the definition of clinical research, as currently defined by HMS COI policy, and, once modified at HMS, implement similar revisions at Partners.** The new definition should exclude from the HMS I(a) definition of clinical research certain defined types of research that present very little risk to the human subjects involved in the research. Possible examples include certain types of research using human tissues and fluids, and medical record reviews.

Framework for Evaluating Research Conflicts

Recommendation #10:

- **Partners should refine its current rules-based approach to incorporate a more robust tiered approach to evaluate research conflicts of interest, in both clinical and non-clinical research.** This tiered approach would specify certain low-risk circumstances to be acceptable; certain high-risk circumstances to be prohibited (maintaining the current thresholds from the HMS COI policy for the “I (a) rule”, but with the more limited definition of clinical research as previously described); and middle ranges of circumstances that would warrant different levels of review, in some cases requiring that an exception be obtained before research may proceed. (See Appendix J for further detail.) All financial and significant associational interests will continue to be disclosed.

Definition of Financial Interest

Recommendation #11:

- **Partners should continue to exclude royalties flowing through the institution from the definition of “financial interest” for the purposes of determining whether the investigator is prohibited under the HMS 1(a) rule from participating in a particular clinical research project.** Partners employees should, however, continue to disclose any royalty payments they receive or to which they are entitled. Royalties do not include milestone payments; such payments should be included in the definition of “financial interest.”
- Royalties that do not flow through the institution, but flow directly from a company to an individual, may be treated as royalties flowing through the institution (i.e. excluded from the definition of financial interest as noted above), but only if the individual makes a specific request to the institution to review such an arrangement and presents information that allows the institution to conclude that the financial arrangement is comparable to what would have been agreed to in an institutional agreement with the company. Before direct company-individual royalty arrangements are treated in the same way as royalties flowing through the institution, they should be reviewed by the COI Review Committee to ensure that the royalty payments are appropriate. This will be a significant administrative burden, so the policy must be clear that the burden is on the

investigator to make the request and to present the necessary information supporting a conclusion that the royalty arrangement is appropriate.⁵

The Role of Institutional Officials

Recommendation #12:

- **An institutional official who holds a Board of Directors or other fiduciary position with any biomedical company, or any other company that does, or is reasonably likely to do, significant business with any Partners entity⁶, may only retain personal cash compensation, not to exceed \$5,000 per day, equivalent to the fair market value payment, based upon time spent on Board meetings, that would be appropriate for a consulting or scientific advisory board relationship between the individual and the company. The institutional official holding the fiduciary position may not retain any equity compensation from that company for serving in that position.** The standard compensation for such a position (including equity) in excess of the allowed level may be donated to a non-Partners charitable organization, subject to restrictions deemed appropriate by the COI Review Committee.⁷ (See Recommendation #17.)
- Institutional officials may not acquire any additional equity in any biomedical company, other than through mutual or pension funds over which the institutional official has no control.
- In addition to maintaining current rules about disclosure and permission, and adding the additional process relating to institutional purchasing contracts as described in Recommendation #4, all relationships between institutional officials and industry should be reviewed and approved by the COI Review Committee (see Recommendation #17), which shall have the authority to approve, disapprove, or approve with restrictions as it determines appropriate, and to adopt additional substantive rules relating to the relationships between institutional officials and industry.
- Partners policy should address the financial and other potentially conflicting interests of supervisors of individuals conducting research, even when those supervisors are not institutional officials.⁸

⁵ This policy change implicates HMS' conflict of interest policy and therefore would require HMS to modify its policy; Partners should work to achieve such a modification.

⁶ "Significant business" for companies other than biomedical companies would need to be defined.

⁷ In this context, it is considered that donating the compensation to a Partners-affiliated institution creates the appearance of continuing conflict and therefore should not be permitted.

⁸ For example, where a lab director who is not an institutional official and who has a significant amount of equity in, and/or has a fiduciary position with, a company, when the lab director's direct reports are participating in research sponsored by or on the technology of the same company.

Consulting

Recommendation #13:

- **With regard to Partners employees' participation in outside activities:**
 - **Partners should require COI Review Committee approval in order for full-time staff or employees to serve (or continue to serve) on a Board of Directors, or in any other position with fiduciary responsibility, in a biomedical company.** Any approval granted may be subject to such restrictions as the Committee deems appropriate, including restrictions on compensation. (See Recommendation #12 for stricter policy applying to institutional officials.)
 - **Partners should retain the 20% cap on professional effort dedicated to consulting and other outside activities for full-time staff members.** However, Partners should review the thresholds and mechanisms currently set to trigger supervisor review (specifically, the total dollar compensation and the number of agreements per employee) to confirm that these are at the appropriate levels and develop a process that ensures that the reviews occur. Partners should develop better mechanisms to evaluate whether the employee is committing sufficient effort to his/her home institution in light of these outside activities and whether the compensation paid is appropriate for the services performed, whether through enhanced supervisor review, the COI Review Committee, or otherwise. Partners should also consider a more robust way of tracking individuals' consulting arrangements, to more easily identify consulting arrangements that may in total exceed the 20% cap.

Speakers Bureaus and "Ghostwriting"

Recommendation #14:

- **Partners should ban faculty participation in industry speakers bureaus,** which is meant to refer to situations where there is inappropriate company control over or influence on the content of the talk, or where for other reasons, the speaker is acting in an inappropriate manner to further the commercial interests of a company. As the line between inappropriate speakers bureaus and legitimate and valuable academic speaking engagements is often difficult to determine without a review of the content of the talk and an understanding of how it was prepared, determining whether specific situations involve an inappropriate speakers bureau may require case-by-case review by the COI Committee. The Committee shall work to establish clear definitions of the types of situations that should be prohibited on a going forward basis without the need for case-by-case review. For example, giving substantially the same lecture about a company's technology or products more than twice a calendar year and supported by the same company should be considered one form, although not the only form, of a speakers bureau engagement. In consideration of Partners employees who may rely on income from speaking engagements that may be defined as inappropriate, this policy recommendation should be implemented after a one-year grace period (except that engagements involving presentations of slides prepared by the company, or which otherwise indicate inappropriate control by the company, should be banned immediately).
- **Partners should have a policy that expressly prohibits faculty from being listed as an author on a paper ghostwritten by others.**

Institutional Service Contracts

Recommendation #15:

- **Partners should continue to allow institutional service agreements, but should establish a structure to ensure some degree of consistency in how these arrangements are approved and managed, including the mechanisms described in Recommendation #17.** Further attention will need to be focused on this issue.

Other Relationships with Industry

Recommendation #16:

- **Partners should ensure proper administrative oversight for the acquisition and expenditure of all industry support for activities at Partners.** In most cases, it is anticipated that this oversight will be provided by the mechanisms contained in the specific recommendations of this report (for example, oversight of funding for educational programs and for institutional service agreements); or by existing institutional offices (for example, the offices of Research Ventures and Licensing and/or Partners Clinical Research Office for industry support of certain types of research activities). The acquisition of industry support for any activity that is not subject to the oversight of any such mechanism or office shall require the approval of the Department Chairman and the applicable hospital Vice President, who shall also have oversight responsibility for the expenditure of the industry funds related to this activity. Any such support that exceeds \$50,000 per year shall also require approval by the hospital President.

Education, Compliance, and Enforcement

Recommendation #17:

- **Partners should commit the necessary resources to ensure the development of new policies and the successful rollout, oversight, and enforcement of these recommendations. The development of these policies and the implementation of these recommendations should be done collaboratively between the entities and Partners.**
- To ensure a successful rollout, Partners should implement an aggressive educational initiative to inform the Partners community about the new policies and procedures resulting from the Commission's recommendations. Additionally, COI topics should be integrated into the curriculum for fellows and house staff.
- **Ongoing organizational resources for oversight and enforcement should include:**
 - **Establishment of two Committees responsible for key aspects of COI policy: a COI Review Committee to be actively engaged in reviewing and deciding COI cases; and an Educational Review Board responsible for approving, monitoring, and reviewing industry-supported educational programs.** These committees should be positioned at a high organizational level, as befits their vital role.

- Establishment of an administrative office, to report directly to the Partners CEO or his designee, to oversee compliance with COI policies and to provide administrative support for the COI Review Committee and the ERB. This office needs to be allocated sufficient resources to execute this responsibility and shall have the authority to take such actions, including audits, as it deems appropriate to oversee implementation and compliance with COI policies.
- Creation of an all-encompassing electronic COI disclosure and tracking system, including a comprehensive database that catalogues all financial interests, both those held by individuals and those held by the institution, that are relevant to COI analysis.
- **New policies should include clear sanctions, and any programs developed to educate the Partners community about the new policies should highlight the sanctions associated with them.** Noncompliance can be addressed by a variety of sanctions, including suspension or revocation of professional billing, clinical or research privileges, parking privileges, operating room booking times, and/or withholding a bonus/paycheck/pay increase, etc. In the most serious cases, where willful noncompliance with COI policies is clearly established, termination of employment may be considered.