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AND MASSACHUSETTS GENERAL HOSPITAL

Partners Commission on Interactions with Industry

REPORT

April 2009

REPORT OF THE PARTNERS COMMISSION ON INTERACTIONS WITH INDUSTRY

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REPORT OF THE PARTNERS COMMISSION ON INTERACTIONS WITH INDUSTRY

EXECUTIVE SUMMARY

Interactions with industry are fundamental to the mission of Partners and other academic medical centers in supporting research and its translation into advances that improve medical care. Academic scientists and clinicians generate intellectual property that has great potential for benefiting patients, but with very few exceptions, the desired advances in health require the transfer of that intellectual property to, and the deep engagement of academicians with, industry. It is therefore essential to preserve, and perhaps even to enhance, this vital relationship between the academic and industrial sectors of our society.

However, the convergence of a number of factors, internal and external, which have become even more compelling in recent months, led Partners leadership to conclude in the fall of 2007 that it was timely to undertake a review of a number of the types of relationships that Partners has with industry, to ensure that they could continue productively and in a way that met all appropriate ethical standards. This review, undertaken by a Partners Commission on Interactions with Industry (the Commission), focused on the policies germane to those interactions, including those governing potential conflicts of interest (COI). It also included attention to the need for new or enhanced mechanisms to ensure consistent and complete compliance with all existing policies, as well as those now being recommended in this report.

The formal charge to the Commission was to:

- Formulate principles to guide Partners approach to industrial interactions.
- Review Partners relationships with industry, in light of current policies and practices within Partners, as well as at peer institutions.
- Consider the potential need for change in current policies and practices, recognizing that Partners faculty remain subject to relevant Harvard Medical School (HMS) policies.
- Develop recommendations regarding:
 - Modifications to policies and the need for any new policies.
 - Organizational issues, i.e. the governance and staffing necessary to ensure implementation.¹
 - Assessment of budget needs.¹

¹ The charge to the Commission was subsequently revised, and it was agreed that organizational and budget issues would be addressed by a subsequent group that would be appointed to develop implementation plans for the accepted recommendations.

The Commission met for ten three-hour meetings between December 2007 and November 2008, and then interacted by written communication in December 2008 and January 2009. Initial meetings were dedicated to reviewing current Partners policies and practices with regard to industry interactions as a whole, and featured internal and external testimony pertaining to the Commission's charge. Subsequent meetings delved further into policies and practices, focusing systematically on the areas that constitute the mission of academic medical centers: clinical care, education, and research. In addition, the Commission considered the cross-cutting topics of consulting, speakers bureaus, and institutional service contracts. For each of these topics, the Commission articulated Partners objectives in interacting with industry in that area, and then took a closer look at current policies and practices within Partners and among key peer institutions, as well as relevant national policy trends. The final meetings were dedicated to synthesizing the Commission's views and to reviewing potential policy changes, leading to the final recommendations contained in this report. (A complete set of the recommendations may be found in Appendix K.)

The Commission's key recommendations may be summarized as follows:

- Partners policy should prohibit all gifts (including meals) provided directly to staff members by pharmaceutical companies, medical device companies, or other vendors, and should prohibit such vendors from providing to the institution any items for the personal use of staff members, whether provided on a Partners site or off-site.
- Partners should identify, and establish a process for managing, significant financial interests held by physicians in companies that make products that they prescribe or use in their clinical practices.
- Partners institutions should only accept direct industry funding for institutional educational programs (whether for Continuing Medical Education credit or not) and for Graduate Medical Education programs (e.g. fellowships) if approved by a newly-instituted Partners-wide Educational Review Board, which will apply stringent rules to ensure the insulation of funding from content. Partners should also establish a President's Fund at each institution to support institutionally-determined educational priorities, to which industry partners will be encouraged to contribute.
- Partners should refine its current rules-based approach to research-related conflicts of interest to incorporate a more robust tiered approach to evaluate potential conflicts, with certain low-risk circumstances deemed always acceptable; certain high-risk circumstances that would always be prohibited; and a middle range of circumstances that would warrant different levels of review. As part of this approach, Partners should work with HMS to modify the definition of clinical research in the context of COI policy and implement similar revisions at Partners.
- Partners should adopt a more comprehensive policy to address institutional financial interests. As part of this new policy, institutional officials should be held to a higher standard, befitting their organizational role, than other staff members.
- Partners should strengthen oversight of permitted outside activities (e.g., consulting). Partners should ban faculty participation in industry speakers bureaus (as defined in the full report) and should prohibit faculty from being listed as authors on papers "ghostwritten" by others.

- Partners should commit the necessary resources to ensure the successful rollout, oversight, and enforcement of these recommendations, and implement them in close collaboration with the entities. This will require an aggressive educational initiative and substantial ongoing organizational and financial resources, and will include the establishment of two high-level committees responsible for key aspects of Partners COI policies. New policies should include clear sanctions, and these sanctions should be highlighted when the new policies are introduced to Partners staff.

The full report provides background information on the Commission's formation and approach to its work; discusses the Commission's findings and recommendations in each of the areas it considered – clinical care, education, research, and cross-cutting activities; and concludes with a section on implementation.

The Commission's recommendations reflect Partners fundamental commitment to interactions with industry, and they also reflect the opportunity – and indeed the obligation – currently before Partners to recalibrate its policies and procedures so that these ongoing interactions can optimally serve Partners mission and role as a national leader in patient care, education, and research.

REPORT OF THE PARTNERS COMMISSION ON INTERACTIONS WITH INDUSTRY

BACKGROUND

Context for Establishing a Partners Commission on Interactions with Industry

Interactions with industry are fundamental to the mission of Partners and other academic medical centers in supporting research and its translation into advances that improve medical care. Academic scientists and clinicians generate intellectual property that has great potential for benefiting patients, but with very few exceptions, the desired advances in health require the transfer of that intellectual property to, and the deep engagement of academicians with, industry. It is therefore essential to preserve, and perhaps even to enhance, this vital relationship between the academic and industrial sectors of our society.

However, the convergence of a number of factors, internal and external, which have become even more compelling in recent months, led Partners leadership to conclude in the fall of 2007 that it was timely to undertake a review of a number of the types of relationships that Partners has with industry, to ensure that they could continue productively and in a way that met all appropriate ethical standards. This review focused on the policies germane to those interactions, including those governing potential conflicts of interest (COI), and it also included attention to the need for new or enhanced mechanisms to ensure consistent and complete compliance with all existing policies, as well as those now being recommended in this report.

The internal factors prompting this review included:

- A recognition that many of our policies had not been examined for some years, during which time much national attention has been directed to the issue of academic-industry relations.
- An increasing awareness within Partners that current rule-based policies in the research arena were not sufficiently dynamic to appropriately address the variety of potential conflicts.
- A concern that the application of current policies has frequently proven difficult, leading at times to apparent (or actual) inconsistent management within Partners.
- The recognition that systems have been inadequate to assure implementation of and compliance with policies regarding interactions with industry.
- The concern that COIs, whether real or perceived, may be widely publicized and can damage the reputation and lower the esteem in which Partners, its constituent institutions, its physicians, and Harvard Medical School (HMS) are held.

Externally, over recent years a greatly heightened public interest, including congressional inquiries and press attention about COIs in health care, especially research, education, and clinical care at academic medical centers (AMCs), created further incentive for reviewing Partners policies and practices. Widely publicized examples of such conflicts, real or perceived, were seen as potentially erosive of the public trust in academic physicians and their institutions, leading the Association of American Medical Colleges (AAMC), along with the Association of American Universities (AAU), to issue extensive reports on COI in human subjects research. (See Appendices B and C for copies of the 2001 and 2008 AAMC reports.)

By the fall of 2007, many Partners peer institutions, including Boston University/Boston Medical Center, the University of Massachusetts/UMass Memorial Medical Center, Cleveland Clinic, Duke University, Johns Hopkins University, Stanford University, Yale University, University of Pennsylvania, University of Pittsburgh Medical Center, the University of Michigan, the Mayo Clinic, and Washington University in St. Louis, had undertaken a re-examination of their COI policies in light of the 2001 AAMC report and national focus on these issues. In general, these efforts produced tighter and more explicit COI policies at these institutions.

Based on these multiple factors, James J. Mongan, M.D., Partners President and CEO, established the Partners Commission on Interactions with Industry in November 2007, comprised of leaders from across the Partners system and chaired initially by Daniel K. Podolsky, M.D., Partners Chief Academic Officer, and after July 2008, by Eugene Braunwald, M.D., a founding trustee and former Partners Chief Academic Officer.² A list of Commission members is provided in Appendix A.

Charge to the Commission

The formal charge to the Commission was to:

- Formulate principles to guide Partners approach to industrial interactions.
- Review certain types of relationships that Partners has with industry, in light of current policies and practices within PHS, as well as at peer institutions.
- Consider the potential need for change in current policies and practices, recognizing that Partners faculty remain subject to relevant HMS policies.
- Develop recommendations regarding:
 - Modifications to policies and the need for any new policies.
 - Organizational issues, i.e. the governance and staffing necessary to ensure implementation.³
 - Assessment of budget needs.³

² Dr. Podolsky led the Commission through the end of June 2008, but as part of the transition occasioned by his selection to become President of the University of Texas Southwestern Medical Center in Dallas, Dr. Mongan asked Dr. Braunwald to take over leadership of the Commission in July, to guide the completion of the Commission's work by overseeing the determination of its final recommendations and the drafting and ultimate submission of its report.

³ With the change in Commission leadership from Dr. Podolsky to Dr. Braunwald, Dr. Mongan also revised the charge to the Commission, indicating that he now expected to appoint a separate, follow up group after the report was submitted, to focus on implementation issues.

Overview of Commission Approach

The Commission met for ten three-hour meetings between December 2007 and November 2008 and continued its interactions by written communication in December 2008 and January 2009.

The initial meeting on December 20, 2007 set the context for the Commission's work, provided an overview of current Partners policies and practices with regard to industry interactions, and included a discussion of the Commission's charge and work plan. In 2008, the January 24th and February 20th meetings featured internal and external testimony pertaining to the Commission's charge. Drs. David Blumenthal and Thomas Stossel, distinguished Partners faculty who are national thought-leaders on the subject of academic-industry interactions, reflected the range of views held within Partners, while Drs. Harry Greenberg of Stanford University School of Medicine and Michael Camilleri of the Mayo Clinic, leaders responsible for industry interactions at their respective institutions, shared highlights and lessons learned from their recent, highly praised policy revisions. The discussions that followed these four presentations led the Commission to develop a set of overarching principles to guide the group's review of current Partners policies and practices in regard to interactions with industry. (These overarching principles are summarized on page 8.)

The March 20th, April 18th, and May 30th meetings were dedicated to considerations of policies and practices within each of Partners core missions: clinical care, education, and research; in addition, the June 25th meeting included a review of the cross-cutting topics of consulting, speakers' bureaus, and institutional service contracts. For each mission area, the Commission began by articulating Partners objectives in interacting with industry in that area, and then took a closer look at current policies and practices within Partners and among key peer institutions, as well as relevant national policy trends. Specifically, the Commission approached each area by considering five questions:

1. What are we trying to optimize in our interactions with industry in this arena?
2. What is the impact of current Partners policy?
 - o What is current policy at Partners?
 - o How does it help or hinder what we are trying to optimize in our interactions?
3. Should we/can we change our policy to better optimize our interactions with industry?
 - o What is the range of policy possibilities, and where does Partners fit along the continuum?
 - o What are the arguments for and against changes in our current policy, and how do we evaluate them?
4. What additional mechanisms and practices should we consider to facilitate and encourage more positive interactions with industry in this arena?
5. What is needed for implementation, and how can we measure the impact of our changes to policy and practice?

The June 2nd and June 25th meetings focused on synthesizing the Commission's views on all the matters discussed in the prior meetings. The October 10th and November 14th meetings were devoted to reviewing specific potential policy changes, leading to the final recommendations contained in this report. The recommendations represent the majority, and in many cases, unanimous, opinion of the Commission. Where there was a significant minority view held by Commission members, it is indicated in the report.

Events Since the Commission Was Formed

In the time since the Partners Commission was launched, the National Institutes of Health (NIH), stimulated in part by Congressional concerns, has begun a detailed examination of its policies and procedures for dealing with COI, and it has now posted an Advanced Notice of Proposed Rulemaking on COI. At the same time, the Institute of Medicine of the National Academies convened a Committee on Conflict of Interest in Medical Research, Education, and Practice; this Committee held a series of meetings ending in October 2008, and is expected to publish its findings in February or March of 2009. In addition, the Macy Foundation supported a conference on continuing education in the health professions, issuing a report that urged elimination of industry support. (See Appendix D for a copy of this report.)

This past August, Massachusetts Governor Deval Patrick signed legislation⁴ that required the Massachusetts Department of Public Health to promulgate regulations to establish a marketing code of conduct for all pharmaceutical and medical device companies that would be at least as strict as the PhRMA's code adopted earlier in the summer – i.e. payments, in the form of particular gifts from such companies to health care entities, encompassing both individual physicians as well as hospitals, will be significantly restricted. Proposed regulations were issued for review in early December 2008, and they will be finalized in due course. The Commission's recommendations, while not driven by the new legislation, are generally consistent with the direction of the legislation and proposed regulations.⁵

In late August, Stanford University announced that it would no longer accept industry funding for Continuing Medical Education (CME) for specific programs, but would continue to accept industry funding through a central school-wide fund designated for all CME courses. This decision was reported in the press as a reflection of Stanford's concern that an institution's reliance on industry funding of continuing medical education could affect the types of CME courses offered by the institution. More recently, both the Cleveland Clinic and the University of Pennsylvania have announced plans to disclose the financial interests of physicians associated with their institutions on public websites.

⁴ To review the specific legislation that Governor Patrick signed, see Section 14 of Chapter 305 of the Acts of 2008, "Pharmaceutical and Medical Device Manufacturer Conduct".

⁵ The Commission recognizes that when regulations implementing the state legislation are finalized, Partners policies will need to be reviewed to ensure that they are consistent with the regulations, and to the extent that they are not, revised to be in complete accord.

COMMISSION FINDINGS AND RECOMMENDATIONS

(As noted in the Executive Summary, a complete set of the recommendations may be found in Appendix K.)

Overarching Principles

The Commission determined at the outset of its deliberations that it needed to establish a set of overarching principles to provide a framework for Partners interactions with industry and to guide the Commission's review of current policies and practices in each area. As a first principle, the group agreed that its work should proceed in the context of a shared belief that interactions with industry, properly managed, are fundamentally important for successfully fulfilling our academic mission. In this context, Partners policies and practices governing industry interaction should encourage and facilitate interactions where there are clear and strong benefits, and where the potential risks of COI, including the real or perceived betrayal of public trust, and potential harm to the esteem in which Partners institutions are held, are minimal. Conversely, Partners should avoid interactions where the potential risks clearly outweigh the potential benefits, and Partners policies should be structured to enable judicious and efficient management of the gray area between these two ends of a spectrum.

The Commission expects that its recommendations will be applied to Partners entities beyond the academic medical centers in a way that is consistent with determinations that have been made for other Partners policies on similar issues.

Clinical Care

The Commission reviewed industry interactions in the clinical care arena in two categories. First, the Commission considered industry interactions where industry representatives seek to educate and influence individual physicians' prescribing decisions, specifically via gifts, free samples, company presentations or meals, and direct access to clinicians. Second, the Commission discussed interactions with industry where individuals who might have a COI make decisions regarding the purchasing and/or use of products.

Industry Marketing Practices and their Influence on Prescribing

Substantial public attention has been paid to the pharmaceutical/medical device industry marketing practice of providing small gifts, meals, and drug samples to physicians, particularly since the publication of an article in JAMA in 2006, raising concerns about some aspects of these practices and urging stricter COI policies at AMCs. (See Appendix E for a copy of this article.) The Prescription Project was launched by Community Catalyst, a national non-profit advocacy organization, in partnership with the Institute on Medicine as a Profession (IMAP) and with funding by the Pew Charitable Trusts, to promote the recommendations espoused in the JAMA article. Partners was invited by Prescription Project leadership in August 2007 to attend a meeting of Massachusetts AMCs regarding conflict of interest policies, and has since participated in several such meetings. A number of peer institutions, including Stanford University, Yale University, University of Pennsylvania, University of Pittsburgh Medical Center, and the Mayo Clinic have already taken steps to eliminate gifts and meals. Locally, in collaboration with the Prescription Project, Boston University/Boston Medical Center, Tufts University/Tufts Medical Center, and University of Massachusetts/UMass Memorial Medical Center have instituted strict

policies over the past year that limit interactions between physicians and industry representatives.

Gifts

Current Partners policy places limits on, but does not prohibit, the receipt of gifts from pharmaceutical companies, device companies, and other vendors; specifically, gifts that primarily serve a patient care or educational purpose (including pens and pads) and are valued at less than \$100 are now considered acceptable. In its deliberations, the Commission concluded that insofar as these gifts have the potential to be perceived as influencing physician behavior, however subtly, the potential benefits associated with the gifts are far outweighed by the costs and risks.

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

In regard to the acceptance of free drug samples, the Commission concurred that the distribution of free samples to patients can be beneficial – e.g. it allows patients to quickly begin therapy with starter packs of drugs, and it obviates the need for a patient with limited financial resources to pay for a long-term supply of an expensive drug that after a short time may be deemed ineffective. However, the distribution of free samples through a mechanism whereby pharmaceutical representatives provide them directly to physicians, who in turn provide them directly to their patients, is not ideal. The Commission therefore affirmed the principle that free drug samples ought to be managed by the pharmacy, not by individual physicians.

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

With regard to the presence of industry representatives at Partners institutions, the Commission considered it essential to continue to allow industry representatives on site in particular situations – for instance, in providing assistance in the use of devices, given the representatives' specialized knowledge of the proprietary technology involved. However, the Commission felt these visits should be more closely monitored.

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.

Financial Interests and their Influence on the Purchase or Use of Products

A potential COI arises when an individual who makes—or participates in making, or has the ability to influence – a decision to purchase or use particular products at an institutional or individual clinician level, also has a financial interest in, or another association with, the vendor of such products. (For simplicity of drafting in this section, the term “financial interests” will be considered to include associational interests, such as board memberships, as well.)

Institutional Purchasing

For institutional purchasing decisions, current Partners policy makes it clear that an individual who has a financial interest in a company is not allowed to be the one to make a final decision about whether to enter into a contract with that company. The policy further stipulates that if an individual has a financial interest in a company, and Partners is considering entering into a contract with that company, that individual cannot participate in the final decision-making for that transaction. Such an individual is allowed to have limited involvement in the *discussions and recommendations* (but not the final decision-making) concerning the contract, if the final decision-maker determines that such involvement is appropriate and beneficial.

Under current policy, if the person with final decision-making authority to enter into a contract with a company is aware that there is someone within Partners with a financial interest in the company in a position to influence the final decision, the decision-maker is required to undertake a multi-step process to document the basis for the decision and confirm that there was no undue influence.⁶ This process, while rigorous on paper, is often not triggered, as it relies upon the decision-maker’s actual awareness that a potential conflict exists.

In reviewing current policies for institutional purchasing, the Commission concluded that a more proactive approach was warranted.

Recommendation #4:

- **Partners should institute a more proactive system for managing conflicts in institutional purchasing transactions by making the following changes:**

⁶ Specifically, the decision maker must document that the person with the financial interest had only a limited involvement in the decision and that a competitive bid process was undertaken (or if not, why it was not possible or practical), and must make a written determination that the transaction is fair, reasonable, and in Partners best interest.

- **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

There are currently no Partners guidelines or policies that address the issue of how clinicians choose to implant a particular device over another device, or prescribe one drug over another, either by defining ranges of financial interests that are not permissible, or by requiring disclosure or other management mechanisms. In this regard Partners is not alone – this is a relatively new area of attention for AMCs. The Mayo Clinic is one of the few institutions that has addressed this issue in a recent policy revision. Mayo now issues a blanket disclosure statement to patients acknowledging the institution and/or staff’s potential financial interests in companies whose products are prescribed at Mayo, and Mayo reviews all staff who earn either more than \$10,000 per year or 20% of their salary from a given company to assess and manage any conflicts.

Stanford has recently added clinical care conflicts to its annual disclosure process: all physicians are asked if they have a financial relationship with the manufacturer of a product that they recommend or prescribe to their patients, and the respective Chief reviews all cases above a de minimis of \$10,000 per year. In addition, Stanford is requiring all vendors to provide a list of all Stanford employees who have a financial relationship with the company before Stanford will enter into a purchasing relationship with such vendors. The Cleveland Clinic has recently updated its publicly-accessible online physician biographies to include each physician’s consulting income, royalty payments, equity, fiduciary roles, and inventor shares over a certain threshold. To date, the Cleveland Clinic has not required that physicians disclose the monetary value of their interests, but the Clinic has plans to implement this requirement in the future. The University of Pennsylvania and its affiliated health system have announced a plan to publicly disclose physicians’ interests as well, but have not yet done so.

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.⁷

⁷ De minimis values should be reviewed periodically to ensure the levels remain appropriate.

Institutional Royalties from Institutional Sales

Finally, the Commission discussed whether institutional royalties earned on the sales of drugs or devices to patients at Partners-affiliated hospitals (or otherwise used within our institutions) generated a potential conflict of interest. While the Commission did not believe such royalty payments were likely to influence purchasing decisions, the group felt it was important to eliminate even the appearance of conflict.

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.

Education

Industry has historically provided financial support for educational and training activities, and the Commission examined industry support at Partners for continuing medical education (CME), for a broad range of non-CME activities, for fellowships, and for the education of non-Partners staff at Partners sites (e.g., observerships, preceptorships, and vendor-specific training for non-Partners staff).

In its deliberations, the Commission weighed the educational value of industry-supported programs, and considered whether it was possible to insulate completely the influence of the funding from the content of the education, which it considered a precondition for continuing to accept industry support. Although the group's recommendations in this area were not unanimously approved, they do reflect a strong consensus that was developed after sustained and robust discussion of these important issues.

Industry Support of Continuing Medical Education and other Educational Programs

Industry support of education has come under increasing scrutiny in recent months, with some expressing the concern that such funding may affect the substance of medical education. Continuing medical education (CME) is a particular concern, and has been a focus of Senator Grassley's current investigation of industry-AMC relationships. The AAMC and Macy Foundation have recently recommended substantial changes in the current approach to industry support of CME,⁸ and national trends suggest that AMCs are likely to heed these

⁸ The AAMC issued a report in 2008 recommending that manufacturers support CME only by contributing to a central repository, which would then disburse funds to ACCME-approved programs. The Macy Foundation issued a report in January 2008 recommending that accredited organizations that provide CME should not accept any commercial support from pharmaceutical or device companies, whether provided directly or indirectly, and suggested that this be implemented over a five-year period. (See Appendix D.)

recommendations and will therefore be placing further restrictions on industry support of CME.⁹

Current Partners policies and guidelines governing interactions with pharmaceutical and device companies state that all accredited CME programs supported by industry must be in compliance with ACCME's Standards for Commercial Support. (See Appendices G and H.) However, the Partners policies and guidelines go further, including limiting access of industry representatives at educational events, promoting the practice of discussing more than one company's product at an educational course to prevent the appearance of endorsing a single company's product, and charging participants reasonable tuition to attend industry-supported courses.

Pharmaceutical and device companies sponsor a range of educational activities beyond CME, including support for educational events for which CME credit is not available, visiting speakers at a non-CME event, educational materials and equipment, websites and newsletters, and phone consultation services. Partners policies and practices do not explicitly apply all ACCME standards to non-CME education and training activities as some peers have begun to do, although they go beyond ACCME standards in many aspects.

The Commission became aware that industry funding of CME and other non-fellowship educational programs is disproportionately distributed across departments, and the group was concerned that an absolute prohibition of industry support could impair important programs. At the same time, the Commission felt more needed to be done to deflect potential criticism that the content of programs was not fully insulated from outside funding sources. With some key restrictions and more rigorous oversight, including reviewing the content of proposed industry-supported programs that pose any concern, the Commission concluded that industry funding of educational programs was still acceptable.

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 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 research,¹⁰ and it shall include

⁹ Stanford announced in August 2008 that it will only accept pooled funding from industry for CME. Sloan Kettering is the first peer institution known to have completely eliminated industry support of CME; it has reported no ill effects from the elimination of industry support, and indeed has earned abundant praise for taking this step. (Oregon Primary Care Physicians and the Massachusetts Psychiatric Society have also reportedly stopped accepting industry support for CME.)

¹⁰ 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

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 companies¹¹; 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.
- 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 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.

¹¹ De minimis values should be reviewed periodically to ensure the levels remain appropriate.

- 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 and Observerships, Preceptorships, and Other Similar Arrangements

Industry support of trainees has the potential to be perceived as affecting those trainees in a subtle but potentially direct and lasting way. The Commission examined industry support of Partners fellowships, as well as industry funding for the training of non-Partners physicians and company employees via observerships, preceptorships and other similar arrangements.

Partners currently accepts industry funding for fellowship programs, but with a number of limitations, including the stipulations that payment cannot be earmarked for a specific individual and that a clinical trainee cannot be designated as an industry-sponsored trainee.¹² It is, however, considered acceptable for industry funding to support specific fellowship programs, creating at least the appearance of a very close relationship between the two. The Commission was also concerned that industry support of specific fellowships may influence the number and type of training slots at Partners – suggesting that industry plays a significant and unintended role in shaping Partners training priorities.

In considering Partners approach to industry support of fellowships, which appears to be consistent with policies at peer institutions, the Commission weighed the benefits and potential risks associated with industry support of fellowships. While the overall amount of industry funding of trainees is relatively small compared to the total investment in education at Partners, the amount of funding varies disproportionately by department. Thus completely eliminating such support would have an asymmetrically detrimental impact on certain programs. At the same time, a majority of the Commission members were concerned about at least the appearance

¹² *Guidelines Regarding Gifts from Industry to Support Educational Programs*. Furthermore, the Partners Education Committee has developed a 14-point document, “Guidelines for Industry Support of Fellowship Gifts” to codify the “case law” regarding the management of these industry relationships. (See Appendix I.)

created in cases where a single company supported a single fellowship program. There was consensus that, where the institution has set pre-determined institutional targets for particular fellowship slots, the concerns about industry funding would be adequately addressed if multiple companies supported a particular fellowship, along with a number of other safeguards.

The Commission did not feel a prohibition of direct, single-source support should apply to merit-based fellowships awarded to Partners health care practitioners by nationally-recognized professional or scientific associations,¹³ since the recipients of these prestigious, merit-based awards are selected by a jury composed primarily of members who do not represent a for-profit industrial entity.

The Commission also supported a prohibition of industry-supported observerships, preceptorships and similar mechanisms, in which Partners receives funding from industry in exchange for allowing non-Partners physicians and company staff to receive training by observing and participating in Partners activities, with possible exceptions to be made for programs with charitable goals.

Recommendation #8:

- **Partners institutions may not accept industry funding for fellowship programs with clinical components¹⁴ 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.
 - 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

¹³ An example is the General Electric-Association of University Radiologists Research Academic Fellowships.

¹⁴ 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.

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.)

Research

Relationships with industry are essential for translating Partners discoveries into improved health care, which is the ultimate purpose of our academic biomedical research enterprise. Without these relationships, many, if not most, promising discoveries would never become products available to the public. Companies provide important funding, critical reagents and other materials, and expertise to Partners investigators, in support of Partners research. Furthermore, Partners collaboration with industry in commercializing technologies results in licensing income that is used to support Partners core research and other charitable missions.

However, as recognized in our policies for decades, financial interests of individual investigators or the institution, in companies supporting or which make products that are the focus of Partners research, present potential conflicts that are undesirable. The Commission thus closely examined Partners policies and practices with regard to clinical and non-clinical research, both at the level of the individual and the institution. The Commission was cognizant of the fact that some types of proposed changes to policies governing individuals that materially change current research

conflict rules would need to be made in parallel with Harvard Medical School, since the source of most of those rules is HMS policy, which governs virtually all Partners researchers through their faculty appointments at Harvard Medical School.

Two main topics emerged from the Commission's discussions on handling conflicts in research: (1) whether the current rules-based approach, with its strict definitions of "clinical research" and "significant financial interest," was still appropriate for our institutions; and (2) what are the correct policies to address institutional conflicts, including those of supervisors and institutional leaders, and to what extent should those policies be identical to the policies that apply to individual researchers.

Applying a Rules-Based vs. an Exception-Required Approach to Potential Conflicts

Harvard Medical School and Partners HealthCare have long followed a strict rules-based approach for certain aspects of COI in the research context, based on precise definitions, for determining which financial interests held by individuals should preclude the individual conducting research sponsored by or on the technology of the involved company. Specifically, Rule I(a) of the Harvard Medical School policy prohibits an investigator from participating in clinical research on the technology of a company while holding any financial interest in that company, and Rule I(b) prohibits an investigator from receiving sponsored research support from a company in which the investigator holds equity. (Partners has an identical counterpart rule to each of these.) Certain "de minimis" financial interests do not trigger these prohibitions, including cash payments of under \$20,000 per year, equity holdings of \$30,000 of publicly-traded stock (with some other conditions), and royalties received through the institution. Additional scrutiny is accorded for federally-funded research, to comply with Public Health Service and National Science Foundation regulations (as well as some private foundations which have adopted these regulations), and all human subjects research, which is reviewed by the IRB.

The Commission discussed whether the current rules-based approach employed at Partners and HMS is the correct one and concluded that, with some refinements, it was.

Definition of Clinical Research

In light of the recommendation to refine the current rules-based approach, the Commission felt it desirable that the definition of "clinical research" be reconsidered. The Commission deemed the current definition, under the existing HMS policy, to be unduly broad, covering situations, such as certain types of research involving human tissue, that do not present significant risks to human subjects. The Commission recommended modifying the language to narrow the definition of clinical research to exclude any research that presents little genuine risk to human subjects.

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

The Commission also recommended refinements to the overall current Partners framework for evaluating COI in research:

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

Along with the refined definition of clinical research, the definition of “financial interest,” including de minimis levels, plays an important role in determining what is prohibited in a rules-based regime, and what is presumed forbidden under an exception-required model. The goal is to identify those financial interests that could be viewed as jeopardizing the integrity of the research and/or the health and safety of human subjects, and properly address them, while maintaining incentives for investigators to be engaged in research and other activities that lead to the commercialization of their discoveries.

The Commission concluded that the current Partners and HMS definition of “financial interest” permitted in the clinical research context, including the current de minimis levels of \$20,000 for income and \$30,000 for equity, appeared to strike the right balance. It was noted that these thresholds were not inconsistent with the NIH de minimis of \$10,000, which applies specifically to the level at which interests must be disclosed. Under the NIH structure, so long as an interest is disclosed, research can generally proceed, possibly with some management. Under the current Harvard/Partners policies, disclosure for NIH grants is always required at the \$10,000 NIH threshold, and in its other COI processes, Harvard/Partners has no threshold, thereby requiring disclosure of any financial interest regardless of value. Therefore, Partners disclosure policies are at least as tight as, and in many instances tighter than, the NIH rules.

The Commission also considered the current treatment of royalties. With respect to the general approach of not considering post-market royalties to be financial interests that count for purposes of determining whether clinical research may go forward, a majority of the Commission was persuaded that royalties warrant less concern than other financial interests. Notably, royalties are earned only if the research leads to a product that is successful in the marketplace; in most cases regulatory approvals are required prior to the product being marketed; and generally, the financial return occurs years after the research has been completed. Thus, there is less of a concern about the possibility of distorting research results for financial gain.

In addition, the Commission discussed the distinction that is currently drawn in Partners policies, between royalty income that flows through the institution (which does not count in the COI calculation), and royalty income that does not flow through the institution, but rather goes directly from a company to an individual (which, under current policy, does count in the COI

calculation). While the Commission appreciated the concerns that led to this distinction, a majority of the Commission felt that it was unjustified to have a policy that categorically stated that all royalties that flow directly from a company to an individual are suspect, since many of the same “safeguards” as described above may exist in those situations as well.

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.¹⁵

Definition and Policies Addressing Institutional Conflicts

The death of Jesse Gelsinger at the University of Pennsylvania in 1999 called attention to the need to address COIs at the institutional, as well as individual, level. In the years following Gelsinger’s death, the NIH, AAU, and AAMC all issued reports with guidelines for managing institutional COIs and research.

The 2002 AAMC report urged AMCs to develop explicit policies addressing COIs at the institutional level. The report identified two types of institutional COIs: those held directly by the institution and those held by key institutional officials. An AAMC update to the earlier report, issued in February 2008, emphasized the “significance of this two-pronged definition,” asserting that *“For individuals in high level positions of institutional responsibility, such as a dean, department chair, or division chief, a conflict between their personal financial interests and the institution’s human subjects research is more than an individual conflict; rather, it constitutes an institutional conflict of interest.”*¹⁶

¹⁵ 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.

¹⁶ *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Studies Research*, AAMC, February 2008.

With some notable exceptions, including Stanford and the Cleveland Clinic, peer institutions have been relatively slow in adopting institutional policies, and most of these have focused on clinical research only. Duke and Hopkins report that they are in the process of developing institutional COI policies for human subjects research.

Partners current policy on institutional conflicts, which has been implemented by PICC, focuses on clinical research only and is limited to the prohibition of clinical research, or the clinical validation of unvalidated technology, if the institution owns company equity that was acquired in a research/technology-transfer transaction. More specifically, the rule states that it is not acceptable for a Partners hospital to conduct clinical research on the technology of a company; or to validate or test on patients the unvalidated technology of a company, when that hospital, or a closely related Partners entity, holds equity in the company that was received outside of normal Treasury investment/Development Office stock acquisitions.

Many members of the Commission expressed the view that, in principle, institutions ought to be held to the same standards as individuals. Members were concerned about a perception of a double-standard resulting from a difference in the rules for individual researchers and the rules for the institution and its officials. However, it was noted that the position and activity of an individual involved in research is significantly different from that of the institution and its leadership. While the institution and leadership can undoubtedly have some influence on which research programs to favor and support, the degree of influence on the outcome of a specific research project is much more distant and detached than that of the individual researcher. Therefore, different rules might be justifiable in various circumstances, as long as the basis for the differences can be articulated. Furthermore, it was noted that Partners has more latitude to define its own rules for institutional conflicts than individual conflicts, which must be done in conjunction with HMS.

The Role of Institutional Officials

It is recognized that relationships between senior institutional officials and industry can be of great value, both for the individual and for his/her institution, and, within appropriate boundaries, are to be not only allowed, but encouraged. However, given that these senior officials have a particularly high level of responsibility and authority within the institution, and that, given these responsibilities, their relationships with industry can create at least the appearance of a conflict with institutional research and other activities, the Commission felt it appropriate for industry relationships of such officials to be held to standards set specifically for these leaders. In this context, "institutional officials" should be defined as presidents, senior vice presidents, department chairs, and other senior officials designated by the president of each Partners institution.

One important instance for considering the standard to which institutional officials might be held is in the case of holding Board of Directors or other fiduciary positions in companies. While a minority of the Commission felt that this practice created undue industry influence (or the perception of same) within Partners and thus should be banned, a different minority saw great benefit to having Partners leaders in these roles and felt the practice should continue to be allowed without new restrictions. The majority of the Commission felt it was on balance desirable for Partners leaders to serve on such Boards, but that their compensation should be capped at a level befitting an academic role.

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 entity¹⁷, 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.¹⁸ (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.¹⁹

¹⁷ "Significant business" for companies other than biomedical companies would need to be defined.

¹⁸ 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.

¹⁹ 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.

Cross-Cutting Activities

The Commission also addressed a number of areas of activity that cut across mission areas, rather than fitting within a single AMC mission.

Consulting

Consulting provides an important forum for Partners faculty to exchange knowledge and information with industry to accelerate advances in medical care. It gives faculty members an opportunity to participate in key aspects of their field outside of the academic setting, while helping them to build a national reputation, which in turn, reflects positively on Partners. However, Partners must ensure that faculty members' outside interests neither eclipse their primary commitment to, nor contribute to a COI with, Partners core clinical, research, or educational missions.

The Harvard Medical School Policy on Conflicts of Interest and Commitment and the Partners Policy on Consulting and Other Outside Activities both limit faculty members consulting and outside activities to no more than 20% of a full-time faculty member's total professional effort. The HMS policy adds an additional, and important, further limitation that the time spent is "not to exceed the equivalent of one working day per week." The Partners policy requires a written agreement for all outside activities with entities that may do business with Partners, including all pharmaceutical and medical device companies, and contains a number of provisions to ensure the relationship is appropriate – including stipulating that compensation is at fair market value and set in advance.

With some minor exceptions, under Partners current policy, all written agreements must be reviewed by the institution to ensure compliance with key policy issues. Supervisor approval is required if the agreement presents "heightened concern." Current policy describes examples of "heightened concern" as including cash income over \$30,000 per year; equity valued at more than \$30,000 or constituting more than 1% of the company's outstanding equity; any fiduciary position; or "other unusual provisions or circumstances (including, without limitation, multiple simultaneous Written Agreements). For all such circumstances, current policy requires supervisor review and approval before an individual can enter into a new arrangement.

A comparison with other academic medical centers found that Partners 20% limit is very much in line with its peers. Notably, however, Partners policy appears to be stricter insofar as all consulting arrangements at Partners require written agreement and review.

Nevertheless, the Commission assessed whether the current system sufficiently guards against conflicts of commitment or interest. The Commission discussed whether the total dollar compensation from consulting ought to be capped, in addition to the percent effort limit. However, it was observed that it would be difficult to set a cap on "fair market value," which varies in light of the high value (and therefore fair market value) to companies who seek advice from world-renowned academicians. Instead, the Commission agreed it made more sense to adhere to the present structure, which sets a threshold of compensation and number of consulting arrangements that require supervisory review for the Partners faculty member.

The Commission concluded that the 20% limit remained reasonable, but felt there should be a closer look at the thresholds that should trigger further review – specifically, the dollar amount and the total number of agreements per employee – as well as the process for reviewing and managing these arrangements.

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"

Speakers bureaus (as described more fully below) and ghostwriting are two distinct activities where faculty members essentially act as part of a pharmaceutical or device company's marketing arm. Given the national attention these activities have received, the Commission decided this topic warranted attention.

Members of speakers bureaus deliver talks on behalf of the company at company-designated forums (often using slides provided by the company). "Ghostwriting" refers to the practice of physicians allowing articles to be published under their names when these articles are in fact written by industry representatives or others who are not listed as authors, and where the physician does not make an appropriate level of contribution to the paper. A number of high-profile media articles have recently detailed such arrangements, and there have been public efforts to curtail these activities. The influential 2006 JAMA article, "Health Industry Practices that Create Conflicts of Interest," by Brennan et al., highlighted these practices, urging AMCs to prohibit them, and the Prescription Project has championed this cause. More recently, the AAMC Task Force on Industry Funding of Medical Education recommended that AMCs should "strongly discourage participation" by their faculty in industry speakers bureaus and prohibit presentations of any kind to be ghostwritten.

Partners does not have a policy that explicitly or directly addresses speakers bureaus, although the Policy on Consulting and Other Outside Activities applies to some extent (e.g., all consulting arrangements require a written agreement, and compensation cannot exceed fair market value). Being listed as an author on a paper ghostwritten by others is to a large extent prohibited by the HMS Guidelines on Authorship, although the policy does not explicitly address industry participation in publication.

Evidence suggests that few institutions currently ban their faculty from participating in speakers bureaus.²⁰ Based on information reviewed by the Commission, it seems that more institutions prohibit being listed as an author on a ghostwritten paper.

The Commission recognized that many speaking activities that discuss company products or technologies are legitimate academic endeavors, including talks that report the results of the speaker's research activities, which often involve a company product or technology. As used in this section, the term "speakers bureau" 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. The Commission also recognized that 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.

As so defined, the Commission held that Partners should ban faculty participation in industry speakers bureaus, given the risk of potential or perceived COI and the lack of any foreseeable benefit vis-à-vis Partners charitable missions. However, the Commission recommended that the policy carefully define what is meant by the term "speakers bureau," to clarify the distinction between such inappropriate activities and legitimate academic activities. With regard to ghostwriting, the Commission held that while Harvard's current authorship policy is a strong one, Partners should have a policy that explicitly bans being listed as an author on a ghostwritten paper.

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.**

²⁰ "Ban Urged on Gifts at Medical Schools," *New York Times*, April 28, 2008.

Institutional Service Contracts

Institutional service contracts refer to arrangements in which the institution provides services to an outside third party that draw on the professional capabilities of hospital personnel. For example, a department may enter into an agreement with a pharmaceutical company to help design a clinical trial, or a radiology department may do readings pertaining to clinical trials conducted at non-PHS sites. In essence, this can be seen as consulting on an institutional, rather than individual, level. While often of value to the institution, these contracts present certain legal risks and a significant administrative burden to handle them correctly.

While these activities are appropriate if managed properly, there is some concern with the increasing scale of these activities at Partners and the current lack of centralized oversight or guidelines – e.g., with regard to defining fair market value for the services. Currently, there is no Partners policy that directly addresses institutional service contracts, and the current process is fairly ad hoc – with VP approval required for individual agreements, but a limited ability to maintain consistent review across agreements and no evaluation of the aggregate level of agreements.

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

The Commission also recognized that while most academic relationships with industry are captured within the scope of the above recommendations, there might be arrangements proposed that do not fit squarely within the predefined categories in this report. For those situations, the Commission proposes the oversight approach noted below.

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

The need for effective policy implementation surfaced repeatedly throughout the Commission's deliberations. Specifically, the Commission discussed the need for better education of staff about Partners policies; greater attention to compliance with policies; and more consistent enforcement of policies, including the imposition of sanctions for violations.

In a number of instances, the Commission noted that the current Partners policy was sound, but that the implementation of the policy was not uniform – for example, in the areas of obtaining institutional review of written consulting agreements, and the standards for supervisor review of outside activities.

The introduction of new and revised policies as a result of the Commission's work will provide an important opportunity for education about Partners policy -- a "teachable moment". An aggressive communications strategy should be put in place before the new and revised policies are instituted. In addition, the Commission recommends that training about COI be incorporated into the curriculum for house staff and medical students (in conjunction with HMS), as some of Partners peers have done. Such training could include a primer on Partners policies, as well as guidance on interacting with industry.

With regard to compliance, the recent implementation of electronic disclosure is an important advance. However, disclosure is just a first step; it is necessary but not sufficient for compliance with policy. There is even some evidence to suggest that disclosure without adequate follow-up may be counterproductive; in his testimony to the Commission, Dr. David Blumenthal cited research suggesting that individuals who disclose industry relationships may feel somehow absolved of responsibility for their conflicts. It thus behooves Partners to make use of the data it now has available electronically to go beyond confirming disclosure, in order to identify and more actively manage potential COIs. This might include linking the COI disclosure database with IRB and technology transfer databases to provide a fuller picture of faculty members' interests, something Hopkins has recently done. In addition, having a COI Review Committee which is actively engaged in reviewing and deciding problematic cases is an essential part of ensuring compliance with the substantive COI rules, increasing consistency and efficiency, and making Partners process more consistent with best practices.

Finally, Partners policy must be strictly enforced. Sanctions for non-compliance should be made clear, and should be acted upon. The specific roles and responsibilities of supervisors and oversight bodies (including PICC, the Professional and Institutional Conduct Committee) should be spelled out in this regard.

The Commission acknowledges that the aforementioned approach to implementation will require a substantial investment in administration and administrative systems. For example, the cost associated with educating all Partners staff about Partners COI policy should not be underestimated. And if a database with individual-held financial interests becomes a useful tool in proactively identifying potential COIs and/or enforcing policies, as the Commission endorses, the creation and maintenance of such a database will require substantial resources. This investment is necessary to ensure that the spirit of Partners policies is fully realized, and the Commission urges that the appropriate funding be allocated towards this end.

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.

PROPOSED NEXT STEPS FOR IMPLEMENTATION

The Commission's work has laid the groundwork for more productive relations between Partners and industry. For this goal to be realized, careful attention must be paid to how the Commission's recommendations will be implemented. The implementation group that Dr. Mongan plans to create will need to flesh out policy details as needed, define the organizational and financial resources required for effective execution of these policies, and plan the rollout of these new policies. Some specific suggestions for next steps follow.

Flesh out policy details

The Commission's recommendations provide clear direction as to how Partners should interact with industry going forward, but need further clarification before new policy documents can be prepared and implemented. The implementation group will need to define key terms more concretely and specify procedures for carrying out the new policies.

For example, the implementation group will need to consider how to define:

- A "significant transaction" for which a decision-maker must document that he or she checked the Partners COI database to identify conflicts held by individuals contributing to pricing conversations (Recommendation #4).
- A "significant financial interest" with respect to interests held by physicians prescribing/using products (Recommendation #5).
- The types of research that are currently included in the definition of clinical research, which should no longer be included in that definition, and the thresholds warranting review for potential research conflicts, per Appendix J (Recommendations #9 and #10).

In addition to defining policy terms, the implementation group will also need to describe procedures for complying with these new policies in greater detail, including:

- The proper contents of, and method of documenting, a written invitation to an industry representative to visit a Partners site (Recommendation #3).
- The specific procedure that a decision-maker needs to follow when a conflicted individual participates in pricing discussions (Recommendation #4).
- The appropriate manner to document that physicians disclosed their interests to patients, if required (Recommendation #5).
- The procedure that needs to be followed when granting institutional approval of arrangements for royalties that do not flow through the institution, so that such royalty payments are excluded from the definition of "financial interest" for purposes of determining whether the investigator is prohibited under HMS 1(a) rule from participating in a particular clinical research project (Recommendation #11).

- A procedure by which consulting arrangements should be tracked and monitored by supervisors (Recommendation #13).

Define administrative needs (organization and financial resources)

As the policy and procedure details are elucidated, the implementation group will need to identify whatever incremental administrative support, both organizational and financial, will be required to successfully carry them out.

Additional administrative support will likely be required, and thus will need to be specified, for at least the following recommendations

- Staffing two new committees: the COI Review Committee and the ERB.
- Implementing a more robust tiered approach to reviewing and managing research conflicts.
- Establishing oversight for institutional service agreements.
- Establishing an office to oversee COI policy compliance.

Insofar as administrative roles are envisioned to accomplish the above tasks, the reporting structure will need to be defined.

In addition to the staffing expense and budget associated with any new administrative roles, substantial financial outlays may be required, and should be quantified, for the following:

- Creating and maintaining a Partners-wide database of individual financial interests.
- Providing transitional financial assistance to departments to replace industry funding of education.
- Educating all Partners staff about new policies and procedures, and incorporating COI education into house staff and medical student training.

Plan rollout of new policies

Finally, the implementation group will need to plan for a successful rollout of the new policies. New staff will likely need to be hired and in place before new policies can go into effect, the COI committee and ERB will need to be established, and an aggressive education campaign will need to be designed and ready for execution in time for the announcement of the new policies. It may be important to create a project management director and team to ensure a smooth introduction of the new policies and systems.

CONCLUSION

Since industry plays a critical role in translating scientific discoveries to improved human health, interactions with industry are essential for academic medical centers to successfully fulfill their charitable missions. Having examined the nature of industry interactions at Partners and peer institutions, the Commission concluded that there was an opportunity, and indeed an obligation, to recalibrate these interactions to better serve Partners mission as an academic health care system.

The Commission's recommendations lay the groundwork for such changes, but much work remains to translate them into solid policies and effective processes. It is hoped that the values and goals reflected in the Commission's recommendations, which are being put forth to promote the best interests of patients, faculty, and leadership associated with Partners institutions, will be realized as fully as possible in the months and years ahead.

APPENDICES

- A. **Commission Membership**
- B. **“Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research,”** AAMC, December 2001
- C. **“Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research,”** AAMC, February 2008
- D. **“Continuing Education in the Health Professions”,** Chairman’s Summary of the Conference, Josiah Macy Jr. Foundation, 2007
- E. **“Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers,”** Brennan et al., JAMA 2006
- F. **Template Memos for Documenting “Conflicted Transactions”,** Partners OGC, September 2008
- G. **“Policy on Interactions with Pharmaceutical and Medical Device Companies”,** Partners OGC, March 2005
- H. **ACCME Standards for Commercial Support, 2007**
- I. **“Guidelines Regarding Gifts from Industry to Support Educational Programs”,** Partners Education Committee, April 1999
- J. **Outline for Proposed Revised Partners Research COI Approach,** Partners OGC, February 2009
- K. **Commission Recommendations**

Appendix A

Commission Membership

Commission Members

Daniel K. Podolsky, M.D. – Chair, November 2007-June 2008
Eugene Braunwald, M.D. – Chair, from July 2008
Dennis Ausiello, M.D.
W. Gerald Austen, M.D.
Barbara Bierer, M.D.
Richard Bringhurst, M.D.
William Crowley, M.D.
Gary Gottlieb, M.D.
Daniel Haber, M.D., Ph.D.
Brent Henry
Michael Jellinek, M.D.
Thomas Kupper, M.D.
Edward Lawrence
Joseph Loscalzo, M.D., Ph.D.
G. Marshall Moriarty
Robert Norton
Scott Rauch, M.D.
Paul Ridker, M.D., M.P.H.
Jerrold Rosenbaum, M.D.
Frederick Schoen, M.D.
Charles Serhan, Ph.D.
Peter Slavin, M.D.
Allen Smith, M.D.
Thomas Thornhill, M.D.
David Torchiana, M.D.
Andrew Warshaw, M.D.
Ross Zafonte, D.O.

Harvard University and Harvard Medical School Representatives

Gretchen Brodnicki (from May 2008)
Margaret Dale (through March 2008)
Isaac Kohlberg, Ph.D.
Richard Mills

Commission Resources

Christopher Clark
Christopher Colecchi
Geoffrey Grant (through March 2008)
Kaley Klanica (from April 2008)
Eileen McCarthy
Pearl O'Rourke, M.D.
Debra Weinstein, M.D.
Nikki Zapol

Commission Consultant and Staff

Jill Altshuler, AltshulerGray LLC
Robin Jacoby, Ph.D.

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.

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

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 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

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.

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.

- 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.

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

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.
 - 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.

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 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.)

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.

- 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

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.

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.

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.