

# White Paper Conflicts of Interest and Academic Industry Relationships

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## 1. Introduction

Harvard Medical School educates physicians and scientists to assume leadership roles in society and to conduct research to improve human health. It should come as no surprise that the integrity of our faculty in the conduct of their clinical, research, and teaching missions is of paramount importance to the School. One potential challenge to our integrity arises from financial conflicts of interest, a topic that is receiving substantial attention in the press and in national oversight and legislative bodies. HMS is actively working to define the problem and address it responsibly, by conducting a thorough review of its Policy on Conflicts of Interest and Commitment. This policy (<http://www.hms.harvard.edu/integrity/>) has been in effect with periodic modifications since 1990.

However, what is sometimes seen as a single problem or issue is revealed upon further analysis to be a complex amalgam of different issues, each with distinct characteristics. Failure to take note of these complexities can result in discussions of conflict of interest topics that are less informative than they could be, sometimes diminishing rather than enhancing the public's understanding of the subject. With this in mind, I offer this statement as a starting point to frame some of the issues around financial conflict of interest for discussion within the HMS community and beyond.

**Who are the HMS faculty and why might they want to interact with industry?** The faculty of HMS are approximately 10,500 members employed by Harvard University or its affiliated academic health centers/institutes. Their goals are to pursue fulfilling careers by conducting innovative research and providing high quality medical education and patient care to benefit the sick and suffering. Our faculty represent an unparalleled source of knowledge and expertise that can be deployed to enhance therapeutic discovery and development. Collaboration with industry can be an important means to accomplish this, and many faculty desire to participate in that process. Despite the potential benefits, some believe that relationships between HMS faculty and industry represent a nearly insoluble problem. Those holding this view assert that such interactions can be so injurious to the public health and welfare as to warrant their prohibition and see many risks with few benefits. Others view these risks as limited and emphasize the benefits. Some go as far as to say that such interactions are required if HMS and its faculty are to have maximal opportunity to improve human health through the discovery, evaluation and eventual introduction and use of new drugs and devices. Although nearly all agree that both benefits and risks exist, the balance of the two is the subject of vigorous debate.

**Risks do exist and must be managed.** Some relationships among our institutions, our faculty and industry create issues that require scrutiny, analysis, institutional guidance, and, in specific cases, prohibition. These issues include both the risk of faculty diluting their effort and commitment to the school or to the institutes and hospitals that are their primary employers, and the risk that financial inducements could cause some faculty to

breach accepted standards of professional conduct, reducing the public's confidence in the endeavors of HMS faculty as a whole.

A conflict of interest (COI), which for purposes of this discussion is defined as a situation in which there is a conflict between the private interests and the official responsibilities of a person in a position of trust (Merriam Webster Online), can present challenges to fulfilling one's duties impartially. Conflicts of interest of all kinds are widespread and inherent to the human experience. Moreover, most conflicts of interest, including financial conflicts, exist without unethical or improper acts resulting from them. One reason for this is that medicine and research have professional codes of ethics in place, and these are largely internalized and adhered to by most. At HMS, we have a proud history of unwavering commitment to these high professional standards of ethical conduct. In fact, our policies and practices that address scientific integrity and professional conflicts of interest have existed long before these topics have come under sharp scrutiny at other academic medical institutions.<sup>1</sup> Nonetheless, as a leader in this area, we must continue to take these risks and potential for harm extremely seriously. We will periodically update and clarify our expectations for faculty behavior, as we are currently doing.

**Our faculty in context.** I have interacted with hundreds of physicians and scientists, as both a faculty member and academic leader, and have been extraordinarily impressed by the high ethical standards of my colleagues. Nonetheless, ethical failures do arise, as they do in all professions. Questionable or overtly unethical behavior on the part of our faculty appears historically to have been caused less by financial inducements than through other motivations, including competitiveness, hubris, sloppiness and, occasionally, antisocial behavior. In most cases, we manage deviations from accepted norms through prevailing social, professional and ethical codes of conduct, supplemented where necessary by institutional rules and, increasingly, by laws. Regarding our faculty, the question is not whether financial interests are appropriate, since such interests are ubiquitous in all professions, but what is the nature of the conflicts that arise from those interests. We should clarify the diverse contexts in which financial conflicts confront our faculty and institutions. The goal is to identify the harms that these conflicts might impose, so that we can promulgate appropriate responses based upon reasoned study and objective evidence. At the same time, we should seek to understand the real risk of harm that could arise as unintended consequences of institutional or legislative responses to COI.

## **2. Diverse arenas relevant to financial COI should be examined and understood independently.**

There is a tendency to conflate disparate issues under the rubric of COI. I will first try to deconstruct some of the diverse issues that can appropriately be considered to fall within the sphere of financial COI.

**Sponsored research and COI.** Industry sponsorship of faculty research at HMS or the affiliated institutes and hospitals is an important element when considering the types of

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<sup>1</sup> When HMS originally adopted the Policy on Conflicts of Interest and Commitment in 1990, it was one of a select group of medical schools to have a comprehensive policy of this kind. Since that time, HMS has periodically reviewed the policy to ensure that it appropriately evolves with the continually changing medical field. In addition, HMS has throughout the years adopted and revised several other policies and procedures addressing scientific integrity in various forms, including [Principles and Procedures for Dealing with Allegations of Faculty Misconduct](#), [Faculty of Medicine Statement on Research Sponsored by Industry](#), [Guidelines for Investigators in Scientific Research](#), [Guidelines for Investigators in Clinical Research](#), [Authorship Guidelines](#), [Guidelines for Editors and Authors of Medical Textbooks](#), [Guidelines for Attribution of Credit and Disposition of Research Products](#) and [Letters of Reference Guidance](#).

financial relationships that universities, academic medical centers and faculty may form with industry. In the past, it has proven useful to distinguish basic, laboratory-centered research from research involving human subjects, although the separation of these spheres sometimes blurs. The existing HMS Policy was initially drafted largely to address financial COI in sponsored research, rather than in education and clinical care.

Sponsored research agreements provide funds to support laboratory research when the research question is of interest to the faculty member as part of his or her academic program, and is also of interest to a company. Such sponsored research is conducted under an explicit written agreement developed between the company and the institution (HMS or one of its affiliates), with input from the faculty member. The HMS Statement on Research Sponsored by Industry demands and requires freedom for the faculty member to design and conduct his or her own research, and, perhaps most importantly, freedom to publish the results. HMS does not approve sponsored research agreements that allow a company to control or suppress the direction of the research or the data produced.

All sponsored research agreements are entered into by our institutions and HMS faculty with the primary goal of obtaining funding for ongoing academic research to pursue new knowledge, not because of the remote possibility of future financial gain from product royalties or other income streams. In the rare event that sponsored research does produce such revenue to the institution, the proceeds are typically divided among the institution, the investigators (PIs) and their labs by a distribution formula in place at each institution.

NIH funds the vast majority of our sponsored research, and non-profit foundations fund a much smaller but still significant fraction. Why should sponsorship of research by companies be desired, when NIH and other funding sources exist? Most faculty, even the best funded, have some ideas and projects that will not be funded by organizations like NIH, for a wide variety of reasons independent of the quality and importance of the proposed work. In this light, industry-sponsored research is another important means for faculty to support their research aspirations. Industry-sponsored research can also provide faculty access to unique reagents and tools possessed by the company and can create stimulating interactions with company scientists who may possess unique skills and knowledge. Interactions with companies may provide stimulating intellectual engagement with areas of biotech or pharmaceutical science and development that would otherwise not be available. Many faculty who have research interactions with industry believe that such interactions facilitate their ability to have a greater impact on the future health of their patients through discovery, which is an important motivation and professional benefit. Finally, Congress and the government through the Bayh Dole Act actually direct universities to have certain relations with industry in order that inventions that arise through federal funding benefit the public.

For the most part, there is broad support for industry-sponsored basic research agreements, although some have expressed concerns. Some propose that industry-sponsored research is less meritorious than research funded by NIH or foundations and might thereby dilute the quality of the faculty research effort. However, we normally allow such research decisions to be made by faculty, in full light of their research interests and career goals and aspirations. Others believe that the academy should only pursue scholarly research and that “applied research,” or research with the goal of developing a practical application, is more suited to industry or less elite academic settings. This view has been much less prevalent in recent years, though some adherents remain. Some are concerned that basic research funded by industry is more likely to be manipulated and dishonest, though evidence to support such a belief is lacking, and, in

fact, the evidence suggests that precisely the opposite may be the case. It would be useful if a thoughtful evaluation of these issues, relying on empirical evidence, could be obtained.

**Clinical research and COI.** Agreements for sponsored research involving human subjects are also common in medical schools and hospitals. The issues are largely the same as those for basic research, with one exception: the researchers have direct interaction with patients. There is, therefore, a concern that a faculty member's financial interest in the outcome of the research may negatively affect patient welfare and standard of care. Generally, if there is no personal outside financial interest on the part of the faculty member, there is limited concern about the propriety of such a sponsored clinical research agreement. It should be remembered, however, that a researcher's desire for recognition, grant funding and promotion are sources of potential bias and COI quite apart from outside financial involvement, and these are not typically identified within our COI framework. The research itself is reviewed by an Institutional Review Board (IRB) and is conducted under IRB oversight. The IRB process should be one important locus where financial interests are assessed. If agreements between academia and industry for sponsored clinical research were not possible, then company-sponsored clinical research would rarely be overseen or led by academic physicians, who have much to add to the process.

When the physician conducting the clinical research on a technology owned or contractually obligated to a company has a simultaneous personal financial relationship (whether from consulting income, stock ownership or any other payment) with that company, further issues do arise. The concern here is that such a financial connection might consciously or unconsciously induce the physician to make decisions that might not be in the best interest of the study subject, or alternatively, create the appearance that such an outcome was possible, thereby potentially undermining trust in the profession. Responding to this concern, current HMS rules limit the amount of financial interest in such cases to a *de minimus* amount, with no exceptions. Many other peer institutions do allow the possibility of greater financial relationships while conducting clinical research under specific oversight plans.

One counterargument to our current prohibition beyond the allowed *de minimus* might be that for some types of research, such as investigator-developed devices, the character and complexity of the research is such that only the "inventor" may be capable of doing the initial studies. If so, exceptions to the prohibition, allowing greater financial interest with strict oversight, might offer society and human health a greater benefit than an outright ban of the practice would. A true risk/benefit analysis of allowing versus limiting such situations has never been established and is a worthy subject for study. In addition, the selection of a specific *de minimus* level may seem arbitrary, as there are no empirical data on which to base a decision about the most appropriate level. Further evidence-based analysis of this policy question may be desirable.

**Faculty consulting activity and COI.** Traditionally, academic institutions permit faculty to spend a portion of their time on outside activities, for which they may be remunerated directly, apart from their institutional salary. Current HMS policy permits this unless the faculty member is engaged in clinical research on the company's products and he or she has more than the permitted *de minimus* financial interest (see above). Faculty may pursue private activities, such as writing and publishing books and monographs and working as consultants for non-profit organizations or for-profit companies in areas of their expertise or interest. Consulting may provide stimulating and useful experiences. Such outside activities may also translate into richer educational opportunities for our students. With additional experience outside the academic walls, faculty members may

become better equipped to teach students about subjects to which they would not otherwise be exposed—be it the specifics of a medical or scientific subspecialty or simply the practicalities of the medical business. Although some believe that faculty should be content to limit their faculty and professional experiences exclusively to academia, others are not convinced that such a view is realistic or appropriate.

Are there negative consequences that could arise from consulting activities? Excessive pursuit of outside activities could lead some faculty to fail to fulfill their primary obligations. The HMS COI policy limits income from consulting to a *de minimus* amount in cases where a faculty consults for and conducts research sponsored by the same company, which discourages these potential negative consequences.

Finally, specific financial relationships between faculty and companies, while portrayed as “consulting,” may more accurately be described as payments to faculty as part of a marketing strategy, with the goal of increasing product sales. While faculty consulting activities that fully educate health care professionals about the risks and benefits of a particular therapy to advance the public’s health should be beyond reproach, other interactions raise legitimate questions about the appropriate role of the faculty as educator versus paid agent of a company promoting its commercial interests. In extreme instances, consulting payments may mask bribery or kickbacks for use of products. The latter relationships are clearly a very serious issue, already illegal under existing statutes, and merit unequivocal and severe institutional response.

**Authorship and COI.** Independent of the COI policy and its management, HMS has long prohibited our faculty members from engaging in guest authorship, the practice of attributing authorship in a scientific journal article, abstract, poster or other work to an individual who had no role in the planning or conduct of the research reported. As our Authorship Guidelines, adopted in 1999, state, “Everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work,” and “Honorary or guest authorship is not acceptable.” Other HMS Integrity in Science Policies rightly call the practice of honorary or ghost authorship “deplorable.”<sup>2</sup>

**Misconduct versus COI.** Also independent of the COI policy and its management, HMS has a clearly defined policy addressing faculty misconduct that is taken extremely seriously and strictly enforced. Many of the behaviors that are discussed as possible adverse outcomes from industry relationships—for example manipulation, suppression or falsification of research data—fall squarely within the faculty misconduct policy. Our institutional remedies for these behaviors are clear and decisive.

### **3I. Education and COI.**

The existing HMS policy on COI does not explicitly address education as it relates to financial interests, apart from requiring that financial interests be disclosed in papers and public talks where appropriate (see HMS COI Policy, Section II(e)). It is, therefore, timely to focus attention on this issue in the context of HMS’s review of its Policy on Conflicts of Interest and Commitment. Because distinct issues arise during the different phases of medical education, it may be helpful to examine these distinct phases of the education process as relates to COI.

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<sup>2</sup> See the [Guidelines for Investigators in Scientific Research](#) and [Guidelines for Investigators in Clinical Research](#).

At the outset, one overarching principle must be stated: HMS requires its teaching faculty to be excellent educators, based on their ability to transmit information and concepts objectively and rigorously, along with other skills as educators. HMS can and should be proud of its great and continuing success in the education arena, and the School continues to strive so that this remains the case.

**Preclinical medical education and COI.** By and large, the teaching of HMS medical students during their first two years is under the direct control of the school. This phase of the curriculum is heavily weighted to basic science, normal physiology and disease mechanisms, much of which has little to do with therapeutics. In addition, these students are years from treating a patient or making independent therapeutic decisions. Nonetheless, pharmaceutical and sales representatives have long been prohibited from coming to the HMS campus to interact with students. Perhaps for these reasons, this phase of education has historically generated minimal concerns on the part of HMS about the potential of bias due to faculty interactions with pharmaceutical companies.

In thinking about the potential for financially induced bias in the preclinical curriculum, we should examine how the curriculum is developed and assessed at HMS. The content of the curriculum is determined under the leadership of the dean for medical education, working with a curriculum committee composed of faculty with major and often passionate interest in teaching and course content, and with course directors, lecturers and tutorial leaders chosen for their expertise and excellence as teachers.

Although HMS now compensates most hospital-based preclinical teachers by contributing an hourly stipend to help fund their salaries, faculty rarely, if ever, engage in teaching at HMS to enrich themselves financially. Why, then, do HMS faculty teach? In the vast majority of cases, faculty teach out of dedication to the educational process and the students. Although we need to acknowledge the possibility that our faculty could theoretically seek to teach preclinical students for the purpose of biasing them toward treatments that might financially benefit the faculty, or a company that they might have consulted for, the possibility of such an unethical practice seems quite remote.

Stimulated by requests from some students who were concerned about potential faculty bias, HMS now requires preclinical lecturers to disclose financial relationships potentially relevant to their lectures. While such disclosures have long been the standard for lectures in the clinical arena due to continuing medical education (CME) accreditation requirements, this was not previously done at HMS for preclinical lectures. Time will tell whether this proves to be useful to the students, and if so, in what ways.

Should our choice of lecturers or tutors be influenced by whether the faculty member has financial associations requiring disclosure? Those who perceive a great threat of faculty bias from financial interests might recommend that such faculty be removed from teaching roles. Many of our most renowned faculty, however, are sought after as consultants by industry. If we allowed only those faculty without financial interests in industry to teach future physicians and scientists, those students may well be deprived of valuable learning experiences through contact with some of our most accomplished faculty. This topic could be a worthwhile subject for future surveys of students and faculty and for academic study. Do preclinical faculty members with industry consulting or sponsored research give biased presentations with adverse educational consequences, with or without disclosure? There would appear to be no data bearing on this question, and it would be in our interest to obtain such data.

**Promoting critical thinking by our students.** In addition to teaching of curricular information, much of which is forgotten and relearned in a new form as understanding

evolves, perhaps our greatest challenge is to help our students become critical thinkers. Students need to be exposed to the entire range of biomedical research, including the research undertaken by our broad and diverse faculty, in order to learn these critical thinking skills. During their long professional careers, students will be continually exposed to reports and claims of uncertain or unknown validity from patients, colleagues, professional organizations, companies and government. Their capacity to act independently, with integrity and in the best interests of their patients, will require that they learn how to judge for themselves which sources of information they can trust. If the ability of our students to discern trustworthy information is a problem within the relatively cloistered domain of the HMS curriculum, it will be a far greater problem once they enter the “real world.”

**Hospital based education of medical students and COI.** The third and fourth years of HMS education are primarily conducted at our affiliated hospitals, which are independent corporate entities linked to Harvard via affiliation agreements. HMS is responsible for this educational effort, in extremely close collaboration with numerous HMS faculty and educational leaders who, in addition to holding HMS faculty appointments, are employees of the hospitals. Some hospital-based education is also carried out by house officers who are not HMS faculty. HMS has an obligation to ensure that our students are properly educated at each site and that attention is paid to appropriate principles of ethical behavior.

How should HMS approach the oversight of education of our students at the hospitals and what rules should be established to prevent faculty financial COI from diminishing the quality of their education? Although further research is necessary to understand the potential harm, if any, to our students arising from faculty financial conflicts during the course of clerkships and electives, some faculty and students are concerned about this possibility. In our upcoming deliberations, HMS will need to consider the manner in which financial interests of faculty might be disclosed (and, if necessary, managed) related to the many informal and formal teaching rounds that take place on the wards (as opposed to lectures, which tend to be covered by the disclosure requirements of CME certifying agencies).

While the actual adverse effects on faculty and students of the “pens, pads and pizzas” sometimes provided by companies to the ward teams is uncertain, prohibiting such gifts, as well as gifts of meals and travel, may be useful to reduce even the appearance of gratuitous industry influence. In addition, a version of such restrictions is now a matter of law in Massachusetts.

As students read journals and magazines, or even watch TV, they will be exposed to advertising and detailing by pharma and device companies, as will their patients. As faculty responsible for their education, it might be argued that our goal should include teaching students how to read and interpret such materials, as opposed to simply sheltering them from these materials or advising them not to read or watch them. Likewise, though we want to discourage gratuitous student contact with pharma detailing reps, and such contacts are prohibited on the HMS quad, it may sometimes be useful for students to hear their presentations, and under the tutelage of faculty, learn how to critically judge these and respond to them.

Finally, on a more philosophical level, it is important to note that the truth of an assertion reflects the details of the assertion itself, and is independent of the identity and interests of the person or organization from whom the assertion derives. Or, stated more concretely, some statements by financially non-conflicted but otherwise biased or misinformed faculty will be erroneous, while others from pharma reps will be entirely

accurate. While the ratio of the former to the latter is hopefully very low, it is the accuracy of the statement and not the source that ultimately matters.

**CME and COI.** Continuing medical education primarily targets practicing physicians, and state licensing board requirements that include certification of participation in a certain number and type of CME courses ensure that these educational events will be numerous. Typically, these requirements will conform to guidelines by accrediting agencies such as the American Council on Continuing Medical Education (ACCME), which require financial disclosure by faculty and provide protections to ensure separation of content and sponsorship. The HMS Department of Continuing Education (DCE) is run by a dean for CME, and this department organizes and certifies hundreds of courses and conferences each year, all within accepted ACCME guidelines for financial disclosure and relationships with industry. The vast majority of our HMS CME courses are supported by tuition, with only a small fraction of revenues deriving from industry under ACCME guidelines. All new courses undergo rigorous analysis and review by a committee of senior faculty before being approved.

What are the major questions that we now face regarding CME and COI? First, we must ask whether it is appropriate for accredited HMS CME courses to receive funding from industry sources. At one end of the spectrum are those who assert that the answer is no. No matter how it might be done, these people argue that, as for-profit entities, companies would only provide funds if it served their interests, and their interests will always be counter to values that we support. Further, they assert that HMS and the hospitals should have adequate resources to accomplish all reasonable CME goals without seeking additional revenues. Let us examine this viewpoint.

Although every hospital-based medical educator would wish it not so, the funds to support hospital lecture series and CME programs are always limited. In many hospitals, with financial margins and hospital profits decreasing and expected to decrease further, funds to invite outside speakers and develop and run courses are in short supply from internal sources. Some clinical divisions in the hospitals lack revenues to fund such educational activities, and in the absence of unrestricted educational grants from companies, there might be inadequate funds to bring in experts from other cities and pay them honoraria.

While lack of funds should not by itself justify the acceptance of industry funds, the key issue is whether the industry funding brings with it influence over the content or is truly unrestricted. Efforts by companies to influence the content of academic, hospital-based presentations that they fund would, to the extent that it occurs, raise serious concerns. The HMS Committee reviewing our COI policy will likely consider in what ways industry support for CME, if permitted, can be managed so as to benefit our educational programs while preventing inappropriate influence over content.

**Paying faculty to give CME lectures.** Another question relates to the practice of our faculty lecturing at a variety of venues, generally on topics involving therapeutics, with honoraria paid by one or more companies. For example, industry may pay a faculty member to deliver a lecture because of his or her status as an expert, with the imprimatur of a Harvard appointment an additional gain from a marketing perspective. An occasional company-sponsored lecture by a faculty member would likely arouse limited concern, if the faculty member disclosed the association, was exclusively responsible for the material presented and was, of course, prepared to defend its accuracy. Under Harvard policy, payments for such lectures are permitted but must be disclosed, whether coming directly from the company or through an intermediary. If the faculty member also conducted



research on the therapy, the current HMS Policy would apply, including the prohibitions on receiving more than *de minimus* financial payments.

A more vexing problem can arise when a faculty member gives a very large number of such industry-sponsored lectures, even more so if the content of the lecture is provided by or substantially influenced by the sponsoring company. This circumstance raises several issues for consideration by HMS. 1) When might we consider that a faculty member is spending too much time on these outside activities given his or her full-time status? 2) Can a faculty member, by virtue of the large number of lectures, cross the line between balanced academic pursuit and explicit promotion on behalf of the company? 3) If the latter, would the activity be inherently inappropriate, or would it be necessary to examine the details and veracity of what is actually being promoted? 4) In a case of real and explicit industry promotion, should the faculty member be allowed to use his or her Harvard faculty status in publicity associated with the activity?

#### **4. Transparency, public disclosure and other operational issues.**

In our current policy, faculty disclosures are submitted to the school, and HMS and representatives at each of the affiliates fully resolve any reports that indicate prohibited activity. The disclosures are otherwise confidential. Over the past several years, there has been a major interest in the possibility of providing elements of this information to the public. Some members of industry and some academic health centers have expressed their intention to publicly post information on payments to faculty and institutions, ideally in a form that makes clear the distinct purpose for the payments (e.g., sponsored research, consulting, lecturing or expense reimbursement). Whether this change in sentiment toward public disclosure will be reflected in changes in the HMS policy is now under discussion.

Implementation of such public disclosures may be more complex than some expect, and the implications of such disclosures are far from clear. But this direction does seem to be gaining favor. Whatever happens with public disclosure, it is likely that information about our faculty's financial interests already collected through their disclosures to HMS (not just potential violations), should be made more accessible to key institutional leadership in useful formats to permit the identification of potentially problematic patterns of outside activity. HMS strives to ensure that 100 percent of its faculty members complete the submission of their disclosure forms and that any identified conflicts with the current policy are resolved. However, HMS does not currently have an active auditing and monitoring program to assess the accuracy of COI disclosures. The benefit of some form of audit sampling is clear, and is being discussed by the COI committee. Finally, it is exceptionally important that new disclosure rules and forms be as clear and free of ambiguity as possible.

#### **5. How to view industry in the context of COI at HMS?**

In considering academic–industrial relations in the context of biomedicine, we confront varying views of the ethics and goals of for-profit biopharmaceutical and device companies (BPDC) with which we collaborate. Depending on one's views in this regard, the preferred contour and extent of the interactions will vary. Just as it was important to examine distinct domains of medical education and research in the foregoing discussion, it might be useful to treat BPDC as a complex ecosystem with distinct elements, rather than as a monolithic entity with a singular identity.

**For-profit versus not-for-profit.** Does the fact that BPDCs are for-profit, while medical schools and hospitals are not, create a serious barrier to collaboration between these kinds

of organizations in the service of important values? Although interactions between these “worlds” are possible and productive in other segments of our economy, some argue that there are special problems in the intersection of biomedicine and BPDCs. It is true that the mission and professional ethics of physicians are an essential and revered tenet of the profession, and the oath to act always on behalf of our patients’ interests has no precise analogue in the industrial sphere. However, for-profit businesses and their employees are not inherently unethical in their goals and behavior, nor are physicians and not-for-profit organizations and their employees necessarily ethical. High ethical standards should be expected from people and organizations regardless of their profession or tax status. Greed unchecked by values, leading to dishonest or otherwise objectionable and immoral behavior, is unfortunately part of the human condition, and is found in some physicians and scientists in both for-profit companies and not-for-profits, in government and even in religious organizations. We must devise approaches, both private and governmental, to limit such behaviors and protect us from them when they occur.

It may be useful to distinguish between those elements of BPDCs that focus on discovery and development and those that deal with marketing and sales. When HMS faculty interact with BPDCs they are most often dealing with company scientists and physicians, many of whom have spent time in academia. The main currency in such interactions is data and truth, and although perspectives on some issues may differ between those inside and outside industry, the cultural divide is often not very wide. As more and more faculty, including those at high levels of accomplishment and recognition, have moved from academia to industry, and others have moved in the opposite direction, the divide continues to narrow.

Not surprisingly, the core goals of marketing and sales divisions of BPDCs are focused on profit, rather than science and medical value. How may we be protected from potentially dishonest marketing efforts? The fact that companies marketing drugs are under substantial legal and regulatory oversight provides one substantial, if not fully adequate, bulwark against bad behavior. Nonetheless, there are many examples of marketing and sales organizations seeking to influence physician prescribing behavior through techniques that rely on gifting and other inappropriate financial inducements. There is evidence from many quarters that companies, even those with longstanding records and reputations for ethical behavior, have made serious mistakes that led to questions about their internal standards and corporate culture.

Having said this, not all marketing activities are dishonest or illegitimate. A substantial portion of explicit BPDC marketing is accurate and consistent with FDA guidelines, and may be useful to some practitioners along with many other sources of information. Certainly, the existence of unquestioned financial interest on the part of the marketer should cause medical professionals to be cautious in accepting any presentation at face value. On the other hand, viewing all marketing information as erroneous and all such personnel as *persona non grata* may not be appropriate.

**The emerging opportunity.** It is increasingly evident that the pharmaceutical industry has been less successful than expected in recent years at developing breakthrough treatments based on the torrent of new information that bioscience has produced. Both within and outside industry, many people recognize this problem and are seeking a new model of academia-industry collaboration to achieve greater success at discovery and development of new treatments while fully protecting academic values and those of the medical profession. As many breakthrough drug classes go off patent, and the pipeline has insufficient replacements, the profitability of the industry will likely fall and the motivations for industry to partner with academia in new ways to accelerate progress will likely increase. From this perspective, it may be desirable to create a culture that is open

to creative new approaches to collaboration on scientific development, rather than one that seeks to make novel interactions more difficult.

## **6. How will HMS address COI going forward?**

HMS is now conducting a thorough and comprehensive review of its COI policy, involving our faculty from the HMS preclinical departments and affiliated hospitals and our students. This review will define our current state, identify the current challenges, take testimony from individuals and groups representing distinct perspectives, and propose a revision of the policy going forward. And this time, since Harvard University is simultaneously undertaking a University-wide review of this topic, our policy will be fully consistent with emerging University standards.

Although the final recommendations will not be clear until the process is complete, it is certain that we will address education in a way not previously considered in the policy, and we will identify ways to make the policy more explicit in several areas. We will likely expand the transparency of disclosures and find approaches to enhance the way that information is used by our leadership. Finally, we will work hard to synergize and make as seamless as we can the policies of HMS with those of our affiliates.

## **7. A future academic agenda regarding COI in biomedicine.**

In the course of my consideration of these issues, it has become apparent that there are major knowledge gaps in this area. As a result, many differences of opinion are not easily resolved by consulting scholarly discussion and analysis. Since COI issues lie at the critical interface between research, education, patient care and the public, I believe that HMS should play a leadership role in defining and elaborating an academic agenda for this field in the future. The field of inquiry is broad and interdisciplinary. It will involve expertise from the worlds of research, education and clinical medicine, as well as philosophy, law, business and public policy. Some of the insights will arise from convening the right people to address focused issues in a new way. Others will require objective study and the acquisition of data from the real world. I commit HMS to advancing this agenda over the course of the next several years.

## **8. Conclusion.**

Over the course of a 31-year career on the faculty of HMS, and now as dean of the faculty of medicine, I have observed and had to deal with a certain number of transgressions of ethical norms. Nonetheless, I have repeatedly been struck by the fact that our faculty is remarkable for their dedication to ethical patient care, unbiased education on many levels and pathbreaking research. Interactions with industry have provided many members of our faculty with opportunities to extend their research and expand their horizons. The preponderance of these activities are not only defensible but praiseworthy and important to maintain.

There are, however, increasing concerns about some kinds of financial relationships between faculty and industry. Many, but not all, of these relationships emerge from marketing efforts of pharma and device companies. These range from small gifts and meals provided to physicians; to lecture programs in which faculty may subtly evolve from being academicians compensated to present their views on a topic of interest into roles as paid spokespersons for a particular product; to behaviors that have the appearance or reality of being explicit payoffs and bribes. The foregoing activities range from being unseemly but potentially harmless, to being inappropriate for a full-time academic and subject to review, to being criminal, and we must address them in a manner

that takes account of their actual status. In their zeal to market, pharmaceutical companies have too often overstepped lines that demarcate reasonable and appropriate marketing, which is their right, from dishonest and otherwise unethical behavior, which is not. Leaders of this industry, who have been chastened both by negative publicity and some major court settlements, are becoming aware of this fact. Our academic leaders have a responsibility to work with industry, and in particular the scientific leaders within industry who have often moved there from academia, to rein in practices that we can all agree are inappropriate. Similar considerations apply in determining the appropriateness of non-marketing relationships between faculty and industry.

Having said that, it would be a mistake of enormous consequence if attention to these important concerns were to create a false conclusion regarding the many important ways in which academia and industry could work together productively and ethically for the benefit of human health. I hope that I have at least begun the process of providing a framework for discussion as we deliberate on the best policy for the future.