

Establishing Policies for the Relationship Between Industry and Clinicians: Lessons Learned From Two Academic Health Centers

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Abstract

The relationship between faculty in academic health centers (AHCs) and commercial entities is critically important to improving the public health, yet it may be prone to conflicts of interest that adversely affect medical education, research, and clinical care. The Association of American Medical Colleges has recently recommended that medical schools and AHCs develop policies that better manage and occasionally prohibit interactions between academic medicine and industry. Because the development of more stringent policies is complex and potentially contentious, the author reports the lessons learned from developing new policies for the

interactions between faculty and industry related to medical education and clinical care at Yale School of Medicine and Boston University School of Medicine/Boston Medical Center. The content of the policies was strongly influenced by the tenets of medical professionalism. Faculty support for new policies was strong, an iterative and inclusive process of formulation was critical, compromises in content were necessary, and the views of faculty concerning industry relationships were complex. After implementation of the new policies, the departmental food-related expenses increased, the loss of gifts was not appreciably missed, the faculty assumed

more responsibility for educating trainees on the evaluation of new products, a central repository for receiving and evaluating grants from industry was useful, enforcement of the policies has been a lingering challenge, and the new policies generated positive publicity. Several recommendations are proposed. Creating these policies affirmed the importance of an inclusive process, open communication, support of institutional leadership, and focus on professional values.

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There is widespread interest in fortifying the ethical precepts of the relationships of faculty at academic health centers (AHCs) and industry. Indeed, the Association of American Medical Colleges (AAMC) has recently recommended that medical schools and AHCs develop policies that better manage and occasionally prohibit those interactions between academic medicine and industry that create conflicts of interest or threaten medical professionalism.¹ In AHCs, the process of formulating new policies to restructure the relationship is lengthy, complex, and controversial. In view of the recommendations of the AAMC¹ and the observation that a substantial number of AHCs are considering formulation of new policies on the relationship with industry related to medical education and

clinical care,* I describe below the lessons learned from developing more restrictive policies at Yale School of Medicine (YSM) and Boston University School of Medicine/Boston Medical Center (BUSM/BMC). As will be mentioned below, I believe that the process of developing viable and sustainable policies should generate a consensus by respecting and incorporating the divergent views of the individuals involved, and that the resulting policies should protect the interests of the public, institutions, industry, and individual clinicians.

Background

A productive and ethical relationship between academic physicians and the health care industry is vital for the development of effective approaches to prevent, diagnose, and treat disease. The public and scientific community expect

the evaluation and use of new products to employ the highest standards of rigor and integrity in order to optimize the public benefit and minimize the potential for commercial bias in therapeutic decisions. Relationships involving the marketing of new medications have the potential to jeopardize the public trust, particularly those that do not meet standards of medical professionalism or that exhibit conflicts of interest. Understandably, the potential impact of marketing practices and the pervasiveness of real or perceived financial conflicts of interest among physicians have raised concerns among the public and academic institutions.¹⁻⁵ Among these are the fear that the lofty and hard-earned reputation of these institutions, and the trust in physicians as sources of unbiased expertise, will be undermined by perceptions of conflicts of interest or interactions with commercial entities that are not in the public interest. The substantial influence of the marketing efforts of industry on the treatment decisions of physicians has been extensively reviewed in the literature.¹⁻⁶

In addition, conflict-of-interest concerns affect medical education. Physicians who are faculty in AHCs have an important

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responsibility to both model and teach strategies for acquisition and application of new knowledge to trainees. This responsibility adds a compelling need for those faculty to use the most objective educational sources and to teach trainees how to evaluate and use new clinical information.

Capitalizing on the scientific opportunities of the future will require the relationship of academic medicine and industry to be conducted with the highest ethical standards. Therefore, the content of policies governing the relationship between commercial interests and physicians should be based completely on the precepts of medical professionalism. Namely,

- physicians must act in the interests of their patients first and foremost if they are to fulfill their responsibilities to patients and to society;
- physicians must use the most up-to-date and objective sources of information in determining which interventions are best for their patients;
- physicians must be attentive to the cost and value of medical interventions; and
- physicians' therapeutic relationship with patients must not be influenced by personal gain.

Although many agree with these basic precepts, physicians may believe that marketing does not substantially affect their practice patterns despite considerable evidence to the contrary and that a wide range of behaviors in their relationships with industry are ethically acceptable.⁷⁻⁹ Because my colleagues and

I at YSM and BUSM/BMC believed otherwise, we helped develop new policies at our institutions, which I now describe.

Lessons Learned at Two Institutions

Working with a number of colleagues, I led the development of new policies governing relationships with industry at YSM and BUSM/BMC while serving as chair (interim chair at YSM) of the department of medicine at each institution. The process at YSM required 11 months and culminated in the publication of new guidelines in May 2005.⁶ After nine months of deliberation at BUSM/BMC, new policies were approved in August 2007.¹⁰ The content of the YSM and BUSM/BMC policies are summarized in Table 1. The resulting policies were more stringent than the previous policies at the two institutions and required substantial effort to achieve a consensus. Moreover, enough time has passed that the effects of implementing the policies at the two institutions can be partially assessed.

Achieving a consensus

A deliberate process is important. An inclusive and iterative process to formulate the policies was critically important in reaching consensus and faculty and institutional buy-in. The process for developing policies was similar at YSM and BUMC/BMC. At both institutions, the chairs of the clinical departments were asked to initiate an inclusive process to examine and develop new policies. A subcommittee of chairs

created a draft set of policies for further review by the larger group. The draft policies were distributed to faculty and organizational leadership, including representatives of the conflict-of-interest committee at each school, to secure broad input into further modifications of the policies. At YSM, the Faculty Practice Plan Board (Yale Medical Group) refined the guidelines and insured that they were consistent with the policies of YSM's major affiliate, Yale-New Haven Hospital. A draft of the guidelines was distributed to representatives of local pharmaceutical companies for comment as well. At BUSM/BMC, the policy was reviewed and approved by the Medical Executive Committee of Boston Medical Center and by the Clinical Chairs Committee of the Boston University School of Medicine.

Multiple drafts of the policies were modified after receiving faculty input and were tabled on several occasions at the board level of both institutions. Incorporation of the input on the draft policies improved their clarity and increased the level of support among the faculty. The suggestions of the respective offices of the general counsel at both institutions were very useful in identifying potential legal ramifications of the policies as well as improving their wording.

The governance structure of each institution includes both a faculty practice plan and also a research-intensive medical school with a single major affiliated hospital. This structure facilitated discussions among the stakeholders. Medical schools with

Table 1

Summary of Policies on Interactions of Clinicians With Industry at Yale School of Medicine (YSM) and Boston University School of Medicine/Boston Medical Center (BUSM/BMC), 2008*

| Institution | Gifts | Meals | Free samples for MDs | Free samples for patients | Central repository for education grants | All on-campus education events ACCME-compliant [†] | Industry reps in patient-care areas |
|-------------|-------|-------|----------------------|-----------------------------|---|---|-------------------------------------|
| YSM | No | No | No | Yes, controlled by pharmacy | Department | Yes | No |
| BUSM/BMC | No | No | No | Yes, controlled by pharmacy | School or hospital | Yes | Yes, under specific conditions |

* Complete policies may be found at (1) Coleman DL, Kazdin AE, Miller LA, Morrow JS, Udelsman R. Guidelines for interactions between clinical faculty and the pharmaceutical industry: One medical school's approach. *Acad Med.* 2006;81:154-160, and (2) BUSM/BMC Policies on Interactions Between Clinicians and Representatives of the Healthcare Industry at (http://www.bumc.bu.edu/www/busm/ood/images/policies/BMC-BUSM%20Industry%20Interactions%20_July%2026_.pdf).

[†] ACCME, Accreditation Council for Continuing Medical Education.

multiple affiliated hospitals or with substantial numbers of community-based faculty would likely need more diverse representation in the process of formulating new policies.

Support for more stringent policies is strong.

The most striking aspect of composing the policies at YSM and BUSM/BMC was the remarkable degree of interest in strengthening existing policies. Although there were disagreements regarding content, the overwhelming majority of faculty and chairs supported the initiative and ultimately voted affirmatively on the policies. Similarly, the leadership of YSM and BUSM/BMC were also very supportive of the initiative.

Compromise is necessary. Although there was agreement with most of the provisions and intent of the policies, opposition to one or two elements arose during the course of the discussion. It should be noted that the votes for approval of the final policies were overwhelmingly affirmative but were not unanimous at either institution. To reach consensus during the deliberative process, compromises in content were made.

- First, the policies focused on activities that occurred on campus. Many faculty believed that it would be too difficult to enforce provisions governing activities off campus, and some believed that it was too intrusive to dictate behaviors off campus.
- Second, the policies were focused on physicians (YSM) and clinicians (BUSM/BMC) but not on nonclinical staff such as administrators. Although there was no opposition from the administration at the two institutions to being included in the policies, we chose to limit the focus to the professional standards of clinicians, including trainees, both medical students and residents.
- Third, the policies did not apply to community-based or voluntary faculty, because the decision-making bodies at YSM and BUSM/BMC did not represent that group of physicians. Moreover, we felt that enforcement of the provisions of the policies at practice sites in the community would be impractical.

- Fourth, participation in speaker's bureaus or other similar activities was not prohibited. Instead, both institutions developed more explicit guidelines for participating in industry-sponsored educational activities.
- Fifth, although the requirement that all industry contributions to continuing medical education (CME) be submitted through the respective development offices provides additional oversight, it does not provide the same level of protection against conflict of interest as that recommended by Brennan et al.⁵
- Finally, we chose not to address the relationships involving collaborative research with industry. The complexities of this relationship are governed by a number of federal, state, and local rules. In addition, other university committees were charged with considering research relationships.

These experiences illustrate the challenges in reaching a consensus on the policies and the need to continually refine the policies in the future. The admonition that “perfect may be the enemy of good” seems particularly relevant in retrospect. Nonetheless, the modifications in content should not obscure the strong consensus regarding the fundamental tenets of the policies.

Faculty viewpoints of the industry relationship are complex. The process of formulating the policies revealed several important viewpoints concerning the relationship with industry. First, many faculty were unsettled by the implication that they would be vulnerable to marketing efforts of industry or subject to bias in their assessment or use of medications and devices. Many faculty objected to the implication that they may not be objective in their own clinical decision making, yet they were much more comfortable in assuming that other faculty may be biased. Published surveys of physicians have also affirmed that attributions of bias are generously given and very reluctantly accepted.^{7–9,11} Second, the discussions revealed different and dearly held viewpoints reflecting the complexity of the issues and the personal experiences of many faculty with industry. Far more agreement was achieved regarding educational and clinical standards than standards involving clinical research. Hence, the policies at both institutions focused on educational and

clinical standards rather than research standards. Finally, it was critically important to justify the formulation of more stringent policies on the need to maintain and enhance professional standards. The debate was most productive when directed at physicians' professional standards. Therefore, instead of engaging in “pharma bashing” as part of the rationale, we emphasized that industry has a primary obligation to market its products and that the fundamental rationale for more stringent policies regarding the education of faculty and trainees should be determined by the precepts of medical professionalism and the obligations of academic medicine to society.

Effects of the policies

The implementation of the policies at the two institutions has had several important effects. The policies brought clarity to the rules and enabled faculty to use a more explicit set of guidelines in their relationships with industry. As such, the rules have had the effect of increasing the comfort level of faculty seeking to engage industry representatives, while reducing potential conflicts of interest.

Food costs increase. The exclusion of commercial support for food for meals resulted in a substantial increase in the food costs of departments sponsoring educational conferences. For example, the BUSM/BMC Department of Medicine's food cost increased by more than \$80,000 per year after industry sponsorship of food was eliminated. Nonetheless, the option of eliminating meals at noon conferences was not seriously considered. Interestingly, there has been little interest in restoring industry sponsorship of meals despite the cost. Indeed, the house staff responded positively to departmental rather than commercial sponsorship of meals at conferences. Other costs of implementing the policies, such as those attributable to a reduction in other forms of industry support of educational activities, have not been observed, although rigorous tracking data are not yet available.

Gifts are not missed. In contrast to the visible and costly implications of eliminating industry-sponsored meals on campus at the two institutions, the prohibition of gifts has had minimal impact. Although there has been some concern expressed about the lack of free educational materials for trainees or

patients, the absence of gifts has not generated requests to alter the ban.

The need for teaching curricula is highlighted. A persistent concern in medical education is whether we are preparing trainees to critically analyze new products and their potential clinical usefulness. Because industry can be an important source of information on new drugs and devices, some faculty felt that constraints on interactions with industry could compromise medical education. In recognition of the potential merits of this argument, a curriculum in clinical pharmacology has been developed in the Department of Medicine at BUSM/BMC that includes principles of new drug assessment, pharmacodynamics, and toxicology. It will be important to develop additional educational strategies to provide objective approaches and information on new products.

A central repository for the receipt and distribution of funds is helpful. The use of the development offices at BUSM/BMC as a central repository for receiving and reviewing funds from industry has enabled the compliance officers to more directly ensure that the grants comply with the policy. In addition, it has helped to reduce the possibility that the funds would contain a quid pro quo from the faculty or trainees. Although this approach does not eliminate potential conflicts of interest, the use of a central repository renders the transactions more transparent and creates standardization across departments in the procurement and use of the funds.

Enforcement is a work in progress. Enforcement of the policies described herein has been delegated to department chairs and to the respective institutional compliance officers. The challenge of enforcing the policies for off-campus activities prompted both institutions to focus the policies primarily on educational events on campus. The YSM policy was composed as a set of guidelines rather than policy, in part because of potential difficulties in enforcing the provisions. The BUMC/BMC policies were approved as policies with the expectation that the department chairs would enforce the provisions.

More stringent policies generate positive publicity. The approval of the policies at YSM and BUMC/BMC, along

with those at other academic institutions across the country, has been generally well received in the lay press and has generated positive publicity for the respective medical institutions. The positive publicity is not surprising, because surveys of patients and stories in the press have indicated that patients are concerned about the acceptance of gifts from industry by physicians and the lack of transparency in the relationships of their physicians with industry.^{12,13}

Recommendations

On the basis of the experience of composing and implementing more stringent policies for the interactions of clinicians with industry at two major AHCs, I suggest that similar efforts in the future incorporate the following considerations. (For convenience, these are summarized in List 1.)

Focus the discussion on professional standards of clinicians. As described above, policies governing interactions with industry should be based on the ideals of medical professionalism. Faculty characteristically share a common set of professional values that can serve as the basis for constructive dialogue and alignment of institutional policies.

Moreover, a focus on the behavior of industry representatives rather than on professional ideals may distract faculty from the broader goals of the initiative.

Target all full-time clinical faculty and nonphysician clinicians. A common approach for all clinicians in the AHC creates a single common practice, simplifies enforcement, and makes it easier for clinicians and industry to comply with local policies. Extension of the policies to include voluntary or part-time clinical faculty is very difficult unless appropriate representatives of this group can participate in the formulation and enforcement of policies.

Focus on educational standards and consider research standards separately. As described above, relationships regarding research are regulated by a number of existing policies and are very complex. The formulation of educational standards as part of a broader policy that includes research relationships will retard progress in developing standards governing educational activities. Therefore, depending on institutional goals and existing policies, it may be more productive to develop additional policies on research and on clinical care and

List 1

Recommendations for Developing Policies for Interactions of Clinicians in Academic Health Centers with Industry*

- Focus the discussion on professional standards of clinicians.
- Target all full-time clinical faculty and nonphysician clinicians.
- Focus on educational standards and consider research standards separately.
- Target the relationship with both the pharmaceutical and device industries.
- Use existing policies at other institutions as a basis for discussion.
- Employ an inclusive process that provides iterative and substantive opportunities for input.
- Educate the faculty about the impact of conflict of interest and the impact of marketing in influencing prescribing decisions.
- Remain patient and persistent.
- Engage the institution's general counsel in composition of the policies.
- Ensure that the policies of the school and hospital are concordant.
- Do not distinguish between educational events that award formal continuing medical education credit and those that do not.
- Use a central repository for receipt of funds from industry.
- Anticipate how the policy will be enforced, and describe the responsibilities for enforcement explicitly in the policy.
- Anticipate the additional cost of food for meals at educational events.
- Develop educational initiatives to improve training of faculty and trainees in assessment and use of new drugs and devices.
- Disseminate the updated policy widely to industry representatives, faculty, and trainees.

* These recommendations are proposed by the author on the basis of the process of developing and implementing such policies at Yale School of Medicine and Boston University School of Medicine/Boston Medical Center. Full discussion of each recommendation can be found in the text.

education in parallel rather than as a single process.

Target the relationship with both the pharmaceutical and device industries. The professional standards that govern relationships with industry are not restricted to a type of industry, and they should apply broadly. The relationship with representatives of the device industry is complicated by the common practice of using their expertise in patient-care settings. The BUSM/BMC policy contains a separate provision for device representatives in patient-care areas, but, otherwise, it is applicable to all commercial health care entities.

Utilize existing policies at other institutions as a basis for discussion. A number of institutions have developed thoughtful and creative standards to govern the relationship with industry. These initiatives have been summarized online to facilitate development of “best practices.”¹⁴ In addition, the recent AAMC recommendations are particularly useful.¹

Employ an inclusive process that provides iterative and substantive opportunities for input. As with most forms of institutional change, stakeholders may react negatively to the content if their views are not sought in the formulation of the policies. As important, however, is that because the relationship with industry elicits heartfelt and thoughtful opinions, an inclusive process greatly enhances the clarity, potential impact, and acceptance of the policies.

Educate the faculty about the impact of conflict of interest and the impact of marketing in influencing prescribing decisions. A considerable literature on the impact of conflicts of interest and marketing in clinical decision making is available. The evidence should be made available to faculty as they react to the proposed policies. Grand rounds were held at YSM and BUSM/BMC on conflicts of interest to facilitate dialogue among the faculty and trainees. Because some faculty may react negatively to the underlying assumption that they are vulnerable to bias, a review of the available literature may lessen the emotional impact of the discussion.

Remain patient and persistent. The development of the policies at YSM and BUSM/BMC required nearly a year of

deliberation and formulation. The inevitable disappointments and disagreements that characterize any complex negotiation can potentially obscure the broader goal of refining professional standards. It is worth emphasizing that the protracted discussions substantially improved the clarity of the policies.

Engage the institution’s general counsel in composition of the policies. Attorneys from the respective offices of general counsel at YSM and BUSM/BMC were extremely helpful in delineating areas of legal risk and in improving the text of the policies. They also provided an important institutional perspective on risk and enforcement.

Ensure that the policies of the school and hospital are concordant. The process of formulating new policies in AHCs depends in part on the relationship between the medical school and hospital or hospitals. Because separate boards govern the medical school and hospital at both YSM and BUSM/BMC, it was necessary to ensure that the policies in both institutions were similar.

Do not distinguish between educational events that award formal CME credit and those that do not. The recent changes in the standards of the Accreditation Council for Continuing Medical Education in the accreditation of CME activities has required more proactive declaration and resolution of potential conflicts of interest that may influence educational content.¹⁵ Because educational events in an AHC that does not award CME credits are not covered by the new standards, AHCs should decide on the applicable standards. Because having two standards for declaring and managing conflict of interest in educational activities seems highly undesirable, a common policy to govern educational activities should be employed regardless of whether formal CME credit is awarded.

Use a central repository for receipt of funds from industry. Creation of an institutional repository for receipt of funds from industry has been recommended to create an additional barrier to commercial influence of educational content.⁵ Our experience to date suggests that such an approach creates additional opportunities for review by the institutional compliance

officer to minimize institutional and individual risk.

Anticipate how the policy will be enforced, and describe the responsibilities for enforcement explicitly in the policy. A variety of enforcement provisions have been considered. These include, in addition to self-reporting of relationships, a hotline to anonymously report violations, reporting and enforcement by chairs or division chiefs, and a mechanism whereby industry representatives can report policy violations.

Anticipate the additional cost of food for meals at educational events. As noted above, the incremental cost of providing food for trainees in educational meetings is substantial. Because eliminating food from noon conferences may substantially reduce attendance, it is important to identify a funding mechanism in anticipation of the loss of industry support.

Develop educational initiatives to improve training of faculty and trainees in assessment and use of new drugs and devices. The dependence on industry sources for information on new products may have had the effect of diminishing such initiatives from within academic departments. A core responsibility of leading academic programs should be to teach trainees to critically evaluate studies of the effectiveness of new products. Ceding of this responsibility to industry will not serve the public interest. With the development of policies that restrict industry sponsorship of educational events on campus, it will be important to fortify efforts to fill in this gap.

Disseminate the updated policy widely to industry representatives, faculty, and trainees. Despite attempts to publicize the policies at the YSM and BUSM/BMC, many questions about the policies were raised in the first few months after implementation. Similar efforts at other institutions have highlighted the need for continued education and discussions after implementation of the policies.¹⁶ Understandably, compliance with the policies by industry representatives is also enhanced by systematic efforts to inform them. Some institutions have developed a more formal process for “certifying” industry representatives on institutional policies and procedures.

Closing Thoughts

As the preceding observations indicate, the development of more stringent policies governing the interactions of clinicians with industry at two major AHCs has affirmed many of the common lessons of organizational change. Namely, an inclusive process, open communication, support of institutional leadership, and focus on professional values are critically important. The policies have the potential to reduce conflicts of interest or bias in the educational programs at YSM and BUSM/BMC. A long-term review will be necessary to determine whether policies developed at the level of the AHC will improve the objectivity and impact of educational programs. The willingness of academic medicine to develop more stringent policies may also influence the nascent legislative efforts under way at the state and federal levels. In view of the critical importance of the relationship between academic medicine and industry, it will be increasingly necessary to develop new approaches that reinforce the highest professional standards of medical education while facilitating discovery and improvements in the public's health.

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Did You Know?

In 1952, the University of Pennsylvania School of Medicine hosted the first televised surgery which was broadcast on WPTZ-TV.

For other important milestones in medical knowledge and practice credited to academic medical centers, visit the "Discoveries and Innovations in Patient Care and Research Database" at (www.aamc.org/innovations).