

Guidelines for Interactions between Clinical Faculty and the Pharmaceutical Industry: One Medical School's Approach

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Abstract

A productive and ethical relationship between the pharmaceutical industry and physicians is critical to improving drug discovery and public health. In response to concerns about inappropriate financial relationships between the pharmaceutical industry and physicians, national organizations representing physicians or industry have made recommendations designed to reduce conflicts of interest, legal exposure, and dissemination of biased information. Despite these initiatives, the prescribing practices of physicians may be unduly influenced by the marketing efforts of industry and physicians may inadvertently distribute information that is biased in favor of a commercial entity.

Moreover, physicians may be vulnerable to prosecution through federal anti-kickback and false claims statutes because of potentially inappropriate financial relationships with pharmaceutical companies. Since academic medical centers have a critical role in establishing professional standards, the faculty of Yale University School of Medicine developed guidelines for the relationships of faculty with the pharmaceutical industry, which were approved in May 2005. Input from clinical faculty and from representatives of the pharmaceutical industry was utilized in formulating the guidelines. In contrast to existing recommendations, the Yale guidelines, which are presented

as an Appendix here, ban faculty from receiving any form of gift, meal, or free drug sample (for personal use) from industry, and set more stringent standards for the disclosure and resolution of financial conflict of interest in Yale's educational programs. The growing opportunities for drug discovery, the need to use medications in a more evidence-based manner, and preservation of the public trust require the highest professional standards of rigor and integrity. These guidelines are offered as part of the strategy to meet this compelling challenge.

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Snergies between the pharmaceutical industry and physicians have promoted drug discovery and public health. However, potentially serious conflicts of interest complicate the relationships between physicians and the marketing components of industry. Although the pharmaceutical industry has played a very important role in distributing information about new and existing agents, biased or misleading information

may be disseminated in the education of physicians and trainees.¹ In addition, some physicians may seek relationships with industry that are inconsistent with professional standards. These interactions have affected practice patterns, the cost of medications, and the integrity of educational and clinical programs.² With this problem in mind, we describe herein an approach by one medical school to set more stringent standards for the interactions of physicians with the marketing components of the pharmaceutical industry in order to facilitate the mutual efforts of physicians and industry to enhance the public health.

Background

According to the Pharmaceutical Research and Manufacturers Association of America (PhRMA), member companies spent approximately \$33 billion on research and development in 2003.³ In addition to the vital research and development activities of the pharmaceutical industry, substantial resources are devoted to marketing new or existing medications. According to

industry estimates in 2003, \$25.3 billion was spent on promotional activities, the great majority of which was directed at practicing physicians.³ Common marketing activities include direct-to-physician marketing by sales representatives; distribution of free drug samples to physicians; funding of medical meetings, journals, and educational events including continuing medical education (CME); direct-to-consumer advertising; some forms of research sponsorship; and advertising in print and electronic media.

The industry supports over 80,000 sales representatives; 80% to 95% of physicians meet regularly with sales representatives.⁴ On average, physicians meet with a pharmaceutical representative four times per month⁵ and, in one survey, 83% of internists meet with pharmaceutical representatives.⁶ A survey of physicians by the Kaiser Family Foundation in 2001 found that over 90% of physicians accepted free drug samples, over 60% received meals, tickets to entertainment, or free travel, and more than 10% received financial incentives, or financial

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or other in-kind benefits.⁷ Industry-sponsored promotional activities are also prevalent in residency programs.⁸

Continuing medical education in the United States is substantially supported by commercial sources.⁹ Although an important element of physician education, a review of industry-sponsored educational events revealed that they do not consistently present a balanced view of therapeutic alternatives,⁵ and are associated with subsequent requests to add the sponsor's drugs to hospital formularies and increased prescription rates of the sponsor's drug.⁵ In some instances these changes in physician behavior are warranted by true therapeutic advances, but in others reflect increased use of what may be therapeutically equivalent yet more costly medications.

Despite evidence to the contrary, many physicians believe that marketing does not substantially affect their practice patterns.^{10–14} Surveys of physicians have suggested that physicians in and outside of academic medicine believe that a wide variety of behaviors in their relationships with the pharmaceutical industry are ethically acceptable.¹⁰ In addition, individual physicians believe that they are less susceptible to influence by marketing of pharmaceutical agents than their colleagues.^{12,14}

The potential impact of marketing practices and the pervasiveness of financial conflict of interest among physicians have raised concern among the public and among academic institutions.^{1,2,14–18} Patients have raised specific concerns about the effect of pharmaceutical advertising and conflicts of interest on practice patterns and the cost of medications.^{1,2,16} Indeed, one patient opinion survey suggested that overwhelming majorities would like physicians to stop seeing drug representatives (79%) and to stop receiving gifts (84%). In the same survey, patients believe that physicians should receive their education from independent sources (84%) and the ties between physicians and the pharmaceutical industry should be transparent (96%).¹⁶

In addition to the concerns of the public, two important developments have increased the federal government's scrutiny of the relationship between the pharmaceutical industry and physicians.

The Prescription Drug Plan adopted by Medicare has raised the federal government's stake in the cost and use of medications. Moreover, federal anti-kickback and false claims laws have been used to prosecute several pharmaceutical companies for their marketing practices in addition to their arbitrage relationships with physicians.¹ The possibility that individual physicians will be liable in future criminal or civil litigation cannot be excluded.¹

In response to the growing concern among physicians, patients, and industry, national organizations representing physicians,^{19–21} the federal government,²² or industry²³ have developed guidelines designed to eliminate extravagant gifts and excessive compensation for consulting, reduce financial conflicts of interest, increase disclosure, and to encourage objective educational programs. In addition, the Accreditation Council for Continuing Medical Education has developed more stringent standards for industry support of CME activities.²⁴ These guidelines attempt to manage the relationship between the pharmaceutical industry and physicians to reduce the excesses that have led to legal liability while preserving the beneficial aspects of the relationship. To varying degrees, the guidelines of these organizations have potential to reduce the prevalence and impact of biased information or conflicts of interest. Nonetheless, many of the existing guidelines still permit behaviors and practices among physicians that may not adequately minimize conflicts of interest or ensure the objectivity of educational programs, and may have the unintended effect of increasing costs to consumers.^{1,2,5,6}

Because of their importance in education, training, and research, academic medical centers have a critical role in establishing standards for the interactions among physicians and trainees with the marketing components of the pharmaceutical industry. Erosion of the public's trust in the integrity of physicians and academic medicine will threaten clinical care, research, and education. Accordingly, we believe that academic medical centers must develop and refine their local standards governing these interactions. In order to learn how other academic medical centers have responded to this challenge, we queried

other centers on the University HealthSystem Consortium listserv in December 2004. We received responses from 19 institutions: one banned industry sponsorship of food, three restricted distribution of promotional materials, and one limited food and gifts to a low dollar amount.

The Yale Guidelines

Since we sought a more comprehensive approach for our medical school than that used in the available guidelines of national organizations or other medical schools, the faculty of Yale School of Medicine (YSM) developed new guidelines (see the Appendix) to more rigorously address the potential areas of conflict between our physicians and the marketing components of industry. The overriding goal of these guidelines was to ensure as much as possible that the integrity of clinical decision making is not compromised by financial or other personal relationships with industry. The guidelines were developed and refined with extensive faculty input over a 12-month period. In addition, we sought the input of representatives from several pharmaceutical companies in formulating the guidelines. The Board of Governors of the Yale Medical Group (YMG), which is a group practice composed of Yale full-time faculty, approved the guidelines in May 2005.

The guidelines are not technically binding on YMG physicians, except in certain areas cited in the guidelines that are legally prohibited. The provisions in the guidelines that either reflect legal prohibition or have been identified as having a high potential for abuse have been both **boldfaced and italicized** in the text of the guidelines in the Appendix.

The Yale guidelines contain important differences from those in existing recommendations (see Table 1). In contrast to the recommendations of the American Medical Association, American College of Physicians, Office of Inspector General, and PhRMA, the Yale guidelines do not allow any form of gifts to Yale physicians. The rationale for excluding all gifts regardless of monetary value is as follows. First, gifts have been shown to influence behavior independent of the size of the gift.^{4,5,13,25} Second, the acceptance of gifts may diminish the stature of the medical profession from

Table 1
Differences Among the Yale Guidelines and Four Different National Guidelines Concerning the Relationship of Health Care Providers with Industry, 2005

Organization	Gifts	Meals	Free samples for patients	Free samples for doctors	Stipulations on disclosure
American Medical Association Code of Medical Ethics ¹⁹	No cash; Gifts must serve educational function and not be of substantial value	OK	OK	OK, if short term	Appropriate disclosure of financial support or conflict of interest
American College of Physicians-American Society of Internal Medicine ^{20,21}	... strongly discouraged ... but make decisions on case-by-case basis	OK			Must disclose a financial interest in medical facilities or research studies
Office of Inspector General ²²	OK if gift does not reduce physician expense				
PhRMA Code on Interactions with Healthcare Professionals ²³	No cash; OK if <\$100; Should primarily benefit patients or for an MD's practice	OK	OK		
Yale School of Medicine	No cash, no gifts of any type	No	OK	No	Disclosure and resolution of all financial conflicts of interest

the viewpoint of patients. No gift is worth threatening the public's trust. Third, defining "substantial value" or the exact monetary value of many gifts is too imprecise and arbitrary. Therefore, it is practically impossible to determine which gifts are permissible based on estimates of monetary value. Fourth, gifts may contribute to the cost of advertising and medications. Physicians cannot fulfill their obligation to promote access to health care if their behaviors increase the cost of health care. Finally, physicians may be liable for receiving gifts under anti-kickback laws.¹

In addition to the ban on gifts, the Yale guidelines also eliminate industry-sponsored meals. In contrast, meals are permissible in the other guidelines (Table 1). Since industry-sponsored meals are a form of gift, a ban on meals was included in order to be consistent with the principles described above that led to the ban on any gifts.

The use of free samples of medications by Yale physicians or their family members

was eliminated because faculty have the means to pay for medications. In addition, the dissemination of free samples is a substantial component of the industry's promotional budget.³ Surveys have also suggested that distribution of free samples of prescription drugs may not be sufficiently regulated.²⁶

The Yale guidelines strongly endorse the principle established by the American Association of Accreditation of Continuing Medical Education, the American Medical Association, and PhRMA that the content of CME activities should be controlled by the organizers of the educational activity rather than the sponsor. Indeed, all providers of CME must comply with the new requirements of the Accreditation Council for Continuing Medical Education (ACCME). The Yale guidelines, however, extend beyond formal CME activities. All industry-sponsored educational activities on the Yale School of Medicine campus must be compliant with the standards of the ACCME regardless of whether or not

formal CME credit is awarded. Among the more notable requirements is that faculty must both disclose and resolve their financial conflicts of interest in order to participate in industry-sponsored educational events on the YSM campus. This provision recognizes that disclosure of financial conflicts alone is often not sufficient to eliminate bias, and the impact of the financial conflict may not be fully recognized by learners. Therefore, the Yale guidelines were expanded to include all industry-sponsored educational events. Resolution of the conflict of interest may be achieved by severing the financial relationship with the commercial entity or by submitting the educational materials to independent peer-review prior to the presentation to eliminate any potentially biased content. The ACCME has recently offered examples of how conflicts of interest can be resolved.²⁷

The Yale guidelines also establish standards for the participation of faculty in two major types of educational activities that occur off campus (provision #5 in the Appendix). The first group includes educational activities run by professional societies and partially supported by industry. These activities frequently offer CME credits and are therefore also subject to the ACCME requirements. The second group includes educational activities fully sponsored and run by industry such as industry-sponsored speakers' bureaus. These industry-run educational activities frequently seek to directly or indirectly promote new or existing drugs and are subject to the marketing regulations of the U.S. Food and Drug Administration. Since both of these groups of educational activities may include biased information, the Yale guidelines attempt to further ensure that the content of educational activities involving Yale faculty is controlled by the speaker, the presentation is as balanced as possible, advertising or gifts are not included in the session, attendees are not paid to attend, and that all potential conflicts of interest, including past or planned financial relationships, are disclosed.

In contrast to the policies identified at other academic medical centers, the Yale guidelines are intended to specifically ban all industry-sponsored meals and gifts on the Yale University School of Medicine campus, eliminate use of free drug

samples by physicians or their family members, encourage disclosure and resolution of conflicts of interest in all industry-sponsored educational activities on campus even if formal CME credit is not awarded, and set standards for participation in industry-sponsored educational activities off campus.

The process of formulating the guidelines and building consensus for the provisions in the guidelines was particularly noteworthy. First, we discovered that the faculty from many different departments were generally enthusiastic about developing more stringent guidelines for the relationship between industry and the faculty. Although there was extensive discussion and revision of the text, the guidelines received strong support from the faculty and leadership of the school. Second, the ACCME and the pharmaceutical industry developed more restrictive policies during the period that the Yale guidelines were being formulated. These developments emphasize the broad interest in developing more effective guidelines for the relationship between industry and academic medicine. Finally, the guidelines do not specifically address relationships among Yale faculty and other commercial entities such as those in the device or biotechnology industry. We believe that the underlying principles inherent in the guidelines apply to relationships with all commercial entities, but chose to focus our initial efforts on the more prevalent relationships with the pharmaceutical industry.

Importance of Having Guidelines

The growing opportunities for drug discovery will require a strong partnership between academia and industry. The public must have the highest confidence in the integrity of this relationship. Educational programs with the highest standards of objectivity will be most effective in enhancing the public's trust and in encouraging and sustaining proper use of advances in clinical therapeutics. Moreover, strategies to help physicians comply with new standards of therapy will be aided by the most credible, evidence-based approaches.

We believe that these guidelines will help to preserve the independence of our faculty and reduce the potential for real

or perceived bias in our clinical decision making and educational programs. Since we would also like to enhance the ability of the pharmaceutical industry to perform research and development independently and in collaboration with medical schools, we hope that these guidelines will promote an effective and ethical partnership between medical schools and the pharmaceutical industry that will facilitate drug discovery and more widespread use of effective therapies.

Guidelines alone are not sufficient to eliminate conflicts of interest, substantially reduce health care costs, or ensure that educational programs are balanced and accurate. It will also be important to continue to educate faculty and trainees on how to develop and sustain productive and ethical relationships with commercial entities. In addition, we will need to monitor the effect of these and other guidelines to evaluate their effectiveness in reducing conflicts and bias in educational programs. Nonetheless, the process of developing local guidelines can help the faculty in our medical school—and, we believe, in any medical school—to develop a greater consensus on the underlying principles of professionalism, integrity, and public service that must be incorporated in all aspects of our programs, including the relationships of physicians with industry. The Yale guidelines are offered as an example of how one medical school has attempted to meet this challenge.

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Appendix 1

Guidelines for Interaction between the Physicians of Yale Medical Group (YMG) and the Pharmaceutical Industry

(Note: The provisions that either reflect legal prohibition or have been identified as having a high potential for abuse have been **boldfaced and italicized**.)

1. Provision of Compensation or Gifts from Industry to YMG Physicians

- a. **YMG physicians may not accept any form of personal gift from industry or its representatives.** (Although the acceptance of a gift of nominal value is unlikely to violate the anti-kickback law, acceptance of most types of gifts of more than nominal value is suspect and may carry serious legal consequences. Accordingly, this provision has been highlighted, and the policy adopted that YMG physicians should not accept any form of personal gift from industry.)
- b. Meals funded by industry should not be provided on the Yale School of Medicine (YSM) campus. In addition, Yale faculty and trainees should use discretion in participating in industry-sponsored meals off campus.
- c. **A YMG physician may accept only fair market compensation for specific, legitimate services provided by him or her to the pharmaceutical company. Payment must be commensurate with time and effort. The terms of the arrangements, services provided, and compensation must be set forth in writing.**
- d. **YMG physicians may not accept compensation for listening to a sales pitch (e.g., detailing) by an industry representative.**
- e. YMG physicians who are simply attending a continuing medical education (CME) or other instructional activity and are not speaking or otherwise actively participating or presenting at the meeting, should not accept compensation from companies either for attending or defraying costs related to attending the meeting.
- f. **YMG physicians must consciously and actively divorce clinical care decisions (including referrals, and diagnostic or therapeutic management) from any perceived or actual benefits accrued or expected from any company (including but not limited to personal gifts, research funding, scholarships for CME attendance, consulting agreements, and the like).**
- g. **YMG physicians who are involved in institutional decisions concerning the purchase of or approval of medications or equipment, or the negotiation of other contractual relationships with industry, must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in pharmaceutical companies that might benefit from the institutional decision. This provision is not intended to preclude the indirect ownership, through mutual funds or other investment vehicles, of equities in publicly traded pharmaceutical companies by Yale faculty.**
- h. **YMG physicians may not receive any form of compensation for changing a patient's prescription.**
- i. Pharmaceutical representatives are not allowed in patient care areas. Therefore, YMG physicians should meet with pharmaceutical representatives only in non-patient care areas.

2. Provision of Scholarships and Other Funds to Yale Trainees

YMG physicians should ensure that support of Yale clinical trainees by the pharmaceutical industry through funding mechanisms such as scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training are free of any actual or perceived conflict of interest. Industry funding of trainees should comply with all of the following:

- a. The trainee is selected by the Yale school of medicine department, program, or section.
- b. The funds are provided to the department rather than directly to the trainee.
- c. The department, section or program have determined that the conference or training has educational merit.
- d. The recipient of the funds is not subject to any implicit or explicit *quid pro quo* (i.e., “no strings are attached”).

This guideline is not intended to preclude industry support for YMG physicians to travel to evaluate major clinical equipment for prospective acquisition by the school.

3. Provision of Free Drug Samples to Physicians

- a. YMG physicians may accept free drug samples from industry for distribution to patients.
- b. Since distribution of nonformulary drugs to patients may encourage use of costlier medications, YMG physicians should be cautious in distributing medications that are not on formulary.
- c. **Free drug samples may never be sold.**
- d. Free drug samples should not be used by YMG physicians for themselves or family members.

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Appendix 1, continued

4. Industry Support for Educational Events on the Yale School of Medicine Campus

YMG physicians should be aware of the Standards for Commercial Support established by the Accreditation Council for Continuing Medical Education. A complete description of the Standards of the ACCME to ensure independence in CME activities is available at (http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf).

All educational events sponsored by industry on the Yale campus must be fully compliant with ACCME guidelines regardless of whether or not formal CME credit is awarded.

The standards of the ACCME concerning commercial support of CME activities were made more stringent in September 2004 and are effective for new CME activities after May 2005 and for all CME activities by November 2006. The *new* elements in the ACCME guidelines now require that, if an event is to qualify for CME credit, its provider must ensure the following:

- a. All decisions concerning educational needs, objectives, content, methods, evaluation and speaker are made free of a commercial interest (ACCME Standard 1.1).
- b. A commercial interest is not taking the role of nonaccredited partner in a joint sponsorship relationship (ACCME Standard 1.2).
- c. All persons in a position to control the content of an educational activity have disclosed all relevant financial relationships to the provider of the CME. A relevant financial relationship is defined as one which an individual (or spouse or partner) has with a commercial interest that benefits the individual in any financial amount that has occurred within the past 12 months; and the opportunity to affect the content of CME about the products or services of the commercial interest. Failure to disclose these relationships will result in disqualification of the individual from participating in the CME activity or its planning or evaluation (ACCME Standards 1.1, 1.2).
- d. The lecturer explicitly describes all his or her related financial relationships to the audience at the beginning of the educational activity. If an individual has no relevant financial relationship, the learners should be informed that no relevant financial relationship exists (ACCME Standard 6.1, 6.2).
- e. All conflicts of interest should be *identified and resolved* prior to the educational activity being delivered to learners (ACCME Standard 2.3). Examples of strategies to resolve conflicts of interest include severing the financial ties with the commercial entity that gives rise to the conflict, having a third party without a conflict conduct the educational event, or having the content of the educational materials reviewed and endorsed by a peer expert who does not have a conflict of interest.
- f. Written policies and procedures that govern honoraria and reimbursement of out of pocket expenses for planners, teachers, and authors are in place (ACCME Standard 3.7).
- g. Product-promotion material or product-specific advertisements of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentation) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME (ACCME Standard 4.2).
- h. A commercial interest is not used as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities (ACCME Standard 4.5).
- i. The content or format of a CME activity or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest (ACCME Standard 5.1).
- j. Attendees in the audience are not compensated or otherwise materially rewarded for attendance (e.g., through payment of travel expenses, lodging, honoraria, or personal expenses) (ACCME Standard 3.12).

In addition to the aforementioned ACCME Standards, educational events sponsored by industry on the Yale School of Medicine campus should comply with the following provisions:

- a. Gifts of any type are not distributed to attendees or participants before, during, or after the meeting or lecture.
- b. Funds to pay for the specific educational activity are provided to the department, program, or section and not to an individual faculty member.

5. Guidelines for Delivering Industry-Sponsored Lectures or Participating in Legitimate Conferences and Meetings of Physicians off the Yale School of Medicine Campus

Clinical meetings and scientific meetings sponsored by professional societies frequently derive a portion of their support from industry. Such sponsorship may give rise to inappropriate industry influence on the content of the conference or its attendees. Grants for meetings and conferences that originate from the company's marketing division may be particularly problematic. Industry sponsorship generally takes one of two general forms and different standards apply in each case.

- a. First, industry may partially sponsor meetings run by professional societies. YMG physicians are expected to participate in meetings of professional societies as part of their CME and professional obligations. Nonetheless, faculty should be aware of the potential influence of industry on these meetings and attentive to the guidelines set forth below in evaluating whether and how to attend or participate in these meetings.
- b. A second type of meeting is fully sponsored and run by industry. The following guidelines apply in that case. These guidelines apply to all lectures, meetings, and related publications sponsored directly by industry or by intermediate educational companies subsidized by industry. YMG physicians should actively participate (e.g., by giving a lecture, organizing the meeting) in such meetings or lectures only if

(Appendix continues)

Appendix 1, continued

1. financial support by industry is fully disclosed at the meeting by the sponsor;
 2. the meeting or lecture's content, including slides and written materials, are determined by the YMG physician;
 3. the lecturer is expected to provide a balanced assessment of therapeutic options and should promote objective scientific and educational activities and discourse;
 4. the YMG physician is not required by the company sponsor to accept advice or services concerning teachers, authors, or other educational matters including content as a condition of the sponsor's contribution of funds or services;
 5. attendees in the audience are not compensated or otherwise materially rewarded for attendance (e.g., through payment of travel expenses, or provision of food or gifts);
 6. gifts of *any type* are not distributed to attendees or participants before, during, or after the meeting or lecture;
 7. the YMG physician receives compensation *only* for the services provided and the compensation is reasonable;
 8. time spent in preparing and delivering the lectures does not impair the YMG physician's ability to fulfill departmental responsibilities;
 9. the lecturer explicitly describes all his or her related financial interests (past, existing, or planned) to the audience;
 10. the lecturer makes clear to the audience that the content of the lecture reflects the views of the lecturer and not Yale Medical Group or Yale School of Medicine; and
 11. YMG physicians should not facilitate the participation of Yale trainees in industry-sponsored events that fail to comply with these standards.
6. Disclosure of Relationships with Industry
- a. YMG physicians must disclose all of their related financial interests, including past, existing, or expected interests (e.g., grants and sponsored research, compensation from consulting, speaker's bureaus, advisory boards; investments and ownership interests) to journal editors in manuscripts submitted for publication, and audiences at lectures or presentations.
 - b. **YMG physicians must provide specific written information on financial interests related to their work at Yale on an annual basis to their respective department chair and Yale's Conflict of Interest and Commitment Committee in compliance with Yale University regulations. This disclosure must include a description of all sponsored research, and investments held by the YMG physician that are related to industry (See Yale University Policy on Conflict of Interest and Commitment at <http://www.yale.edu/provost/html/coi.html>).**
 - c. **YMG physicians must disclose their actual and potential conflicts of interest related to any institutional deliberations and generally may not participate in deliberations in which he or she has an actual or potential conflict of interest .**
 - d. YMG physicians with supervisory responsibilities for trainees or staff must ensure that the faculty's conflict or potential conflict of interest does not affect or appear to affect his or her supervision of the activities or responsibilities of the trainee or staff member.
-