
Pharmaceutical Speakers' Bureaus, Academic Freedom, and the Management of Promotional Speaking at Academic Medical Centers

Marcia M. Boumil, Emily S. Cutrell, Kathleen E. Lowney, and Harris A. Berman

Introduction

Pharmaceutical companies routinely engage physicians, particularly those with prestigious academic credentials, to deliver “educational” talks to groups of physicians in the community to help market the company’s brand-name drugs. These speakers receive substantial compensation to lecture at events sponsored by pharmaceutical companies, a practice that has garnered attention, controversy, and scrutiny in recent years from legislators, professional associations, researchers, and ethicists on the issue of whether it is appropriate for academic physicians to serve in a promotional role.¹ These relationships have become so contentious that three years ago the pharmaceutical industry trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), adopted voluntary guidelines stating that drug companies should “stop giving doctors free pens, calendars, sports bags, or tickets to entertainment events.”² Further, numerous medical associations, such as the Association of American Medical Colleges (AAMC), the American Board of Internal Medicine (ABIM) and the Institute on Medicine as a Profession (IMAP), and government bodies such as the Institute of Medicine (IOM) have recommended that medical schools and

teaching hospitals prohibit or strongly discourage faculty from participating in so-called industry “Speakers’ Bureaus” — promotional events designed solely to market pharmaceutical products.³ These marketing efforts sponsored by pharmaceutical companies and generally presented as educational events are effective at influencing prescribing decisions in a way that is based less on the suitability and effectiveness of the product, and more upon the prestige and persuasiveness of the physician-marketer.⁴

A number of state legislatures and most U.S. medical schools and their affiliated teaching hospitals (collectively, academic medical centers or AMCs) consider these industry relationships to have the potential to create conflicts of interest (COI) and have adopted COI policies that limit or discourage physician participation in pharmaceutical marketing activities. Most policies do not contain absolute prohibitions, however, and many AMCs provide some leeway such as permitting faculty to give promotional talks if they prepare their own slides rather than rely upon the company’s marketing department’s pre-packaged presentation. Many physicians, attracted by the generous compensation, have become willing participants. Pharmaceutical companies’ vast marketing budgets for such “educational” events are testimony to the fact that promotional talks are enormously effective at inducing physicians in the audience to prescribe their products. The “conflict” arises because many of the speakers are selected on the basis of their prestigious credentials, but are paid for their willingness to promote the company’s marketing message.⁵

Section I of this paper reviews the literature on why Speakers’ Bureaus have become a lightning rod for academic/industry conflicts of interest. Section II considers the arguments of those who defend AMC

Marcia M. Boumil, M.S., J.D., LL.M., is an Associate Professor of Public Health and Community Medicine and the Assistant Dean for Conflicts of Interest Administration at Tufts University School of Medicine. **Emily S. Cutrell** is a J.D./M.P.H. dual degree student at Northeastern University School of Law and Tufts University School of Medicine. **Kathleen E. Lowney, M.H.S.**, is the Assistant Dean for Faculty Affairs at Tufts University School of Medicine. **Harris A. Berman, M.D.**, is the Dean and Professor of Public Health and Community Medicine at Tufts University School of Medicine.

faculty participation in industry Speakers' Bureaus and whether the institutional restrictions on the right of faculty of AMCs to lecture are consistent with principles of academic freedom. It also examines non-Bureau speaking funded by industry in such contexts as continuing medical education, scientific meetings, and Grand Rounds where marketing has limited or no presence. Section III addresses the legal and institutional efforts to limit faculty participation in Speakers' Bureaus. Section IV discusses some of the difficulties AMCs have encountered in enforcing the speaking provisions of their COI policies.

its. The literature and data on what is understood as "reciprocity" support the outcome that gifts, however minimal in value, create a sense of obligation in the recipient that results in its intended effect — writing more prescriptions of the sponsor's product.¹⁰ The giveaways also serve as a reminder to consider the company's product. Today the COI created by such giveaways is well understood and gifts are largely prohibited by policies of AMCs, the American Medical Association, medical associations, and other leaders in medicine.¹¹ The issue here is the extent to which "reciprocity" influences physicians who are paid to give promotional talks.

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I. Industry Speakers' Bureaus: The New Lightning Rod for Conflicts of Interest

Pharmaceutical company Speakers' Bureaus are a marketing enterprise wherein physicians and other professionals are engaged and trained by one or more companies to give a lecture about a medical condition or drug treatment to an audience of prescribers toward the end of promoting the company's drug which treats that condition. These speakers are generally required to use company-created or company-approved slides⁶ and are expected, prior to their presentation, to collaborate and review the slides with the company medical officers.⁷ This process is intended to focus the speaker on the most positive aspects of a drug, thus increasing the familiarity and appeal of that drug to the speaker — as well as the company's marketing message.⁸ It is widely argued that physicians who participate in Speakers' Bureaus are essentially just paid marketers or spokespersons for industry who use, indeed exploit, their roles as physician leaders to influence their colleagues to prescribe the sponsor's product.⁹ The sentiment that Speakers' Bureaus are promotional rather than educational is reinforced by the fact that the Bureaus are funded through pharmaceutical companies' marketing budgets.

Until recently, pharmaceutical companies routinely showered physicians with gifts such as pens, lunches, and continuing medical education, confident that such giveaways would influence physicians' prescribing hab-

Physicians are selected for participation on Speakers' Bureaus based upon various criteria. In many cases speakers are selected for their prestigious academic credentials; for example, physicians from major medical centers are thought to draw large audiences and successfully influence other physicians simply by virtue of their affiliations.¹² In other cases, practitioners are targeted to talk with small, community-based audiences — not so much to influence other physicians, but to manipulate their own prescribing practices.¹³ It has been demonstrated that physicians who are approached by a pharmaceutical company and "valued" for their "skill and expertise" (by being paid to speak) are thereafter likely to write more of their own prescriptions for the company's products.¹⁴ Such manipulation is one of the factors that has led to the disrepute of pharmaceutical marketing practices in general and Speakers' Bureaus in particular.¹⁵ A recent *qui tam* action against Novartis Pharmaceutical Corp. highlights the issue.

In August 2010, Jeremy Garrity, a former Associate Cardiovascular Metabolic Specialist and Area Scientific Sales Consultant at Novartis,¹⁶ filed a whistleblower action alleging various illegal and unethical marketing tactics, including off-label marketing, in violation of the False Claims Act.¹⁷ Garrity alleged, among other things, that that Novartis implemented "training and learning programs" (Speakers' Bureaus) not to increase scientific exchange regarding its drug,

but to increase the trainer's own prescribing of the drug. Specifically:

[s]peakers were continually used and paid, even though some could not communicate at an acceptable level... [s]everal speakers had difficulty with English. Other speakers were simply very poor communicators. Most physicians were selected based upon criteria related to prescription writing, not related to the identified purpose of the services in the contract. They often did not have the expertise level necessary for a physician to be a "consultant" in the specific sub-fields of cardiology that they were paid to speak about.¹⁸

Novartis settled the suit one month later, agreeing to pay \$422.5 million in civil and criminal fines, albeit without admitting wrongdoing.¹⁹

Pharmaceutical companies reportedly closely monitor the effectiveness of their so-called educational talks. A marketing representative routinely attends the presentation, observing and critiquing the speaker: if the speaker emphasizes the favorable aspects of a drug and effectively finesses questions from the audience that challenge the data, he or she is more likely to be invited to remain on the Speakers' Bureau.²⁰ Speakers who insist upon being more objective and, for example, openly acknowledge side effects or the value of competing products may not be asked to return. The pressure that physicians feel to conform to the pharmaceutical companies' expectations is evident in the story of one physician, Dr. Daniel Carlat, who once served on a pharmaceutical Speakers' Bureau, but has since discontinued his participation. Writing for the *New York Times* in an article entitled "Dr. Drug Rep," Dr. Carlat reports that during a particular engagement he finally "gave in to his conscious" and addressed the limitations of some of the data provided for his lecture by the pharmaceutical company.²¹ He reports that after the talk he was visited by a company representative and asked why he appeared less enthusiastic than usual about the drug during that talk.²² It was after this interaction that Dr. Carlat fully recognized that he "...was being paid to unequivocally endorse their drug" and that "once I stopped doing that, I was of little value to them, no matter how much 'medical education' I provided."²³

As gleaned from an internal Merck study published in the *Wall Street Journal*, engaging physicians by means of Speakers' Bureaus to influence their colleagues is highly effective in increasing prescriptions of their products — supporting Dr. Carlat's impression that such Speakers represent the "new and improved" pharmaceutical sales representative.²⁴ The Merck

study found that physicians who attend a lecture given by another physician are nearly four times more likely to write a prescription for the drug being promoted (in that case Vioxx) than doctors who attended a marketing event led by a pharmaceutical representative.²⁵ The fact that physician speakers are so much more effective than non-physician sales representatives at influencing professional audiences is doubtless the primary motivation in engaging physicians. Indeed, Speakers' Bureaus have become a "large commercial enterprise [that] has no proven legitimacy in relaying to attendees unbiased factual information about the pros and cons of a given drug formulation," but is an undertaking that has certainly shown legitimacy in increasing the profit margin of the pharmaceutical sponsor.²⁶

Many physicians who participate in industry Speakers' Bureaus work for more than one company, thus promoting competing products in their field of expertise. Most Speakers' Bureaus do not prohibit speakers from doing so and, in fact, consider their participation in multiple engagements to be an indication of objectivity: a physician who gives lectures on behalf of several companies is not biased in favor of any one company. While this logic has some appeal, it does not alter the fact that while engaged in any one marketing activity, the speaker's focus is on the subject of the talk, and another gig on another day does not change the promotional nature of the activity.

Despite the perceived negative effects of these interactions and the efforts to prevent or discourage them, pharmaceutical companies' generous compensation continues to attract the participation of physicians. In a 2010 study, 94 percent of physicians reported some kind of financial relationship with industry, and almost half of the practicing physicians and a third of the medical residents interviewed acknowledged that pharmaceutical representatives are moderately-to-very important in influencing their prescribing habits.²⁷ In a recent study of physicians at continuing medical education conferences, 73 percent of physicians reportedly perceived that faculty members who participate in commercial Speakers' Bureaus are moderately-to-substantially biased in favor of the company's product.²⁸ Indeed, numerous studies have shown that payments from a pharmaceutical company, even in the form of small gifts of minimal value, influence physicians' prescribing habits in favor of the company's drug.²⁹ Even physicians who reportedly believe they are impervious to influence by gifts and fees, or who view themselves as educators and "thought leaders" when they are paid to speak about a particular drug, have been shown to write more prescriptions for the drug after speaking about the product.³⁰ The

studies are often interpreted to suggest that receiving gifts or other compensation from a company generates a subconscious sense of obligation in the recipient to reciprocate for the gift or compensation.³¹ Much of the research on reciprocity has been conducted by the pharmaceutical companies, and they are unapologetic in their willingness to use their findings to adapt their marketing practices. In fact, pharmaceutical companies' understanding of how gifts influence physicians has caused some of them to prohibit their own employees, including their physicians, from accepting even small gifts.³²

Pharmaceutical companies walk a fine line but have developed strategic ways to use physician speakers as promotional pawns in their attempt to encourage off-label prescribing while still complying with FDA regulations. In this regard, the suggestion that physicians working on behalf of industry have become the “modern day drug rep” is apropos.

Additionally, there is a growing perception that the marketing efforts of pharmaceutical companies are responsible, at least in part, for the rise in the costs of pharmaceutical products.³³ Since pharmaceutical marketing focuses on encouraging physicians to prescribe newer, more expensive drugs, there is less emphasis on older, less expensive or off-patent, generic brands.³⁴ Numerous studies have demonstrated that physicians who have more contact with pharmaceutical industry representatives are more likely to prescribe brand-name products in lieu of cheaper, generic alternatives and to request that a brand-name drug be added to a hospital formulary.³⁵ A 2000 study analyzing Medicaid prescription drug spending concluded that a potential savings of \$229 million could have been realized within the Medicaid program from greater use of generic drugs without compromising patient care.³⁶ Furthermore, pharmaceutical marketing affects the total number of prescriptions written, and the heavy marketing of drugs may also influence physicians to opt for prescribing medication rather than suggesting non-drug therapies to treat a medical condition — such as altering one's diet or exercise habits.³⁷

Finally, Speakers' Bureaus have been particularly criticized in recent years for engaging in off-label marketing which, while often illegal, is extremely lucrative to the company. Although physicians may

prescribe FDA-approved drugs for any purpose they believe is indicated, the manufacturer is prohibited from engaging in promotional efforts to encourage “off-label” prescriptions³⁸ unless it is in the context of “scientific exchange”³⁹ or investigational use.⁴⁰ In the last three years, at least ten pharmaceutical companies have paid out a combined total of more than seven billion dollars in fines for surreptitiously finding ways to promote off-label uses.⁴¹ One means of off-label promotion is to engage physicians who, on their own and without the overt coaching of the company, discuss off-label uses.⁴² Another is to target for

promotion those physicians who rarely prescribe the drug for its approved uses but do prescribe products to treat those conditions for which the company seeks to promote its off-label use.⁴³ Pharmaceutical companies walk a fine line but have developed strategic ways to use physician speakers as promotional pawns in their attempt to encourage off-label prescribing while still complying with FDA regulations. In this regard, the suggestion that physicians working on behalf of industry have become the “modern day drug rep” is apropos.⁴⁴

II. Speakers' Bureaus and the Spirit of Academic Freedom

A. In Defense of Speakers' Bureaus

Supporters of Speakers' Bureaus point out that the Food and Drug Administration (FDA) approves the company-produced slides and, in fact, generally requires that the slides be presented and ordered in the manner approved by the FDA.⁴⁵ This is because the FDA needs to maintain some control over the *marketing* of drug products and ensure that when certain claims are made, they are followed in due course by explanations, limitations, and cautions.⁴⁶ Since physicians serving on a Speakers' Bureau do so at the behest of the marketing arm of the pharmaceutical company, they are subject to the same promotional regulations as the company's sales force.⁴⁷ The critical issue is that the slides are approved as a *marketing* tool at the same time the presentation is promoted as an *educational* event. The slides are not intended to be either comprehensive or objective — or to discuss the full range of pharmaceuticals used to treat a particular medical condition. They are slides about a *product* or about a *condition that is treated by a sponsor's product*. Additionally, although the slides do not prevent a speaker from discussing such matters as the benefits of a competitor's product, the presence of the pharmaceutical representative in the audience, monitoring the inter-

change with the audience, makes it clear that promotion trumps any educational purpose.

Despite the marketing influence, the pharmaceutical industry and some physicians argue that Speakers' Bureaus are an important tool for educating doctors about various medical conditions and the therapeutic value of the pharmaceutical options.⁴⁸ They argue that physicians are needed to educate other physicians — and the alternative of relying upon pharmaceutical representatives for drug information does a disservice to the audience. They argue that the disclosure of the industry relationship addresses any conflicts of interest. Some physician speakers contend that since they only agree to speak about products they can fully endorse, their enthusiasm for the product, despite their role in the Bureau, is genuine.⁴⁹ Others insist that it is possible to speak objectively about company products uninfluenced by the presence of the company representative in the audience.⁵⁰ Additionally, many physicians believe that the influence is overstated because the compensation they receive for participation in Speaker' Bureaus is a fair reflection of their professional time and not out of proportion to what they earn in other professional settings.⁵¹ Pharmaceutical companies defend this marketing practice by reinforcing the sentiment that their talks provide valuable information — and, in fact, in recent years they have increased recruitment of physicians to speak on behalf of their products.⁵² In 2004, for example, the number of pharmaceutical industry-sponsored meetings and talks featuring physicians as speakers amounted to nearly 240,000, a four-fold increase over the prior six years.⁵³

Others who defend participation in Speakers' Bureaus dispute the literature and data on reciprocity, arguing that the methodology used to study reciprocity is flawed and thus does not support the conclusion that gifts and other perks necessarily result in reciprocity.⁵⁴ They argue that academic medicine's obsession with industry conflicts of interest is hindering innovation by impeding the participation of some of the profession's most talented physicians without adequate evidence that the rules set forth in typical AMC COI policies are either necessary or effective. Harvard University's Thomas Stossel et al. have been vocal supporters of collaboration between academic medicine and industry partners and are concerned that the new rules, despite difficulties in enforcement, will eventually operate to the detriment of these important partnerships.⁵⁵

Certainly it is intuitive that a company influences the content of a promotional speech when it pays a large fee for the lecture and makes decisions about future engagements based upon what it observes. Neverthe-

less, there are those who challenge the data, or absence of data, that a causal connection to bias necessarily exists, or the conclusion that restricting faculty participation in Speakers' Bureaus is the right solution. Academic institutions are generally careful to distinguish industry research and development (R&D) from industry marketing activities, often praising institutional involvement with the former while restricting the latter. Participation in R&D is generously referred to as "bench to bedside" or "translational medicine" where industry and academia collaborate collegially to discover, develop, and test new drug products. The value of translational research is generally undisputed and in recent years academic institutions have been willing participants in such endeavors.⁵⁶ At the same time, of course, they are distancing themselves from the promotional aspects of drug development, at least in part because numerous and notorious reports of the aggressive, even illegal, tactics of pharmaceutical marketing departments make it unseemly and undignified for academic institutions to have faculty participating in such activities.

Those who defend faculty participation in Speakers' Bureaus dispute that a bright line that academic institutions imagine distinguishes R&D from marketing activities is defensible, including the assumption that all faculty participation in industry speaking activities, particularly Speakers' Bureaus, is improper. Some commentators point out that there is no research data that evaluates patient outcomes as a measure of commercial influence on physician decision-making, and that without such data, one cannot prove the deleterious effects of physicians participating in industry marketing efforts.⁵⁷ Indeed, such a study may be impossible to design. Presumably the same products that industry and academia collaborate to design and bring to market are only valuable if practicing physicians are advised about their existence, educated about their efficacy, and, in the case of medical devices, even instructed on their proper use. Is there really a clear distinction guiding faculty participation toward drug development and translational medicine (R&D), but away from marketing when it comes to instructing colleagues about the existence of the new product and its use, efficacy, and limitations? At what point does the dissemination of information "about" a drug move from translational medicine to marketing? And is it a satisfactory answer to simply ignore the promotional effects of certain forms of discussion about new products when the intent is primarily to educate, or vice versa?

Further, while it is strongly intuitive that pharmaceutical marketing endeavors — which include payment to highly-credentialed faculty members to deliver a company's marketing pitch — result in

The AAUP provides that while academic freedom protects individual viewpoints, there is a corresponding obligation of the institution which makes it clear that academic freedom itself is not an individual right, as would be freedom of speech, for example — from which academic freedom is a derivative right. Rather it is instead a privilege bestowed by the profession or the institution — and subject to its policies.

biased messages, what about the fact that a faculty member can actually *believe* in a company's message about a particular product, even though it is delivered via industry-created marketing slides? Presumably there are *some* pharmaceutical and device products that academic physicians can genuinely support, even though the promotional material is pre-packaged in FDA-approved marketing slides. And as to COI policies that permit speakers to participate in marketing if they use their own slides (generally tweaked and approved by the company), is that really any better than using the company-generated slides? Perhaps the current posture of COI policies in many AMC's is just a compromise, recognizing that some products genuinely earn the praise that prepackaged marketing shows deliver — but so many others do not. Thus the compromise is that AMC's require speakers to generate their own slides and hope that in forcing them to do so, they eliminate some of the bias inherent with a speaker trying to satisfy the company which pays his fee. To some extent, the compromise must ignore the research on "reciprocity"⁵⁸ and pretend that while a pen or free lunch can influence behavior, speakers' fees are immune from the demands of reciprocity because faculty members generate their own slides.

B. Academic Freedom

Assuming that there must be at least *some* products that are as good as their advertising (or Speakers' Bureaus' slides) says they are — and that we do not know which they are — can academic institutions really prohibit faculty from speaking by means of Speakers' Bureaus on behalf of *all* such products? Are the blanket COI policy rules that AMC's impose really consistent with the principles of academic freedom? This inquiry begins with a clear definition of academic freedom:

...Academic freedom...protects faculty from intrusions by their institutions of higher education, whether public or private....[W]hile the freedoms of expression are regarded as individual liberties, which equally protect individu-

als from abridgements of their rights, academic freedom does not function in this regard. It does not protect individual professors from all regulation of their work....The function of academic freedom is not to liberate individual professors from all forms of institutional regulation, but to ensure that faculty within the university are free to engage in the professionally competent forms of inquiry and teaching that are necessary for the realization of the social purposes of the university.

The AAUP's 1940 Statement of Principles on Academic Freedom and Tenure provides the following tenets as essential to academic freedom:

1. Teachers are entitled to full freedom in research and in the publication of the results, subject to the adequate performance of their other academic duties; but research for pecuniary return should be based upon an understanding with the authorities of the institution.
2.
3. College and university teachers are...officers of an educational institution. When they speak or write as citizens, they should be free from institutional censorship or discipline, but their special position in the community imposes special obligations. As scholars and educational officers, they should remember that the public may judge their profession and their institution by their utterances. Hence they should at all times be accurate [and] exercise appropriate restraint....⁵⁹

The AAUP statement is clear that rights of academic freedom come with strings attached.⁶⁰ For example, where research is involved, professors are obligated to ensure that the research satisfies the funder.⁶¹ When teaching involves matters of controversy, professors are required to ensure that the content of the teaching is not designed to indoctrinate trainees to a par-

ticular viewpoint.⁶² When a speech is “extramural” or has the potential to interfere with the usual operation of the university, academic freedom is unlikely to succeed as a defense.⁶³ In the case of Speakers’ Bureaus, the AAUP tenets of “accura[cy]” and “appropriate restraint” appear to specifically address faculty participation where such activities are uniformly at odds with institutional policy as well as the current policies of the AMA and AAMC.

Assuming there are some products, however few, for which the promotional packaging really is consistent with a speaker’s genuine beliefs (or so he or she believes), does the AAUP support the ability of an academic institution to impose a blanket policy preventing a faculty member from participating in a promotional pitch not held on university grounds? It appears that it does. The AAUP provides that while academic freedom protects individual viewpoints, there is a corresponding obligation of the institution which makes it clear that academic freedom itself is not an individual right, as would be freedom of speech, for example — from which academic freedom is a derivative right. Rather it is instead a privilege bestowed by the profession or the institution — and subject to its policies.⁶⁴

In *Garcetti v. Ceballos*,⁶⁵ the U.S. Supreme Court held that when a *public* employee makes statements pursuant to official duties, he or she “by necessity must accept limitations on his or her freedom” which includes speech under the First Amendment. The Court explained that such statements made in the course of official duties are not made by the employee in the capacity as a “citizen” for First Amendment purposes.⁶⁶ Following *Garcetti*, however, a federal district court in Ohio addressed the issue of whether *Garcetti* would apply in a matter involving teaching and research activities in a university — in that case a state medical school. In *Kerr v. Hurd*⁶⁷ a professor alleged retaliation by a department chair who did not agree with his teaching concerning various obstetrical techniques. Although the court opined that public and private universities should recognize an “academic freedom” exception to *Garcetti* to protect First amendment principles, it explicitly added the caveat “[a]t least where... the expressed views are well within the range of accepted medical opinion.”⁶⁸

In *Regents of University of Michigan v. Ewing*,⁶⁹ the U.S. Supreme Court held that courts should show substantial respect for a faculty member’s professional judgment *except* when there is a “substantial departure from accepted academic norms.”⁷⁰ The *Garcetti* principle was reiterated by the Third Circuit Court of Appeals in *Gorum v. Sessoms*,⁷¹ where a faculty member challenged his termination by the university after he disinvited the president who was to speak at a fra-

ternity event. The court held that because the speech in question was “[un]related to scholarship or teaching,” the faculty member was not protected by academic freedom and his discharge did not “imperil” First Amendment rights.⁷²

Finally, assuming a medical school makes available an internal grievance process that permits an aggrieved faculty member to challenge the institution’s definition and implementation of its academic freedom policy, courts would likely give considerable deference to institutions’ academic decisions.⁷³ University decisions about implementation of reasonable administration and educational policies implemented pursuant to bylaws are generally accorded substantial deference.⁷⁴

C. Non-Bureau Speaking: Continuing Medical Education and Scientific Meetings

There are contexts in which physicians discuss pharmaceutical products and the conditions they treat without being plagued by the issues that surround Speakers’ Bureaus. Continuing medical education (CME) is an obvious example. Another is hospital grand rounds, which are usually devoted to education on the diagnosis and treatment of a particular medical condition and may include the available drugs as well as non-pharmacologic treatment options. Additionally, physicians can be paid by industry to present their own research findings or clinical practice experience that may relate to a company’s products or to a condition treated by the company’s drugs. Indeed, there are numerous opportunities for physicians to educate one another through speaking activities that do not include participation or payment from industry *as a marketing activity*. The hallmark of these events is that physicians prepare their own presentations and respond to questions and inquiries without reliance on industry-prepared materials. AMCs generally permit faculty participation because the industry sponsor does not control the content of their presentation. But does this mean that industry-funded, but non-Speakers’ Bureau, speaking is largely free of industry influence? The available data suggests that is not.⁷⁵

Research suggests that CME, when it receives support from pharmaceutical companies, results in an increase in the number of prescriptions of the company’s product, even when the education is separated from the sponsor’s marketing activities.⁷⁶ Further, it is reported that CME activities funded by industry tend to address a narrower range of topics, have a greater focus on drug therapies, and give a more favorable treatment to the sponsor’s products than CME programs not funded by industry.⁷⁷ At present, it is estimated that pharmaceutical and medical

device companies support approximately 60 percent of accredited CME, with much of the funding coming directly from the companies' marketing budgets.⁷⁸ Notably, in a 2009 survey of CME participants at accredited CME events around the nation, 88 percent of those who responded believed that commercial support of CME does introduce bias, but only 15 percent were in favor of eliminating commercial support of CME, and only 42 percent of respondents were willing to pay increased registration fees to attend a CME event free of industry participation.⁷⁹

How does this bode for industry sponsorship of CME? Most AMCs require that any CME occurring on campus be in accordance with the Accreditation Council for Continuing Medical Education (ACCME) standards for commercial support. ACCME standards require, among other things, that all CME speaker selection and program content be developed independently without any input from industry⁸⁰ and that there be full disclosure and management of any industry relationships of those presenting or planning the CME event. Further, all presentations must include a balanced view of therapeutic options, such that the content of presentations is focused on promoting improved quality in health care and not on advancing any commercial business interest.⁸¹ To further insulate CME activities, most AMCs have COI policies that require that industry support for CME be contributed as an unrestricted educational grant to the institution. The grant must flow through a general repository for such funds to be distributed for CME activities without any input as to speaker selection or content from the industry sponsor.⁸² Clearly CME can no longer look to industry Speakers' Bureaus for selection of faculty.

Despite the safeguards that insulate CME from obvious industry influence, the question remains as to whether the very sponsorship influences content, much the same way that even small gifts have been demonstrated to influence the writing of prescriptions. Put another way, the issue is whether the industry funding itself compromises the programs. Today many commentators feel that industry support of CME should be forbidden,⁸³ and even the AMA recently adopted the stance that CME "should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."⁸⁴ This recent shift in the position of the AMA could have significant implications as ACCME considers whether to revise its Standards for Commercial Support to reflect the AMA's ongoing concerns about the effects of commercial support of CME.⁸⁵

III. Public and Private Efforts to Restrict Physician Participation in Industry Speakers' Bureaus

A. Massachusetts Law

Over the past decade, several states including Minnesota, Massachusetts, Vermont, as well as the District of Columbia passed laws that require pharmaceutical and device manufacturers to report payments and gifts to physicians.⁸⁶ The most demanding of these laws in terms of transparency is the Massachusetts Pharmaceutical and Medical Device Manufacturers Code of Conduct which was passed in 2008⁸⁷ and took effect in 2009.⁸⁸ The Massachusetts law requires the reporting of all payments over \$50 made by pharmaceutical and medical device companies to physicians, hospitals, and others who prescribe, dispense, or purchase drugs or devices in Massachusetts.⁸⁹ All data collected pursuant to this law is captured and publicly posted on an online database accessible through the Massachusetts Department of Public Health.⁹⁰

The Massachusetts law does not prohibit participation in Speakers' Bureaus; it does, however, require transparency. Specifically, it requires pharmaceutical companies and device companies to publish the names of physicians who participate in their Speakers' Bureaus, as well as other industry-funded activities, and the amounts of money paid. Academic or scientific speaking events that are not funded by industry are not included.⁹¹ In creating these reporting requirements, the Massachusetts law continues to allow pharmaceutical marketing activities, but requires transparency so that consumers and others who are concerned about the influence of industry on their physicians have ready access to the data. This increased transparency may also discourage physicians who are uncomfortable with their participation in industry-sponsored marketing activities being publicized.

B. The Patient Protection and Affordable Care Act of 2009

In response to the increasing concerns about conflicts of interest in academic medicine, and the numerous state laws (enacted and/or proposed), and in an attempt to create uniform, national transparency requirements, COI regulations are contained within the Patient Protection and Affordable Care Act of 2009 (PPACA),⁹² which is federal legislation enacted in 2010. The new law will require most pharmaceutical companies and medical device manufacturers to publicly report to the Department of Health and Human Services (HHS) all gifts and payments made to physicians and teaching hospitals.⁹³ This transparency requirement, known as the "Sunshine Provision,"⁹⁴ went into effect on January 1, 2012 and requires the Department of Health and

Human Services (HHS) to post payment information on a publicly accessible and readily searchable website on an annual basis beginning in March 2013.⁹⁵ Pursuant to the federal provisions, all payments must be reported, specifically including funds for promotional speaking.⁹⁶ The Sunshine Provisions do not prohibit payment for promotional talks; they do, however, impose fines for failure to disclose them.⁹⁷

If and when the Sunshine Provisions are fully implemented, it is expected they will preempt state laws,⁹⁸ such as that in Massachusetts, which mandate disclosure of the same information to the state Department of Public Health.⁹⁹ However, states can still regulate the reporting of information not required by the federal government and can enact additional requirements.¹⁰⁰ Additionally, since the Sunshine Provisions only relate to physicians and teaching hospitals, states can require pharmaceutical companies to report payments to other health care professionals, such as nurse practitioners, pharmacists, and those unaffiliated with institutions.¹⁰¹

C. Conflict of Interest Policies at Academic Medical Centers

Most AMCs have become more vigilant about adopting institutional COI policies that restrict faculty members from engaging in certain financial relationships with industry.¹⁰² COI provisions surrounding speaking engagements have become increasingly contentious “reflecting concerns that promotional talks undermine the credibility of both the physicians giving them and the institutions they represent.”¹⁰³ In response, some pharmaceutical companies have begun accommodating faculty by allowing them to prepare their own slides and assume greater control over the content of their presentations. The major issue for AMCs is often whether the company sponsor — one way or another — dictates the content of the presentation. Additionally, AMCs typically require that the presentation be evidence-based and reflect a balanced assessment of the current science and available treatment options. Some insist that the compensation received must be modest.

Although the essential issue for AMCs is the control of the presentation’s content — which disfavors industry participation in review of the slides and/or talking points — the more difficult issue is the industry funding itself. If “gifts” to physicians such as pens and free lunches are deemed to be inappropriate due to concerns about reciprocity, arguably reciprocity occurs whether or not the speaker prepares his or her own slides. Furthermore, the distinction between permissible, evidence-based and scientifically-reliable educational content and prohibited company-controlled

content (such as through a Speakers’ Bureau) is often much more nuanced, such that meaningful regulation of industry-sponsored programs is difficult.

Currently, most major AMCs have COI policies that address Speakers’ Bureaus and other paid talks on behalf of industry. It is not unusual for teaching hospitals to have separate policies from the medical school where many of their physicians have faculty appointments, particularly if the medical school does not own the affiliated hospital. In those cases, physicians may be required to comply with two or more policies that may be inconsistent on this issue. Ultimately, despite the recent trend to strengthen COI policies at AMCs, few are able to enforce COI policies that are as restrictive as the regulations proposed by organizations such as the Institute of Medicine (IOM), the Association of American Medical Colleges (AAMC), and the combined guidelines by the Institute of Medicine as a Profession and the American Board of Internal Medicine (ABIM-IMAP) would have them.¹⁰⁴ The IOM, ABIM-IMAP, and AAMC all include guidelines for managing COI that either prohibit or strongly discourage faculty participation in Speakers’ Bureaus.¹⁰⁵

In 2008, the American Medical Student Association (AMSA) undertook the task of evaluating the COI policies at U.S. medical and osteopathic schools, including their affiliated teaching hospitals. AMSA “graded” the institutional policies based on various criteria including their handling of industry-funded speaking relationships.¹⁰⁶ As of 2010, AMSA evaluated 152 policies and found that only 23 schools had “model” policies on speaking — those that either prohibit Speakers’ Bureaus or contain strong provisions that limit compensation and ensure scientific integrity by prohibiting the company from determining the content of the talk.¹⁰⁷ AMSA concluded that nearly half of AMCs had speaking policies that regulated speaking relationships but did not place meaningful limits on content or compensation.¹⁰⁸ For example, some COI policies merely require pre-approval of speaking engagements.¹⁰⁹ Furthermore, over one-quarter of the institutions either have no policy on industry speaking, or have a policy that does not effectively restrict it.¹¹⁰

AMCs generally adopt one of the following policy approaches to lectures on behalf of industry (which speaks only to the policy and not its enforcement):

1. *Policies Prohibiting Speakers’ Bureaus:* A few AMCs have taken a “purist” approach that not only specifically prohibits participation in industry Speakers’ Bureaus, but also places substantial regulation on other speaking relationships.¹¹¹ For example, Stanford¹¹² and the University of Colorado at Denver¹¹³ strictly require that speaking engagements be wholly

independent of pharmaceutical company influence, allowing faculty to participate only if they produce their own content and insist upon a balanced and accurate presentation.

2. Policies that Prohibit Speakers' Bureaus with Caveats: A number of AMCs have policies that prohibit lectures on behalf of industry when the company controls the content of the presentation.¹¹⁴ Although these schools do not prohibit all participation on Speakers' Bureaus, they do place substantial constraints that amount to a prohibition if faculty members do not retain full control over the content of their presentation — a provision that is at odds with the requirements of most Speakers' Bureaus.¹¹⁵

3. Policies that "Strongly Discourage" Participation on Speakers' Bureaus: A number of AMCs have policies that "strongly discourage" participation in industry Speakers' Bureaus but do not prohibit it. In essence, these policies leave it up to the faculty member's discretion to determine whether a speaking arrangement is consistent with the school's COI principles.¹¹⁶

Some policies strongly discourage faculty from participating in all industry marketing activities, including lectures, when funded through the company's marketing budget.¹¹⁷ Despite the institutions disfavoring Speakers' Bureaus, however, faculty may continue to participate without recourse.¹¹⁸

4. Policies that Permit Participation on Speakers' Bureaus: Lastly, some AMCs do still permit participation in Speakers' Bureaus or do not impose limits on speaking engagements.¹¹⁹ In these institutions, faculty members are often required to disclose their industry relationships, including industry-sponsored lectures.¹²⁰

Nearly all AMCs require some form of reporting or disclosure of industry relationships — both to the audience at the time of the presentation and to the AMC on an annual basis.¹²¹ The value of disclosure is twofold: on the one hand it urges presenters to be vigilant about the integrity of their presentation;¹²² on the other, it urges the audience to evaluate the presentation in light of the speaker's industry relationship(s). While doubtless important in monitoring industry activities, and while disclosure may deter some people from engaging in industry relationships that are publicly disclosed,¹²³ many argue that simple disclosure of relationships with industry is not enough to motivate change, and disclosure alone is not sufficient to resolve or eliminate conflicts of interest.¹²⁴ Others contend that disclosure does not adequately address the COI since "asking key opinion leaders to reveal their industry ties is not much different than asking them to reveal their honors and prizes."¹²⁵ And still others speculate that restricting disclosure could backfire, instead generating implicit permission, or "moral

licensing," for COI since physicians may feel that their relationships with industry are sanctioned as long as they are disclosed.¹²⁶ With respect to patient care, if disclosure creates the impression that one's physician is honest and trustworthy, it may lead to a false confidence that the disclosure mitigates the likelihood of receiving compromised care.¹²⁷

IV. Can Academic Institutions Enforce Their Own Policies?

Although many AMCs manage industry relationships by means of COI policies, enforcement of the Speakers' Bureau activities has been problematic. Despite most AMC policies requiring annual reporting, only two states (Massachusetts and Minnesota) require companies to post payments to physicians on a public database, which facilitates verification of what is reported.¹²⁸ The federal government promises a similar database through the PPACA, but it is unclear if and when a searchable database will be implemented. Additionally, ProPublica, a non-profit, independent source of public interest journalism, recently started its Dollars for Docs program wherein it maintains a public database reporting payments to physicians from the eight largest pharmaceutical companies. Despite the Dollars for Docs publicity, most of the pharmaceutical companies doing business in the U.S. — more than 70 in all — do not report payments. As a result, enforcement relies primarily on an honor system with no clear or uniform consequences for failure to accurately report. Furthermore, once reporting occurs, few AMCs have yet to either adopt or impose sanctions that are severe enough to force faculty to discontinue their activities. A search of ProPublica's database reveals numerous instances where AMCs have COI policies prohibiting industry talks, but some faculty members participate anyway.¹²⁹

Some AMCs attribute non-compliance with their COI policies to lack of understanding of the provisions, which are sometimes described by physicians as legalistic and hard to follow.¹³⁰ Rather than impose sanctions, the institutions promise expanded efforts to educate faculty.¹³¹ Others have seemingly postponed sanctions until such time that faculty can terminate their industry relationships in an orderly manner.¹³² Yet despite numerous examples of schools where faculty members apparently ignore their institutions' COI policies and continue participation in promotional speaking, the University of Massachusetts and its affiliated hospital, UMass Memorial Medical Center, appear to have successfully divested their faculty — consisting of nearly 1000 employed physicians — of their industry speaking relationships.¹³³ At present the UMass policy, like many others, covers only employed faculty and does

not reach to the community and voluntary staff who have privileges but do not receive significant compensation from the school or hospital. UMass attributes its success¹³⁴ to educating its faculty, establishing a “pharm-free” presence at its facilities, using the public databases for verification and maintaining a culture where the faculty is accountable to one another, such that it is unacceptable for them to evade the rules.

Finally, at the same time more and more AMC are restricting promotional talks, some of their efforts are

Recent evidence suggests that even when the rules are well understood, only a few AMCs are taking strict disciplinary action against faculty who violate the institutional policy on Speakers’ Bureaus. Some commentators have speculated that COI policies are more about protecting the institution from legal liability than about helping physicians and researchers understand and manage conflicting obligations.

countered with pushback from faculty members who have grown accustomed to the substantial income derived from industry lectures.¹³⁵ For instance, in a highly publicized matter, Dr. Lawrence DuBuske gave up his prestigious position at Brigham and Women’s Hospital in Boston, Massachusetts after more than 20 years of service — along with his highly coveted Harvard Medical School faculty appointment that went with it.¹³⁶ Given an ultimatum from Harvard pursuant to its new COI policy, DuBuske chose to maintain the industry speaking relationships that Harvard’s new policy would prohibit.¹³⁷ Reportedly, DuBuske earned nearly \$100,000 from a single pharmaceutical company in a three-month period, not to mention the six other companies for which he speaks and his various other industry roles.¹³⁸ DuBuske may have felt that having been a Harvard Medical School faculty member for two decades is nearly as good a speaking credential as a current appointment. However, as COI are more consistently managed, other physicians will not have the luxury of relying upon a past academic appointment — one of the credentials that are so valued by the pharmaceutical industry in selecting its speakers. In fact, the U.S. Director of Media Relations for GlaxoSmithKline stated after DuBuske’s resignation that she was “not sure whether DuBuske will be as much in demand as a speaker without the prestigious Brigham and Harvard titles.”¹³⁹

Conclusion

At present, evidence suggests that many AMCs continue to “look the other way” as faculty members give industry-sponsored promotional talks, even when restricted by the AMC’s COI policy.¹⁴⁰ In some cases, the AMCs may not want to put their faculty in the position faced by Dr. DeBuske and risk that they choose to relinquish their appointments. In others, AMCs rely upon the honor system and/or allow physicians to interpret the rules as they see fit.¹⁴¹ Recent

evidence suggests that even when the rules are well understood, only a few AMCs are taking strict disciplinary action against faculty who violate the institutional policy on Speakers’ Bureaus.¹⁴² Some commentators have speculated that COI policies are more about protecting the institution from legal liability than about helping physicians and researchers understand and manage conflicting obligations.¹⁴³

Management of AMC provisions on Speakers’ Bureaus is still in its infancy. Even now, the recent attention to industry relationships, coupled with transparency through public reporting, is expected to cause some physicians to discontinue participation. Academic medicine is a competitive career path that is unlikely to be significantly altered by faculty members’ inability to participate in industry Speakers’ Bureaus, particularly since speakers are far less attractive when they do not have their academic credentials. While the current generation of physicians became accustomed to the economic benefits of industry relationships at a time that they were not restricted, medical students are now being trained in a culture that carefully scrutinizes these relationships. In this period of transition, Speakers’ Bureaus are already engaging more and more community physicians as “opinion leaders” to replace AMC faculty members serving in that role. Additionally, academic detailing¹⁴⁴ — the practice of AMCs taking an active, unbiased role in educating their own physicians and the community about new pharmaceuticals and devices — is beginning to gain momentum as an important and reliable source of information about industry products.

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5. T. L. Hafemeister and S. P. Bryan, "Beware Those Bearing Gifts: Physicians' Fiduciary Duty to Avoid Pharmaceutical Marketing," *University of Kansas Law Review* 57, no. 491 (2009): 491-537, at 507.
6. D. J. Rothman and S. Chimonas, "Academic Medical Centers' Conflict of Interest Policies," *JAMA* 304, no. 20 (2010): 2294-2295, at 2294. It appears that in some cases physicians are allowed to add additional material to the officially sanctioned slide deck. However, with the recent crackdown on off-label marketing, it seems that pharmaceutical companies are more and more requiring all speakers to use the slides they provide and to present them in the order specified by the pharmaceutical company. Companies that do allow a speaker to give feedback on the content of slides typically require any modifications to the slide-deck to be pre-approved by the pharmaceutical company.
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8. *Id.*
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10. Research indicates that such influence occurs in ways that individuals cannot perceive and creates subtle biases that are not humanly possible to eliminate. See, T. A. Brennan et al., "Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers," *JAMA* 295, no. 4 (2006): 429-433; see, J. Dana and G. Lowenstein, "A Social Science Perspective on Gifts to Physicians from Industry," *JAMA* 290, no. 2 (2003): 252-255; see, Baylor College of Medicine, *The Scientific Basis of Influence and Reciprocity: A Symposium*, Association of American Medical Colleges, 2007.
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15. Pharmaceutical companies that engage speakers primarily to increase their own scripts are able to cull that information from a process known as pharmaceutical "data mining." Data mining organizations purchase certain prescriber-identified raw data from pharmacies, combine it with physician information purchased from other organizations, even including the AMA, and sell to pharmaceutical companies. Records include such information as the prescribing habits of individual physicians and allow them to identify and target those physicians who routinely prescribe the company's product or a competitor's product. Since one of the goals of Speakers' Bureaus is to engage as speakers those physicians who write certain prescriptions, the purchase of prescriber-identified data achieves that goal. It also makes clear the proposition that Speaker's Bureaus are purely a marketing enterprise.
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69. 474 U.S. 214 (1985).
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72. *Id.*, at 186. Note that this was a public university setting.
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 92. *Patient Protection and Affordable Care Act*, Pub.L.No. 111-148, 124 Stat. 119, amended by the *Health Care and Education Reconciliation Act of 2010*, Pub. L. No. 111-152, § 6002.
 93. The law requires drug, biologics, medical supply, and medical device manufacturers who are covered under Medicare, Medicaid, or the Children's Health Insurance Program to publicly report to the Department of Health and Human Services (HHS) gifts and payments made to physicians and teaching hospitals. Pew Prescription Project, *Fact Sheet: Physician Payment Sunshine Provisions in Health Care Reform*, March 23, 2010, available at <http://www.prescriptionproject.org/tools/sunshine_docs/files/Sunshine-fact-sheet-6.07.10.pdf> (last visited April 19, 2012). These companies must report the physician or teaching hospital's name, address, national provider identifier (for physicians), and the value, date, form (cash or stock), and nature (gift, royalty, consulting fee) of the payment, including, if applicable, the specific drug and device to which the payment was related.
 94. The law provides an exception that allows pharmaceutical companies to ensure intellectual property rights by not having to disclose research support for four years or until a newly developed product is approved, whichever is first. V. Hughes, "Sunshine on Conflicts," *Nature Biotechnology* 28, no. 7 (2010): 641-643, at 642.
 95. See Pew Prescription Project, *supra* note 92. The information on the website HHS will create is scheduled to be publicly available by September 30, 2013 and must be readily searchable by physician so that patients have the opportunity to learn about their physician's potential conflicts of interest.
 96. Exempted from these requirements are prescription drug and device samples, payments less than \$10 (if the person does not receive an aggregate annual amount from that company of over \$100), educational materials provided for the benefit of patients, rebates and discounts, loans of a covered device for a period of less than 90 days, items provided under warranty, dividend or investment interest in a publicly-traded security or mutual fund, and payments made to a physician who is a patient or an employee of the reporting company. See Pew Prescription Project, *supra* note 93.
 97. Each failure of one of the covered companies to report a payment made results in a fine of up to \$10,000, not to exceed \$150,000 annually. Each knowing failure to report results in a fine of up to \$100,000, not to exceed \$1,000,000 annually. *Id.*
 98. As this article goes to press, the final implementing regulations are not yet posted. The legislation requires that the regulations be posted 90 days prior to the effective date of the law (January 1, 2012), but it did not occur. See Proposed Rules at Fed. Reg. Vol. 76 No. 159 (August 17, 2011), available at <<http://www.gpo.gov/fdsys/pkg/FR-2011-08-17/pdf/2011-20776.pdf>> (last visited April 19, 2012).
 99. See Miller, *supra* note 96.
 100. Pew Prescription Project, *Federal Reporting Requirements on Payments to Physicians: Impact on State Laws*, November 2010, available at <http://www.prescriptionproject.org/tools/initiatives_factsheets/files/Sunshine_State-Impact.pdf> (last visited April 19, 2012).
 101. *Id.*
 102. T. Weber and C. Ornstein, "Stanford Faculty Still Taking Drug Firms' Money," SFGate website, December 20, 2010, available at <http://articles.sfgate.com/2010-12-20/news/25209942_1_drug-firms-medical-schools-drug-companies> (last visited April 19, 2012).
 103. C. Ornstein and T. Weber, "Medical School Plug Holes in Conflict-of-Interest Policies," *ProPublica*, May 19, 2011, available at <<http://www.propublica.org/article/medical-schools-policies-on-faculty-and-drug-company-speaking-circuit>> (last visited April 23, 2012).
 104. See Chimonas, *supra* note 3, at 293-299.
 105. *Id.* The policies also address other means of limiting conflicts of interest such as establishing central repositories for product samples and industry funds for CME, scholarships, fellowships and travel, requiring that members of purchasing committees be free of conflicts of interest, and requiring full transparency for industry honoraria and consulting contracts.
 106. AMSA website, "Methodology AMSA Scorecard 2010," available at <<http://www.amsascocard.org/methodology>> (last visited April 23, 2012).
 107. *Id.*
 108. *Id.*
 109. *Id.*
 110. *Id.*

111. This type of approach has been adopted by the Stanford University School of Medicine, Harvard Medical School, and the University of Colorado Denver School of Medicine.
112. Stanford prohibits speaking which amounts to a “contractual relationships to give talks in which the topic(s) and/or content are provided by the company.” Stanford School of Medicine, *Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children’s Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries (“Industry”)*, Revised July 22, 2010, available at <<http://med.stanford.edu/coi/siip/policy.html#v>> (last visited April 23, 2012).
113. The University of Colorado at Denver defines Speakers’ Bureaus as “[c]ompensation by any pharmaceutical company, medical device manufacturer or manufacturer of other health- or nutrition-related products, or their subsidiaries, for speaking engagements whether on a one-time or recurring basis.” University of Colorado Denver School of Medicine, *Faculty Senate Resolution on Conflicts of Interest and Speakers Bureaus*, May 2011, available at <<http://www.ucdenver.edu/academics/colleges/medschool/facultyAffairs/RulesPolicies/Pages/RulesPolicies.aspx>> (last visited April 23, 2012).
114. This approach has been taken by the Tufts University School of Medicine, Boston University School of Medicine, and the University of Pittsburgh Schools of Health Sciences.
115. See Weber and Ornstein, *supra* note 41.
116. See, e.g., Duke University School of Medicine, *COI and Industry Relations*, available at <http://medschool.duke.edu/modules/som_interests/index.php?id=7#Speaking%20Relationships> (no longer available online.) Duke’s policy allows participation in industry Speakers’ Bureaus if “(1) the activity promotes evidence-based clinical care and/or advances research; (2) financial support is appropriately disclosed; (3)...financial compensation [is pursuant to] a speaker’s contract; (4) compensation...[is] reasonable (i.e. fair market value); (5) [the] lecture material represents a balanced assessment of current clinical and/or scientific treatments; [and] 6) the speaker discloses that the [content] represents his or her [own] views and not [just that of the industry sponsor].”
117. The University of Pennsylvania and Duke have adopted this approach.
118. The University of Pennsylvania policy states that “professionals should not participate in Industry marketing activities” but, of course, this falls short of an absolute prohibition. The University of Pennsylvania also allows faculty to “accept reimbursement (of travel, meals, and other expense) for presenting research findings at a meeting, presenting on clinical topics...provided that the expenses are reasonable in relation to the services provided (fair market value).” Though the Chief Medical Officer of University of Pennsylvania recently stated that he believed UPENN’s policy’s prohibition on marketing includes delivering drug-company lectures, the “fair market value” caveat along with the “should” seems to imply that at least some industry marketing “presentations” are fair game. See *Hospital of the University of Pennsylvania/Clinical Practices of the University of Pennsylvania: Clinical Practice Guidelines. Guidelines for Interactions between Health care Professionals and Industry*, effective September 26, 2006, available at <somapps.med.upenn.edu/fapd/documents/ext00159.pdf> (last visited April 29, 2012).
119. This approach has been taken by Weill Medical College of Cornell University and Tulane University.
120. The Cleveland Clinic requires disclosure of industry relationships on a public website but does not restrict industry speaking.
121. To the extent that public disclosure is required, it has the potential to result in heightened public scrutiny of industry-physician relationships by policymakers, the media, and consumer advocacy groups. It also creates pressure on states and AMCs to create policy. D. Grande, “Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention,” *Journal of General Internal Medicine* 25, no. 1 (2010): 79-83, at 80.
122. M. M. Boumil and H. Berman, “Transparency in Research and Its Effect on the Perception of Research Integrity,” *JONA’s Healthcare Law, Ethics, and Regulation* 12, no. 3 (2010): 64-68, at 66.
123. B. Lo, R. P. Kelch, and D. Grady, “Illuminating Physicians’ Financial Relationships with Industry,” *Archives of Internal Medicine* 171, no. 6 (2011): 587-589, at 588.
124. R. Steinbrook, “Controlling Conflict of Interest – Proposals from the Institute of Medicine,” *New England Journal of Medicine* 360, no. 21 (2009): 2160-2163, at 2162.
125. M. Angell, “Warning Doctor/Drug Company Interactions,” *Health Affairs* 30, no. 2 (2011): 363-364, at 364.
126. D. Grande, “Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention,” *Journal of General Internal Medicine* 25, no. 1 (2010): 79-83, at 80.
127. D. M. Cain, G. Lowenstein, and D. A. Moore, “The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest,” *Journal of Legal Studies* 34, no. 1 (2005): 1-25, at 1-25.
128. As is apparent from the three Harvard physicians recently sanctioned for failing to disclose millions of dollars in income that they received from pharmaceutical companies, disclosure without a means of double-checking the accuracy of what is disclosed is likely to result in an inaccurate reporting of physicians true relationship with industry. If and when health care reform goes into effect, it could ease the difficulty of validating accurate disclosure of relationships, but until that time there are only a few medical schools that have the ability to validate the accuracy of their data.
129. See Weber and Ornstein, *supra* note 49.
130. B. Williams-Jones, “Beyond a Pejorative Understanding on Conflict of Interest,” *American Journal of Bioethics* 11, no. 1 (2011): 1-2, at 1-2.
131. See Weber and Ornstein, *supra* note 102.
132. See Ornstein and Weber, *supra* note 103.
133. *Id.*
134. *Id.*
135. See, News Inferno, “Doctor Steps Down to Keep Drug Company Paycheck,” January 26, 2010, available at <<http://www.newsinferno.com/pharmaceuticals/doctor-steps-down-to-keep-drug-company-paycheck/>> (last visited April 21, 2012).
136. *Id.*
137. *Id.*
138. *Id.*
139. See Kowalczyk, *supra* note 12.
140. L. Kowalczyk, “Prescription for Prestige,” *Boston Globe*, October 19, 2010, available at <http://www.boston.com/yourtown/cambridge/articles/2010/10/19/pharmaceutical_money_physicians_support/> (last visited April 29, 2012).
141. See Ornstein and Weber, *supra* note 117.
142. *Id.*
143. See Williams-Jones, *supra* note 130. In 2008 Senator Charles Grassley undertook an effort to examine the influence of drug companies at medical schools. He sent letters to medical schools asking them provide the Senate with their policies. He also targeted specific individuals for detailed inquiry. See, A. Zieger, “Grassley Wants to See Med Schools’ Conflict of Interest Policies,” *Fierce Healthcare*, June 25, 2009, available at <<http://www.fiercehealthcare.com/story/grassley-wants-see-med-schools-conflict-interest-policies/2009-06-25>> (last visited April 23, 2012).
144. S. B. Soumerai and J. Avorn, “Principles of Educational Outreach (‘Academic Detailing’) to Improve Clinical Decision Making,” *JAMA* 263, no. 4 (1990): 549-556, at 549-556.