Is the speakers’ bureau system a form of peer selling?

By Lynette Reid & Matthew Herder

Lynette Reid\*, PhD, is an assistant professor in the Department of Bioethics, Faculty of Medicine, Dalhousie University. Her research focuses on professional ethics and the social role of medicine.

\*Corresponding Author. Contact information: Lynette.Reid@dal.ca; Telephone: (902) 494-1842

Matthew Herder, JSM, is an assistant professor in the Faculties of Medicine and Law at Dalhousie University’s Health Law Institute. His research focuses on university-industry relationships and intellectual property in the life sciences.

Contact information: Email: Matthew.Herder @Dal.ca; Telephone: (902) 494-2567

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**Abstract** (191 words):

**Background**: Physician-industry relations are under heightened scrutiny. In the “speaker’s bureau” (SB) system, physicians are recruited and trained by pharmaceutical, biotech, and medical device companies to deliver information about industry products to other physicians in exchange for an honorarium. **Methods**: We created an estimate of the prevalence of SB participation among Canadian faculty in one sample medical specialty through publically available disclosures. We analyzed the relevant features of a sample SB contract, and applied the CMA guidelines on physician-industry relations to the practice of SB participation. We reviewed the historical development of the CMA Code of Ethics prohibition on product endorsement, in the context of historical changes to the locus of responsibility for safe products and rational prescribing, in order to place the Code of Ethics prohibition in a broader policy context. **Results**: SB participation is likely to be familiar if not common in some specialties in Canada, and constitutes a form of peer selling that should be understood as covered by the CMA Code of Ethics prohibition on product endorsement. **Interpretation**: Academic medical institutions, in conjunction with the regulatory colleges, should continue and strengthen their policy action to address SB participation.

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Physicians need to stay abreast of emerging drugs and devices for clinical practice. The industry that markets these products has the resources and the motivation to educate physicians, but cannot be relied upon to distinguish physician’s professional development needs from their own marketing goals. Meanwhile, time pressures of clinical practice limit many physicians’ abilities to assess independently developments in their field. Historically, physicians’ professional associations, their regulatory bodies, medical journal publishers, governmental drug and device regulatory agencies, and academic medical institutions have debated their roles and responsibilities in ensuring the safety, efficacy and probity of prescribing in light of these pressures.[[1]](#footnote-2)

One current site of this longstanding struggle is the “speakers’ bureau” (SB) system, in which pharmaceutical, biotech, and medical device companies recruit and train physicians to deliver information about industry products to other physicians in exchange for an “honorarium.” Participants in the system argue that physicians are best situated to deliver accurate information about new drugs and devices to other physicians, and industry is best placed to fund such communication; critics reply that the SB system is part of a complex system of drug promotion[[2]](#footnote-3) and relationship-building[[3]](#footnote-4) with physicians that contributes to irrational prescribing, [[4]](#footnote-5) and, in some cases, harm to patients or even society writ large. For example, physicians’ involvement in SBs was part of Purdue Pharma’s promotion of Oxycontin in Canada, the use and abuse of which has had a devastating impact on several Canadian communities.[[5]](#footnote-6)

In this article we argue that the practice of remunerating physicians to present information authored by industry raises significant concerns about ethics and professionalism, especially for academic physicians, and that academic medical institutions and the profession have responsibilities to curtail the practice. In the United States regulatory context, the Code of Ethics and Opinions of the American Medical Association are neutral on physician product endorsement,[[6]](#footnote-7) and by extension neutral on physician activities that constitute product endorsement to their peers. The Canadian Medical Association’s guidelines on industry relations states, by contrast, “physicians should not engage in peer selling”:

Peer selling occurs when a pharmaceutical or medical device manufacturer or service provider engages a physician to conduct a seminar or similar event that focuses on its own products and is designed to enhance the sale of those products. This also applies to third party contracting on behalf of industry. This form of participation would reasonably be seen as being in contravention of the CMA’s Code of Ethics, which prohibits endorsement of a specific product.[[7]](#footnote-8)

Participating in SBs, in our view, falls squarely within this definition of peer selling yet SB participation abounds. After describing empirical evidence about the level of participation in SBs in the US and Canada and distilling the essential elements of SB participation in the first part of our paper, we tackle the more vexing question of enforcement through a historical analysis of the evolution of the CMA Code of Ethics and physicians’ struggle to keep apprized of, yet critically appraise, drug information. We end with recommendations about the roles of academic medicine and professional self-regulation in policing SB participation.

# Speakers’ Bureau Prevalence, Profile, and Policing

Industry covets the aid of highly achieving academic physicians to communicate their message to physicians because these “opinion leaders” influence the prescribing behaviour of their peers.[[8]](#footnote-9) The prevalence of SB participation is not known. In a 2003-4 US survey of primary care physicians in internal medicine, family practice and pediatrics, and non–primary care physicians in cardiology, general surgery and anesthesiology, 16% of their sample received payment for participation in SBs.[[9]](#footnote-10) Cardiologists were the most likely to receive reimbursement (including both SB fees and other honoraria), at rates 2.20 times higher than the average participant. In a 2007 survey of university faculty affiliated with both clinical and non-clinical departments, roughly 24% of the respondents reported being a “paid speaker” for industry, ranking behind “consultant” (~32%) as the second most common type of relationship with industry.[[10]](#footnote-11) The survey showed that the proportion of “paid speaker” faculty was higher in clinical departments (~26%) than basic science departments, and amongst faculty at the rank of full professor (~28%). Paid speakers produced significantly more publications than those who were not paid speakers, suggesting that those participating in the SB system are positioned to influence others in the field.

In Canada, no similar survey data exists. In accordance with the elevated prevalence of reimbursement in cardiology, we scanned the faculty complement in Canadian academic cardiology centres and compared this with disclosures in the published literature in cardiology. The results suggest that SB participation is common amongst faculty in a position to influence others as well (see Appendix for details). In the last five years, one or more of the top five publishing cardiologists at every Canadian medical school with an academic unit or institute dedicated to cardiology has disclosed receipt of “lecture fees”, “speaker’s honoraria”, being “paid to speak for”, and/or participating on an SB (See Figure 1) on one or more occasions (median = 2 out of 5).

[INSERT FIGURE 1 ROUGHLY HERE]

While it is likely that leading Canadian academic physicians participate in SBs, particularly those involved in writing practice guidelines,[[11]](#footnote-12) [[12]](#footnote-13) the precise terms and conditions of that participation are not known. To our knowledge, only one example of a SB contract from a manufacturer in the United States (Schering-Plough) has been made public.[[13]](#footnote-14) Nevertheless, we believe SB participation boils down to four essential elements, the first two of which pertain to the ‘content’ to be delivered by the speaker while the latter two relate to the ‘consideration’ that the agreement is contingent upon (See Table 1).

|  |  |
| --- | --- |
| Content | Consideration |
| Source of Materials (i.e. company or speaker) | Benefit to Speaker (e.g. honorarium) |
| Control of Materials (e.g. ability to revise) | Benefit to Company (e.g. increased sales) |

Table 1. Profile of SB Participation: Four Essential Elements

The Schering-Plough SB contract explicitly covers 3 of these 4 elements. It specifies that the company provides mandatory training, and provides educational materials to which the physician must adhere: the intellectual content of the presentation is entirely in the hands of the company. The speaker’s fee is the only consideration explicit in the contract. However, whether the physician will continue to serve on the SB is entirely at the company’s discretion. Given that industry “reps” often attend SB events to build relationships with attending physicians and track prescriptions of the product by the attendees before and after the event, it is reasonable for any prospective SB participant to conclude that further engagement as a speaker depends on increasing product sales.

Other requirements may seem ethical or responsible, but in fact demonstrate the company’s underlying market objectives. For instance, the contract emphasizes that the physician must present fair, balanced, and scientifically supported information, focused on the educational needs of the audience while giving the physician no control over the presentation materials. Most significantly, it requires the speaker to focus the presentation on indications approved by a regulatory agency (in this case, the US Food and Drug Administration (FDA)). However, the FDA does not regulate the practice of medicine; physicians are free to discuss off-label uses of a drug.[[14]](#footnote-15) Thus, the Schering-Plough contract’s restriction to FDA-approved marketing messages amounts to an admission that the physician is engaged in marketing.[[15]](#footnote-16)

In our view, any instance where the content of a presentation to any audience of physicians does not rest exclusively, or even primarily, in the hands of the speaker, and she or he understands -- whether through an explicit term of a contract or an implied agreement -- that the goal of her or his presentation is to increase uptake of a particular healthcare product, violates the CMA’s guideline against peer selling. Even when not formalized in a contract, these elements are the essential characteristics of any SB arrangement. Yet there is no record of disciplinary action in relation to this practice. This is not surprising insofar as physicians are unlikely to file a college complaint against colleagues who participate in SBs, not least because they tend to occupy positions of seniority and influence. But, as we show in the next section, this stance of non-enforcement is symptomatic of a long and complex struggle to balance independence, education, and entrepreneurialism in medicine.

# Advertising, Education, and Entrepreneurialism in Medicine: A Brief History

There are longstanding tensions within the medical profession between limiting product endorsement and advertising by its members on the one hand, and preserving space for ongoing education, clinical judgment, and (more recently) physician autonomy in business matters, on the other. We can trace these tensions through the evolution of the CMA Code of Ethics’ prohibition on product endorsement,[[16]](#footnote-17) judicial opinions about the boundaries of “professional misconduct,” and developments in industry practices and the regulation of medical products outside the profession, i.e. by government.

In the first two iterations of the Code of Ethics (published in 1868 and 1922), the concern of the CMA was to distinguish physicians from “empirics” and purveyors of “patent medicines” and “secret nostrums.” The 1868 Code went so far as to forbid physicians from holding patents in any form, a prohibition that was dropped in 1922 and never returned. Apart from the “simple announcement” of opening a practice, “promising radical cures” and publishing testimonials were considered “derogatory to the dignity of the profession.” Court cases involving allegations of professional misconduct picked up on similar themes.[[17]](#footnote-18) [[18]](#footnote-19) In the earliest Canadian case, where Dr. Alexander Crichton was found to have distributed circulars promoting “Grippura” as a cure for grippe and influenza, an Ontario Court noted:

In two respects he has violated proper decorum—modesty and propriety have been forgotten in his self-advertising and discreditable proclamation; and he has, in the second place, kept to himself and for himself this apparently valuable remedy, and has not made known the formula, in order that its benefits may be shared in by the profession and the public. […] The vendor of patent medicines and proprietary medicines might puff their uses and publish their testimonials and tout for customers, but not the physicians.[[19]](#footnote-20)

With the onset of government regulation of drugs for fraudulent advertising in the 1920s, distinguishing physicians from those who manufacture and sell patent drugs was no longer a central concern for the profession by 1938, the year of the third Code of Ethics. The rationale for the prohibition against product endorsement was instead framed in terms of the value of an independent voice:

The paid advocacy of any commodity whatever its merits, cannot be reconciled with the ideals of a physician. He must be free to choose from all elements those best for his patient, and not be a merchandiser pushing one particular element for gain. It is precisely because he is a physician that his advocacy has extra market value. In thus advertising a commodity, he presumes to sell that which is not his to sell, the common tradition and inheritance of reputation, esteem and standing of the whole profession.

This iteration of the Code of Ethics articulates a fundamental conflict between remuneration for promoting a particular product, and the independence of judgment expected of a physician in clinical practice.

Maintaining independence in practice was complicated by the reliance of physicians on industry itself for information, and exacerbated by the rapid expansion of therapeutic tools post-WWII.[[20]](#footnote-21) Through their “seal of approval” program, the AMA took responsibility for rational prescribing, for example, certifying drugs advertised in its journal. The program ended in 1955,[[21]](#footnote-22) and was replaced with an emphasis on the role of continuing medical education. The AMA drew a distinction between ‘information’ on new drugs and devices, which industry could provide, and continuing education for the physician, which physicians were obligated to secure, ideally from academic institutions and the AMA itself.[[22]](#footnote-23) Instead, over time, continuing medical education “provided novel sites of intersection between pharmaceutical marketing and physician education.”[[23]](#footnote-24)

In the pages of the Canadian Medical Association Journal during this era, some physicians noted that they were just as susceptible to the “huckster’s art as…the general public”,[[24]](#footnote-25) yet a level of confidence remained that the profession could dictate better interactions with industry:

Once it is made clear that the medical profession is determined to regulate the use of drugs, to use the indicated medication correctly and to stop prescribing either a wrong or useless drug or a right drug in a wrong or useless manner, the pharmaceutical manufacturers will compete with each other to please us. The information they give us will be as accurate as we demand that it be – no more, and no less.[[25]](#footnote-26)

Regulation of therapeutic products soon came, following the thalidomide disaster, but from government rather than the profession. The central feature of this new regulation was to require manufacturers to demonstrate the safety and efficacy of a given product for a defined indication prior to market entry. If safety and efficacy was shown, products could only be marketed for the indications approved on the product label. This in turn made physicians’ speech, not just their scripts, valuable to industry. The freedom physicians enjoy to discuss off-label uses of drugs creates an incentive for drug and device companies to capture the avenue of physician-to-physician communication for their own marketing purposes.

In light of the regulation of communication around off-label use, changes in the CMA’s final two Codes of Ethics become conspicuous. The 1970 Code recommends avoiding all advocacy of products, with the rider that this applies to one’s activities while portraying oneself as a member of the profession. This suggests a new awareness of the possibility that physicians may play various roles and claim freedom to engage in a wider range of business practices. It is not, however, plausible to suppose that physicians are employed in SBs to portray themselves as anything other than physicians. The current statement, enacted in the 1996 revisions, more narrowly recommends avoiding product promotion for personal gain, which would directly address the exchange of fees for delivering promotional materials, as is evidently the practice in SB arrangements.

Three points emerge from this brief historical account that are relevant to the lack of regulatory college action on CMA’s statement that peer selling is a form of prohibited product endorsement. First, since its inception the profession has struggled with the more enterprising amongst its ranks. The carefully circumscribed wording of the 1970 and 1996 rules against product endorsement suggests a re-discovered awareness that individual physicians may have a scope for defining their own commercial activities that lies beyond the claims of the profession to regulate their actions. Physicians may continue to test the boundaries of that space, resisting constraints imposed by regulatory colleges as unreasonable limitations on their freedom of expression.[[26]](#footnote-27) [[27]](#footnote-28)

Second, the fact that the CMA prohibition on product endorsement has been presented without rationale since the 1970s marks a worrisome void. The rationale of the 1938 revision expresses the vision of professionalism as a “third logic,” offering scientific expertise in the public interest (in distinction to the logic of the marketplace) and tailored to the needs of the individual patient (in distinction to the logic of bureaucracy).[[28]](#footnote-29) The absence of a positive vision of the value of independent judgment represents a lack of vision within the profession.

Third, the medical profession has more actively policed competitive advertising to the outside world than it has advertising within. However, the public interest is at stake in both: both undermine public trust in the profession, and the latter further jeopardizes patient’s quality of care. Physicians in the 1960s were optimistic that they could act as a market force demanding more rigorous and balanced information from sales reps. What has actually happened is that physicians have taken up work as participants in marketing, delivering industry materials for pay. The hope that critical appraisal and evidence-based practice would be an effective response seems no closer to realization forty years later. Instead, stronger oversight and the will to enforce the CMA’s existing policies against peer selling and product endorsement are needed.

University Policy, Academic Integrity, and Professional Self-Regulation

In the absence of a regulatory response to the practice of peer selling, US and Canadian academic medical centres are attempting a policy response that applies to the academic physicians who are sought out as credible experts for SB participation. Given their academic roles, SB participation has implications not just for CME, but also for resident and student education. Among the audience that SB participants draw are students and residents, who value opportunities for informal teaching, meals, and networking. Trainees may feel flattered to be included, and so the “gift relationship”[[29]](#footnote-30) can be even stronger than among fellow physicians. Faculty may use the opportunity and resources provided to them by the SB system to meet their teaching requirements imposed by their university affiliation, counting participation in marketing as teaching, and using industry materials when teaching to trainees students. The blurring of boundaries between industry information and independent academically-driven education across the education continuum has brought pressure on academic institutions to address the issue. [[30]](#footnote-31)

The American Association of Medical Colleges (AAMC) has been encouraging schools to adopt industry relation guidelines that address many facets of physician-industry relations. Through mechanisms such as specifying the proper scope and management of permissible industry funding of CME, clearly distinguishing accredited CME from non-accredited programs presented as continuing education, restricting faculty and trainees from receiving meals or other gifts in conjunction with non-accredited “continuing education,” the AAMC is sharpening the distinction between promotion and CME, with the goal of preserving professional independence and control over content in CME. The AAMC is concerned that CME “must not serve as marketing vehicles for industry,” and that institutions’ academic reputation may be put to work for industry gain by the more enterprising among their faculty. In relation to speakers bureaus they state:[[31]](#footnote-32)

With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange, academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers’ bureaus.

Specifically, AAMC states: “under no circumstances should industry be allowed to restrict the content of programs it sponsors or to specify which faculty or other persons should be selected as presenters.” While the AAMC allows that schools may continue to permit participation by their faculty in FDA-regulated promotional programs, perhaps in recognition of the legal and policy tolerance in the US for physician product endorsement, schools must develop standards for such involvement. Sample policies published in a compendium address authorship and control by, for instance, requiring that the content “be determined by the physician” or “reflect his or her own work” or (most strongly) that the lecturer “prepare his or her slides and other educational materials and does not delegate this to industry sponsors.” Some schools specify that accepting industry training or consulting not be required as a condition of receiving funds for speaking.[[32]](#footnote-33)

The Association of Faculties of Medicine of Canada (AFMC) has endorsed the AAMC’s recommendations and medical schools have moved towards implementation. However, a recent analysis of Canadian institutions’ industry relation policies written in the wake of the AFMC endorsement finds that they are weak in discouraging SB participation.[[33]](#footnote-34) This is despite the fact that in Canada, unlike the US, product endorsement is clearly prohibited by the Code of Ethics. The prohibition on product endorsement in Canada would support the academic medical centres taking a stronger, not a weaker, stance than the AAMC recommendations.

Our historical and policy review of ethical and regulatory perspectives on physician involvement in SBs highlights two reasons for academic institutions and regulatory colleges to preclude and police SB activities. First, for physicians affiliated with academic institutions, participation in SBs violates fundamental principles of academic integrity. If an academic does not generate or substantially contribute to the content of a work such as a presentation or article but presents it as such, then she or he commits plagiarism. Some might object that the workings of the SB system are well-known among attendees and participants, and that no one supposes that the work is the SB participants’ own. But even where an academic accurately attributes the work to another, if she or he relinquishes the ability to revise or criticize its content, then she or he has neglected the responsibility that is part and parcel of the privilege of free academic inquiry.

A second reason to preclude and police SB activities concerns the medical profession at large. The non-enforcement of the rule against peer selling in Canada adds new fodder to age-old debates about the merits of self-regulation in medicine. The profession had both ethical and a self-interested motives to enforce norms against drug promotion in the era of patent medicines. Currently, in Canada, physician product endorsement to the public is unknown, while physician participation in promotional activities is common, and lucrative, within the profession. If academic medical institutions or regulatory colleges fail to enforce the guideline against peer selling and product endorsement, it will bolster the argument for stronger government oversight of physician-industry interactions. This is happening in the US: SB payments are coming to light as a result of settlements in lawsuits against drug and device companies for questionable marketing practices, while the Physician Payment Sunshine Act, to be implemented in 2013 as a component of health care reform, is set to broaden and enforce such disclosure.[[34]](#footnote-35) The profession in Canada, with its well-established norm against product endorsement, may be in a position to lead rather than react.

Appendix.

The data encompassed in Figure 1 was generated in three steps. First, we identified all Canadian medical schools with a publicly available list of faculty practising in the field of cardiology. Some of the medical schools have cardiology departments whereas others have institutes or hospitals dedicated to cardiovascular medicine and research. Medical schools that did not have a web accessible list of cardiologists affiliated with the school were excluded from our analysis. Second, using the Web of Science® database we identified the top five publishing cardiologists between 2006 and 2012 with affiliations to the eleven medical schools included after step one. We did this by cross-referencing the list of top 100 authors by record count from Web of Science with each publicly available list of medical school faculty affiliated with a cardiology department or related institute or hospital. Third, we searched Google Scholar® for any disclosures of “lecture fees”, “speaker’s honoraria”, being “paid to speak for”, or participating on a “speaker’s bureau” made by the cardiologists identified in step two between 2006 and 2012. Only cardiologists who made one or more of those disclosures were counted as having participated in a speaker’s bureau (reflected in red in Figure 1). However, some journals lump speaker bureau participation and honoraria into the same category of disclosure.[[35]](#footnote-36) Thus, those cardiologists who disclosed “honoraria” only (reflected in yellow in Figure 1) -- as opposed to “speaker’s honoraria” specifically -- may have in fact participated in a speaker’s bureau as well, elevating the level of participation in speaker’s bureaus to 100% (i.e. 5 out of 5 top publishing cardiologists) in two cases.

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