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# The speakers' bureau system: a form of peer selling

Lynette Reid, Matthew Herder

## ABSTRACT

In the speakers' bureau system, physicians are recruited and trained by pharmaceutical, biotechnology, and medical device companies to deliver information about products to other physicians, in exchange for a fee. Using publicly available disclosures, we assessed the thesis that speakers' bureau involvement is not a feature of academic medicine in Canada, by estimating the prevalence of participation in speakers' bureaus among Canadian faculty in one medical specialty, cardiology. We analyzed the relevant features of an actual contract made public by the physician addressee and applied the Canadian Medical Association (CMA) guidelines on physician–industry relations to participation in a speakers' bureau. We argue that speakers' bureau participation constitutes a form of peer selling that should be understood to contravene the prohibition on product endorsement in the CMA Code of Ethics. Academic medical institutions, in conjunction with regulatory colleges, should continue and strengthen their policies to address participation in speakers' bureaus.

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➤ **PHYSICIANS NEED TO STAY ABREAST OF INFORMATION** about emerging drugs and devices, but the time pressures of clinical practice may limit their ability to do so independently. The companies that manufacture and sell these products have the resources and the motivation to “educate” physicians but cannot be expected to distinguish their marketing goals from physicians' educational needs. Physicians' professional associations and regulatory bodies, as well as medical journal

publishers and editors, drug and device regulatory agencies, and academic medical institutions, have long debated their respective roles and responsibilities in ensuring the safety, efficacy, and probity of prescribing in light of these pressures and interests.<sup>1</sup>

One current context of this long-standing struggle is the “speakers' bureau” system, in which pharmaceutical, biotechnology, and medical device companies recruit and train physicians to deliver information about products to other physicians, in exchange for a fee or other considerations, such as professional development opportunities.<sup>2</sup> Participants in the system argue that physicians are best situated to deliver accurate information about new drugs and devices to other physicians and that industry is best placed to fund such communication. Critics reply that the speakers' bureau system raises significant concerns about ethics and professionalism and that it is part of a complex system of drug promotion<sup>3,4</sup> and relationship-building with physicians<sup>5–7</sup> that contributes to irrational prescribing,<sup>8</sup> inflated health care costs,<sup>2</sup> and even harm to patients or society more generally. Some steps have been taken toward limiting participation in speakers' bureaus. The American Association of Medical Colleges (AAMC), in a report endorsed by the Association of Faculties of Medicine of Canada (AFMC),<sup>9</sup> has stated that faculty participation in speakers' bureaus should be strongly discouraged and that faculty, residents, and students should be prohibited from attending such events.<sup>10</sup> Furthermore, in the United States, lawsuit settlements and health care reform (i.e., the Physician Payment Sunshine Act, passed as a part of the Patient Protection and Affordable Care Act<sup>11</sup>) are bringing some transparency to speakers' bureau arrangements.<sup>12,13</sup>

## Prevalence of participation in speakers' bureaus

Industry seeks the aid of academic physicians to communicate its message to other physicians because these opinion leaders influence the prescribing behaviour of their peers.<sup>14</sup> In a 2003–2004 survey of US physicians, 16% of respondents reported receiving payment for participation in speakers' bureaus.<sup>15</sup> Cardiologists were more than twice as likely as family practitioners, and significantly more likely than certain other specialty physicians, to receive payments, including both speakers' bureau fees and other honoraria. In a 2007 survey of life sciences departments in the 50 US universities receiving the highest levels of funding from the National Institutes of Health, 23.8% of respondents reported

being a “paid speaker” for industry, which ranked behind “consultant” (about 32%) as the second most common type of relationship with industry.<sup>16</sup> These paid speakers were more likely to be from clinical departments, to be at the rank of full professor, and to produce more publications than those who were not paid speakers, which suggests that those participating in the speakers’ bureau system are well positioned to influence others.

We are aware of no similar survey data for Canada, although a recent study suggested that financial conflicts of interest arising from relationships with industry are more common among authors of clinical practice guidelines in Canada than in the United States.<sup>17</sup> For Canada, we found that 1 or more of the top 5 publishing cardiologists at each of 12 out of 13 Canadian medical schools had disclosed receipt of “lecture fees” or a “speaker’s honorarium,” had been “paid to speak for,” and/or had participated on a speakers’ bureau on one or more occasions (median 2 out of 5 faculty members) (see Figure 1 and online Appendix A for details).

### Ethical and professional considerations

Participation in a speakers’ bureau involves 4 essential elements pertaining to control over the content to be delivered by the speaker and to the consideration upon

which the agreement is contingent (Box 1). According to the conventions of contract law, the elements of any agreement may be explicit or implicit, but both parties must receive consideration in order for the contract to be binding.

#### Box 1

#### Profile of participation in speakers’ bureaus: 4 essential elements

##### Content

- Source of materials (i.e., company or speaker)
- Control of materials (e.g., ability to revise)

##### Consideration

- Benefit to speaker (e.g., honorarium)
- Benefit to company (e.g., increased sales)

As an example, a Schering-Plough speakers’ bureau agreement made public by Dr. Daniel Carlat<sup>18</sup> followed this contract law convention, with both explicit and implicit terms and consideration going to each party (see Box 1 and Table 1). With respect to content, the contract explicitly specified that the company would provide mandatory training and would supply educational materials to which the physician had to adhere: the

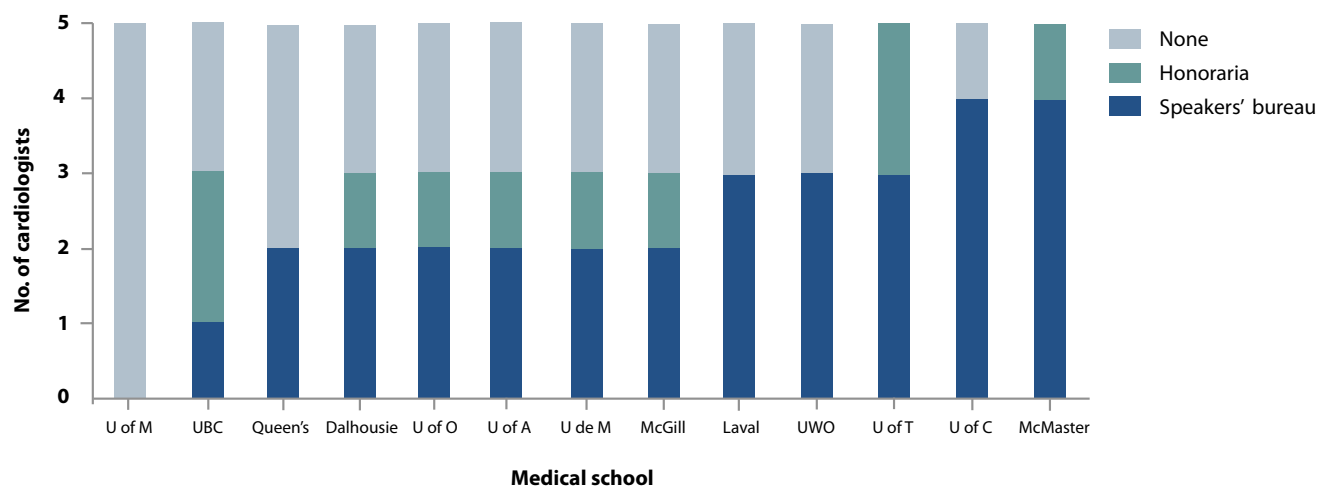


Figure 1

**Participation in speakers’ bureaus by top 5 publishing cardiologists at 13 Canadian medical schools, 2006–2012.** Cardiologists were categorized as follows: (1) participants in a speakers’ bureau, defined as those who disclosed receipt of “lecture fees” or a “speaker’s honorarium” from, being “paid to speak for” by, or participating on a “speakers’ bureau” sponsored by one or more pharmaceutical companies; (2) those disclosing receipt of “honoraria” only, as opposed to specific disclosure of lecture fees, a speaker’s honorarium, or similar fees; (3) those disclosing no participation in a speakers’ bureau or receipt of honoraria. The methods for this analysis are described in more detail in Appendix A. U of M = University of Manitoba, UBC = University of British Columbia, U of O = University of Ottawa, U of A = University of Alberta, U de M = Université de Montréal, UWO = University of Western Ontario, U of T = University of Toronto, U of C = University of Calgary. In several cases, cardiologists were identified through a research institute or hospital affiliated with a university: Institute of Cardiovascular Sciences, St-Boniface Hospital (University of Manitoba); University of Ottawa Heart Institute; Centre de recherche, Institut universitaire de cardiologie et de pneumologie de Québec (Université Laval); Libin Cardiovascular Institute of Alberta (University of Calgary).

Table 1

**Key provisions of proposed agreement between Schering-Plough and Daniel J. Carlat regarding Saphris\* speakers' bureau<sup>18</sup>**

Topic	Provision
Training	Speaker must complete full and remunerated (US\$3000) training session on company-approved materials, including additional training where the company "requires the use of new educational slides"
Services, fees, reimbursement	Up to 125 presentations in term; no minimum Must be "available to Schering to answer reasonable questions about the presentation" Fee of US\$1280–US\$1600 per session, to maximum of US\$170 000 for term Reimbursement for reasonable out-of-pocket expenses (in addition to fees)
Control of materials, compliance with FDA regulations	Speaker may use only company-approved materials for all presentations under agreement Speaker may present only marketed products and FDA-approved indications; presentation must conform to package insert† For questions that go beyond package insert (i.e., beyond approved indications): <ul style="list-style-type: none"> <li>• Respond only to the specific question, on basis of "scientific and clinical expertise"</li> <li>• Disclose that information is not part of the approved product labelling</li> <li>• Move discussion back to approved labelling</li> </ul> Disclose to audience that prepared remarks must remain within labelling because of company's role in the design of the program and its financial support of the presentation
Ethical and scientific standards	Must comport with the highest ethical standards Must focus on educational needs of the audience† Must present fair, balanced, and scientifically rigorous information, covering both risks and benefits† No product comparisons "unless supported by adequate and well-controlled clinical studies" † No disparaging of any product or company† No false or misleading information† No anecdotal evidence, unsupported opinion†

FDA = US Food and Drug Administration

\*The drug in question for this agreement, asenaphine (trade name Saphris in the United States and Canada, Sycrest in Europe), has been approved for the treatment of schizophrenia and the short-term treatment of manic or mixed episodes associated with bipolar I disorder in the United States, Canada, and Europe. The provisions in this company's agreements with physicians may have changed since 2009 and may or may not be representative of speakers' bureau contracts more generally.

†The physician agrees to these standards but has no control over the prepared materials presented.

intellectual content of the presentation was therefore almost entirely in the hands of the company. With regard to consideration, only the speaker's fee was explicit in the contract, but whether the physician would continue to serve on the speakers' bureau was entirely at the company's discretion. The implied term of the agreement was, therefore, that the speaker's performances must be in keeping with the company's interests and objectives—presumably, reputation, image, and, ultimately, sales. Indeed, industry "reps" often attend speakers' bureau events to build relationships with attending physicians, and industry tracks prescriptions of the product by attendees before and after the event.<sup>2,5,19</sup>

In its Code of Ethics,<sup>20</sup> the Canadian Medical Association (CMA) has continuously prohibited product endorsements by physicians.<sup>21</sup> In the United States, by contrast, physician product endorsement—apart from in-office sales with direct returns—is not addressed

by the American Medical Association's Code of Medical Ethics.<sup>22</sup> Historically, Canadian physicians have been disciplined in the courts for the endorsement of products to the public.<sup>23,24</sup> In 2007, however, the CMA adopted a policy entitled "Guidelines for Physicians in Interactions with Industry,"<sup>25</sup> which states unequivocally that the prohibition on product endorsement extends beyond communication by physicians to the public to include communication among physicians:

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.

Speakers' bureau activities fall squarely within this definition of peer selling and hence product endorsement. Determining whether an event is designed to enhance sales involves considering both the explicit and the implicit terms of the contract. Attendance of company representatives at speakers' bureau events and the monitoring of sales<sup>2,5,19</sup> after presentations make enhanced sales an implied term of the arrangement. Any participation by the same physician in events designed to enhance the sale of competitors' products is irrelevant to the question of whether a given act constitutes marketing. By the same token, becoming a member of multiple speakers' bureaus does not confer greater objectivity upon a physician's participation.<sup>2</sup>

Participation in a speakers' bureau is within the ambit of peer selling and should be the target of regulatory attention. The CMA's prohibition on product endorsement by physicians is not enough. In the United States, where physicians are permitted to act as marketers, there is considerable movement toward regulatory oversight. Regulatory response to the practice remains weak in Canada.

### Challenges to enforcement

The Canadian medical profession, its regulatory colleges, continuing medical education (CME) accreditation bodies, and academic medical centres all have critical roles to play in bringing an end to peer selling, but thus far, each has struggled to do so.

Although provincial regulatory colleges are well placed to regulate speakers' bureau participation by adopting the CMA's 2007 guidelines on physician-industry relations,<sup>25</sup> uptake among colleges varies (see Table 2), and we found no record of any enforcement in published disciplinary proceedings. This is not surprising, given that college discipline is largely driven by complaints from the public, and speakers' bureau activities, taking place within the profession, are unlikely to come to the public's attention. Furthermore, physicians are generally reluctant to report their colleagues,<sup>33,34</sup> and this may be particularly true when it comes to reporting prevalent and lucrative activities of influential members of the profession.

Bodies that accredit and, in some cases, develop CME in Canada also have a role to play in addressing speakers' bureau participation. Such bodies consist of CME committees of national specialty societies, CME offices of faculties of medicine, and maintenance-of-certification programs of the Royal College of Physicians and Surgeons of Canada and the College of Family

Table 2

**Uptake of Canadian Medical Association (CMA) guidelines on physician-industry relations<sup>25</sup> by physicians' regulatory colleges**

Provincial college	Adoption of CMA guidelines*
Ontario, <sup>26</sup> Nova Scotia <sup>27</sup>	Guidelines adopted
British Columbia <sup>28</sup>	Guidelines referenced
Alberta, <sup>29</sup> Manitoba <sup>30</sup>	Related principles referenced (independent judgment, distinction between CME and marketing)
Saskatchewan, New Brunswick, Newfoundland and Labrador, Prince Edward Island	No relevant guidelines or policy available on website
Quebec <sup>31</sup>	Posting of guidelines of Conseil de l'éducation médicale continue du Québec and Canada's Research-Based Pharmaceutical Companies (Rx&D), <sup>32</sup> instead of CMA guidelines

CME = continuing medical education.

\*Including prohibition on participation in speakers' bureaus.

Physicians of Canada. We reviewed the posted policies and statements of the AFMC's Committee on Accreditation of Continuing Medical Education and Standing Committee on Continuing Professional Development (representing CME offices of faculties of medicine), the Royal College, the College of Family Physicians of Canada, and the Conseil de l'éducation médicale continue du Québec for their adoption of the CMA guidelines (see Table 3). We found that the CMA guidelines are widely endorsed. Furthermore, the Standing Committee on Continuing Professional Development has endorsed the AAMC recommendation that faculties of medicine should discourage speakers' bureau participation among their faculty.<sup>36</sup>

Naturally, CME bodies cannot directly prohibit or limit speakers' bureau activities: given prohibitions on direct payment from industry to faculty in accredited CME, speakers' bureau activities fall, by definition, outside of accredited CME. However, CME accrediting bodies may prohibit or control speakers' bureau participants acting as faculty in CME, and these bodies do play an essential role in defining and maintaining the distinction between marketing and education that speakers' bureau activities blur. Box 2 lists the approaches that CME bodies can take to achieve these goals, derived from guidelines of the CMA,<sup>25</sup> the US Accreditation Council for Continuing Medical Education,<sup>41</sup> the Standing Committee on Continuing Professional Development of the AFMC,<sup>36</sup> and the AAMC.<sup>10,42</sup> Assessing the extent to which Canadian CME bodies have availed themselves of all these mechanisms is



Table 3

**Uptake of Canadian Medication Association (CMA) guidelines on physician–industry relations<sup>25</sup> by selected CME accreditation bodies\***

CME accreditation body	Adoption of CMA guidelines†
Association of Faculties of Medicine of Canada <ul style="list-style-type: none"> <li>Committee on Accreditation of Continuing Medical Education<sup>35</sup></li> <li>Standing Committee on Continuing Professional Development<sup>36</sup></li> </ul>	Accrediting bodies must justify any divergence from CMA guidelines Described as “minimum acceptable standard”
<ul style="list-style-type: none"> <li>College of Family Physicians of Canada<sup>37</sup></li> </ul>	Adopted, alongside <i>Code of Ethical Practices of Rx&amp;D</i> , <sup>38</sup> with priority to CMA guidelines where they conflict
Royal College of Physicians and Surgeons of Canada <ul style="list-style-type: none"> <li>Guidelines and process for physician organizations<sup>39</sup></li> <li>Guidelines and process for nonphysician organizations<sup>40</sup></li> </ul>	Adopted, alongside <i>Code of Ethical Practices of Rx&amp;D</i> <sup>38</sup> and guidelines of Conseil de l'éducation médicale continue du Québec and Rx&D <sup>32</sup>  Reiterate CMA guidelines' prohibition on industry membership on scientific program committee from CMA guidelines
Conseil de l'éducation médicale continue du Québec <sup>32</sup>	Guidelines developed in collaboration with industry (Rx&D) posted

CME = continuing medical education, Rx&amp;D = Canada's Research-Based Pharmaceutical Companies.

\*Not including individual CME offices of faculties of medicine and of national specialty societies.

†Including prohibition on participation in speakers' bureaus.

beyond the scope of this paper. However, we raise questions about two aspects of the approaches of Canadian CME bodies that pertain to the fundamental distinction between marketing and education.

The CMA guidelines prohibit industry membership on CME scientific planning committees; in the United States, the Accreditation Council for Continuing Medical Education more broadly prohibits any industry influence on content, whether direct or indirect.<sup>43</sup> In contrast, the Conseil de l'éducation médicale continue du Québec, in partnership with industry, has crafted its own code of ethics for CME.<sup>32</sup> This document contains standards that were later embodied in the 2010 Code of Ethical Practices of Canada's Research-Based Pharmaceutical Companies (Rx&D),<sup>44</sup> the trade organization representing research-based pharmaceutical companies in Canada. Both documents explicitly assert the quid pro quo of industry funding for control of content as a principle of ethical partnership (on page 7 in the joint code<sup>32</sup> and in section 4A 3.1 in the 2010 version of the Rx&D document<sup>44</sup>). The Conseil de l'éducation médicale continue du Québec thus appears to maintain a standard requiring industry involvement, one that Rx&D itself abandoned in its 2012 code.<sup>38</sup> The Royal College of Physicians and Surgeons of Canada, by referencing the code authored by the Conseil de l'éducation médicale continue du Québec and Rx&D (see Table 3), appears to endorse this approach. By contrast, the College of Family Physicians of Canada cites the Rx&D code but gives the CMA guidelines priority, whereas the Committee on Accreditation of Continuing Medical

Education and the Standing Committee on Continuing Professional Development of the AFMC indicate that the CMA guidelines should represent the minimum acceptable standard. Whether Canadian CME accrediting bodies tolerate “direct or indirect” influence in the form of a CME scientific planning committee seeking input

**Box 2****Potential mechanisms by which CME accreditation bodies currently address speakers' bureaus<sup>10,25,36,41,42</sup>****Mechanisms for clarifying CME as credible alternative to speakers' bureau events**

- Requiring arms-length arrangements for industry funding of CME programs and offices
- Limiting or prohibiting industry influence on CME content
- Limiting or prohibiting industry attendance or exhibition at educational events
- Applying educational rather than advertising standards to CME content
- Setting standards prohibiting ghost authorship of CME materials; requiring disclosure of co-authorship and forbidding (or requiring disclosure of) industry funding of or employees acting as co-authors

**Mechanisms for controlling participants in speakers' bureaus in terms of acting as CME faculty**

- Forbidding direct industry payment to CME faculty for their CME teaching
- Requiring disclosure from CME faculty and scientific committee members of their non-CME speakers' bureau activities; preferentially recruiting non-speakers' bureau participants to CME faculty and scientific committees; prohibiting speakers' bureau participants from roles with CME faculty and scientific committees

CME = continuing medical education.

or approval from industry appears to be an open question, or even a requirement in CME in Quebec, which raises significant questions about the independence of accredited CME.

Furthermore, CME regulation and guidelines typically rely on several markers for distinguishing scientific and educational activities from marketing. For example, in both the United States and Canada, guidelines may refer to “satellite symposia” as well-known venues for industry-funded activities that resemble but must be distinguished from concurrent independent scientific meetings. A marker relevant to speakers’ bureaus used in the United States is the Food and Drug Administration (FDA) restriction on marketing for off-label indications. As a matter of law, the FDA and Health Canada do not regulate the practice of medicine or the free speech of educators and scientists; rather, they regulate the sale of medical products. Thus, the presence of a responsibility to adhere to FDA-approved indications is one clear signal that a presenter is acting as a marketer rather than an educator under US policy.<sup>2,10</sup> The 2012 Rx&D code,<sup>38</sup> however, states that materials that Rx&D member companies create or assist in creating for faculty who intend to use the materials in accredited CME must conform to the requirements set by the Pharmaceutical Advertising Advisory Board and the Advertising Standards Council—entities established to regulate advertising, not educational and scientific activities. CME bodies that adopt the Rx&D code<sup>38</sup> alongside the CMA guidelines<sup>25</sup> effectively adopt this same restriction. Prohibiting marketing materials in CME from violating marketing laws is very different from prohibiting marketing materials from being presented in CME at all. Ironically, then, through adoption of the Rx&D guidelines alongside the CMA guidelines, Canadian physicians may come to see adopting marketing restrictions on materials they present as their ethical responsibility as educators, rather than a sign that they have taken on the role of marketers.

Clarity around communication about off-label uses is particularly important in the context of speakers’ bureaus, as industry may employ physicians as speakers precisely to skirt (in a limited and perhaps legally defensible fashion) regulators’ prohibitions related to promoting off-label uses of products. In the Schering-Plough contract,<sup>18</sup> for example, a signatory would agree not to present off-label uses in industry-prepared materials, but would enjoy permission to discuss off-label uses based on clinical experience, after or in addition to the formal presentation, and this is more than company

sales representatives may do.<sup>2–4,45</sup> Again, a signatory to a speakers’ bureau agreement may mistakenly understand standards for ethical marketing (an indication that the physician is now engaged in marketing) as standards for ethical education.

CME accreditors, following the example of the AAMC, should abandon misguided attempts to partner with industry in defining ethical standards for continuing education. CME accreditors are uniquely responsible for setting clear and credible standards that distinguish education from marketing. Given their leadership role within academic medical centres, Canadian CME accreditors should also take steps to prohibit or discourage speakers’ bureau participants from acting as faculty in accredited CME, or to control any such activity.

Academic medical centres are well placed to take action on participation in speakers’ bureaus, as most speakers are academics,<sup>13</sup> and Canadian centres have formal ethical standards that apply in all teaching, whether in accredited CME or non-accredited events. The AFMC has endorsed the AAMC’s *Industry Funding of Medical Education* report,<sup>9</sup> which recommends that faculties forbid (or, if they do not forbid, then discourage and regulate) physicians’ involvement in speakers’

### Box 3

#### **Summary of relevant policy recommendations of the American Association of Medical Colleges<sup>10,42</sup> (adopted by the Association of Faculties of Medicine of Canada<sup>9</sup>) relating to participation in speakers’ bureaus for academic medical centres\***

- Discourage or forbid faculty participation in speakers’ bureaus; if permitted, then discourage and set standards, including those listed below
- Forbid use of university logo or affiliation in speakers’ bureau activities
- Forbid attendance by faculty and trainees at speakers’ bureau events
- If attendance is allowed, forbid acceptance by faculty and trainees of meals and other gifts at speakers’ bureau events
- Require disclosure of speakers’ bureau activities (among other industry relations) in standard disclosures (for teaching, presenting, publishing)
- Forbid receipt of payment beyond fair market value
- Set standards (prohibiting ghostwriting and requiring authorship credit for all collaborators and disclosure of financial arrangements) for industry involvement in preparation of educational materials used in continuing medical education and across the educational continuum
- Require disclosure of speakers’ bureau activities (among other industry relations) within the institution and to the public

\* Each item represents a specific activity and a spectrum of approaches from disclosing to limiting to prohibiting.

bureaus (see Box 3 for key recommendations). An unpublished national analysis indicates, however, that Canadian faculties have been weak in implementing this particular AAMC recommendation (Joel Lexchin, Professor, School of Health Policy and Management, York University, personal communication by email, November 2012).

Although interactions between trainees and company representatives have been documented,<sup>46–53</sup> the effects of trainees' interactions with faculty acting as marketers for companies is less well characterized. It is plausible that invitations to speakers' bureau events extended to residents and trainees by prominent faculty who participate in these events may be particularly flattering and thus even more influential than they would be for physicians already in practice. Faculty who are involved in speakers' bureaus may draw from their speakers' bureau materials for teaching at all levels, thus influencing a wider audience of trainees. Future generations of physicians may fail to identify and critically appraise materials prepared by or in collaboration with industry marketing departments when these are presented in an educational context.

## Conclusion

When the content of a physician's presentation to any audience of physicians or other health care providers does not rest exclusively 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 the presentation is to increase uptake of a particular health care product, the physician is violating the CMA's guideline against peer selling and the prohibition on product endorsement in the CMA's Code of Ethics.

Although physician participation in promotional activities within the profession appears to be common, at least in some specialties, there is no record of disciplinary action in relation to this practice, even in provinces where regulatory colleges have adopted the CMA's prohibition on peer selling. Academic medical centres in Canada, unlike those in the United States, may rely on the strong guidance of the CMA Code of Ethics prohibition on product endorsement in crafting institutional policies; however, they are not showing leadership in forbidding faculty participation in speakers' bureaus. CME offices are in the process of clarifying and harmonizing policies, but they lack regulatory oversight of physicians' activities outside of accredited CME. The current non-enforcement of the CMA guideline against peer selling in Canada adds new fodder to age-old

debates about the merits of self-regulation in medicine. The failure of academic medical institutions and regulatory colleges to enforce the guideline against peer selling and product endorsement bolsters the argument for stronger government oversight of physician–industry interactions.

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