

**Defining the relationship: An evidence based review and recommendations on the role of industry funding in medical schools**

Industry Funding Working Group  
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Contributors:

Alyson Holland, Dalhousie University, Class of 2011  
Jessie Breton, University of Alberta, Class of 2010; VP-Global Health (formerly IPP) 2007-2008  
Marko Erak, McMaster University, Class of 2013  
Siraj Mithoowani, McMaster University, Class of 2013  
Denali Elizabeth Kerr, McMaster University, Class of 2013  
Matthew Tenenbaum, McMaster University, Class of 2013

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## **Executive Summary**

This policy addresses the relationship between industry (defined as pharmaceutical companies and medical device manufacturers), medical schools, and medical student societies. We acknowledge that this relationship is complex. It has the potential either to improve patient care through collaboration, or to generate conflicts of interest that may bring patients harm. This policy seeks to outline what forms of student-industry interaction are appropriate, given the ultimate goal of training competent, patient-focused clinicians.

### *EXISTING POLICY FROM FACULTIES OF MEDICINE AND MEDICAL STUDENT SOCIETIES*

Policies from the Association of Faculties of Medicine of Canada (AFMC), as well as the faculties of medicine at the University of Ottawa and the University of Toronto were reviewed. Each policy acknowledges the difficult relationship between physicians and industry, and emphasizes the principles of adequate disclosure and maintaining public trust. The AFMC has not mandated any action on the part of individual faculties, but has allowed that industry funding of medical education is appropriate provided that it is “focused on improving practice outcomes.” Faculties at Ottawa and Toronto have placed different restrictions on their staff and students. Ottawa advises its students against attending any events funded by industry. Toronto, in contrast, allows for industry involvement in medical education so long as it is monitored by the University administration.

Existing student perspectives were found in policies from medical student societies within Canada and around the world. Some organizations, such as the University of Manitoba Medical Students Association, allow for industry sponsorship provided that funds be administered by students without limitations imposed by industry. Others, such as the American Medical Student Organization, have banned industry sponsorship entirely. A commonality, however, is an emphasis on maintaining an open dialogue regarding the issue, and pushing for more scrutiny of and education about clinicians’ relationships with industry.

### *EXISTING POLICY FROM PROFESSIONAL MEDICAL ASSOCIATIONS*

Guidelines from the Canadian Medical Association (CMA) recognize the potential for conflicts of interest, and implore physicians to resolve such conflicts in favour of best patient care. They do not place restrictions on industry funding, however they warn against accepting gifts of any “significant” value. They allow for physicians to be employed by industry (and receive remuneration) provided that they disclose this information when serving as educators. The CMA maintains that these guidelines are just as applicable to medical trainees as they are to practicing physicians.

Policy from the American Medical Association closely mirrors that of the CMA in content and tone. The American Psychiatric Association, however, has taken steps in recent years to eliminate industry funding from any of its events.

### *EXISTING POLICY FROM INDUSTRY*

*PhRMA*, the organization that represents leading American pharmaceutical companies, has established a Code of Conduct defining the principles by which its members self-regulate. It defines the role of industry as an educator, so that “patients have access to the products they need.” It requires that clinicians be given accurate and candid information, and restricts companies from influencing the content of CME. It prohibits gift-giving, but allows for paid meals as a professional courtesy. In some instances, these self-imposed restrictions go beyond those established by medical associations.

PhRMA has disagreed with assertions that industry contributions to CME be limited. Rather, it advocates for the positive role that industry can play in public education and patient care.

## *EFFECTS OF RELATIONSHIP WITH INDUSTRY*

It is well-established that physicians' interactions with industry can have a substantial impact on their practice. Following industry-sponsored CME events, their prescribing habits change to favour the medications produced by the sponsoring company. One study found that physicians were thirteen times more likely to prescribe a drug after speaking with an industry representative, and that this increased to twenty-two times if the physician had received remuneration from that company. Existing evidence suggests that physicians place more trust in the efficacy of drugs as reported by industry, than as reported by the literature.

Though gifts received by clinicians from industry may seem insignificant, their effects can be real. Regardless of the size of a gift, the social rule of reciprocity fosters a sense of obligation to return the favour – whether physicians are aware of this sense or not. This can also impact them in their role as educators, as their biases are included in didactic teaching that may be accepted as fact by students. Physicians generally overestimate their self-awareness and their ability to keep this from happening.

A similar pattern is evident in student-industry interactions. Students report feeling obliged to listen to industry representatives following the receipt of gifts. Further, the more gifts that they received, the more likely they were to believe that such interactions were benign. This is particularly concerning, as it is important for students to develop the critical thinking and habits that they will rely on as practicing clinicians.

## *CONCLUSION*

We call upon the CFMS member schools to implement the following recommendations:

1. Schools have a responsibility to prepare medical students for real-world practice by educating them about appropriate relationships with industry.
  - a. Schools will provide an environment in which medical students can learn about industry relationships ethically and responsibly, for example through:
    - i. Lectures;
    - ii. Seminars; and/or
    - iii. Workshops.
  - b. Complete isolation from industry is neither feasible nor helpful in this process.
  - c. Exposure to industry relationships and topics on conflict of interest should occur early in training.
2. School administrations will develop policies together with their respective medical student societies to monitor any industry involvement in educational and extra-curricular activities in accordance with the principles referenced in this document.
3. Schools will make a requirement for lecturers and educators to disclose conflicts of interest with industry as defined by their home institution.
4. Student societies and students will not accept gifts of any kind from pharmaceutical companies or their representatives.
5. Student societies will not accept funding for any events from pharmaceutical companies or their representatives.

## II. Introduction

The relationship between industry (defined herein as pharmaceutical companies and medical device manufacturers) and medical professionals is necessarily complex. The two should be symbiotic, yet the goals of each are frequently in direct opposition. Industry is for-profit, and accountable to shareholders; physicians are dedicated to their patients and to providing the best care possible.

The objective of the CFMS should be to first minimize and ultimately eliminate conflict of interests that may undermine the credibility of its member schools and students. This is especially true when those conflicts of interest could harm patients in the long run. Marketing strategies used by industry, which are directed at students and health professionals, can result in conflicts of interest that are both real and perceived. We propose this policy statement to address the context in which member student societies and their students should interact with industry. Furthermore, the policies herein will outline to what extent industry support for medical school events and medical students is appropriate. This is an evidence based document that uses policies and examples from existing literature discussing industry funding of medical education and individual physicians. The existing literature provides a context in which to examine our particular situation as medical students.

Understandably, physicians have a duty to monitor conflicts of interest. Our training should promote and develop skills that allow us to make objective decisions unbiased by conflicting factors. In fact, physicians with affiliations to pharmaceutical companies are requested by CMA guidelines to “not allow their affiliation to influence their medical practice inappropriately”<sup>1</sup>. This, however, may be difficult to achieve. As Jerome Kassirer argues, a conflict of interest “may be subconscious and as such can undermine judgment and integrity and lead to self-deception”<sup>2</sup>. In many cases, the level of influence industry has on physician behaviour is less about the nature of a gift or financial compensation, and more about building relationships that create a sense of obligation to particular representatives or companies.

The goal of this policy is not to antagonize industry. Rather, it is necessary to recognize the contributions that industry makes in advancing health care. As Rothman *et al.* note with respect to professional medical associations, there is room for collaboration between industry and the medical profession<sup>3</sup>; removing all relationships is not the goal.

As the CFMS, it is important to clarify our position on issues regarding external industry sponsorship. Currently, the AFMC and other professional medical associations in Canada are in the process of developing their policies on the matter. These policies will have an impact on the resources medical students and student societies can access. This paper establishes the CFMS perspective in the discussion in order to represent the student opinion on the issue.

The three global objectives of this paper will be to:

- 1) Provide recommendations for programs and curricula that educate students about conflicts of interest and relationships with industry
- 2) Define CFMS recommendations to member schools for dealing with industry
- 3) Advocate that the interests of medical students be maintained in any future policies

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<sup>1</sup> Canadian Medical Association (2007): 5.

<sup>2</sup> Kassirer (2005): 51.

<sup>3</sup> David J. Rothman, et al., "Professional Medical Associations and Their Relationships With Industry: A Proposal for Controlling Conflict of Interest," *Journal of the American Medical Association* 301, no. 13 (2009): 1367-1372

### III. Background Research

#### III.I Existing Medical Student Society and Faculty of Medicine Policies

There exist current guidelines that discuss and suggest frameworks for interaction between medical institutions and industry. There is ongoing work being done by Medical student bodies and Faculties both in Canada and around the world. Currently, the CFMS itself will not accept advertisements “which seek to market prescription drugs by pharmaceutical companies”<sup>4</sup>. However, no other official statements by the CFMS on other forms of industry funding or industry funding in general, either for the CFMS or its member societies, exists. This document serves as a general position paper by CFMS on industry funding of medical societies with the purpose of providing direction for future statements.

##### *Canada: The Association of Faculties of Medicine of Canada (AFMC)*

In November 2008, the AFMC Board of Directors voted unanimously to support the principles outlined in the Association of American Medical Colleges June 2008 report: “Industry Funding of Medical Education”<sup>5</sup>. The rationale for this report, and the mandate of the Task Force that compiled it, was to develop consensus principles to manage all real or perceived conflicts of interest in the interest of upholding professionalism and integrity in medical institutions<sup>6</sup>.

Specifically, the report examines the benefits and challenges in relationships between health industries and medical education, and how to optimize and mitigate those, respectively. Although both industry and medical institutions both have a common goal to advance and improve public health, the report acknowledges the inherent conflict of interest between industry and medical institutions: industry has a responsibility to shareholders while medical institutions are responsible to the public and the profession. The report acknowledges the benefit to society in the forms of research and treatment that is derived from regular interaction from the two sectors. However, the avoidance of conflicts of interest is necessary to uphold public trust and maintain a professional and productive relationship. The AFMC acknowledged this fact. In a press release<sup>7</sup>, the AFMC also noted that endorsing the report does not mandate faculties of medicine to take any action; the report itself does not dictate policy, nor is the AFMC in a position to enforce the principles of the AAMC report. The Association will work with industry representatives on implementation of the endorsed principles, and “set the stage for more fruitful interactions<sup>8</sup>.”

More recently, the AFMC Standing Committee on Continuing Professional Development (SCCPD) released a policy statement. This statement was endorsed by the AFMC Board of Directors and it addresses the relationship between Continuing Medical Education/Continuing Professional Development (CME/CPD) offices and industry<sup>9</sup>. This policy acknowledges the important contribution that industry has made to medical education, while acknowledging the fiduciary responsibility of industry to shareholders as a potential to create a bias. The policy suggests this bias is not inevitable, and the policy allows for funding of medical education that is “focused on

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<sup>4</sup> Canadian Federation of Medical Students, "Advertising Policy," Policy Statement (2006)

<sup>5</sup> Association of Faculties of Medicine of Canada, "Association of Faculties of Medicine of Canada Endorses AAMC policies regarding industry funding of medical education," *AFMC Press Releases*, December 9, 2008, <http://www.afmc.ca/newspress-releases-details-e.php?pid=45> (accessed March 2009); Association of American Medical Colleges, *Industry Funding of Medical Education*, Task Force on Industry Funding of Medical Education Final Report (Washington, D.C.: AAMC, 2008).

<sup>6</sup> Association of American Medical Colleges, *Industry Funding of Medical Education*

<sup>7</sup> Association of Faculties of Medicine of Canada, "Industry funding of medical education: Anticipated questions and associated answers," *AFMC Press Releases*, December 9, 2008, <http://www.afmc.ca/news-press-releases-details-e.php?pid=47> (accessed March 2009)

<sup>8</sup> Association of Faculties of Medicine of Canada, *Association of Faculties of Medicine of Canada Endorses AAMC policies regarding industry funding of medical education*.

<sup>9</sup> Association of Faculties of Medicine of Canada, *SCCPD Position Paper on the Role of Industry in University-Based CME/CPD* (AFMC, November 18, 2010).

improving practice outcomes.<sup>10</sup> However, section 3 of the policy notes that a power imbalance exists when CME/CPD offices rely on industry funding for financial viability, and that alternative funding options should be sought. This policy also highlights the importance of public perception, noting that “continuing education for physicians that is free or much less costly than that for professions of similar standing only serves to increase societal perceptions that physicians are unduly influenced by industry.”<sup>11</sup> This policy ultimately allows each individual CME/CPD office to define the specific rules related to industry funding, emphasizing only principles. This includes the expectation that these offices uphold high standards for industry-funded events and deliver programs that are “as free from conflicts of interest and bias as possible.”

*Canada: University of Ottawa Faculty of Medicine<sup>12</sup>*

This 2008 policy paper emphasizes education as paramount in interactions between Industry, Faculty, and learners. Its primary goal is that such interactions result in the advancement of knowledge. It highlights the need for education in ethical conduct between physicians and Industry and the importance of full disclosure of conflict of interest at any educational event. Furthermore, of particular relevance to medical students, this policy advises students against attending “any function sponsored by Industry unless it is primarily for the purpose of medical education” and against accepting gifts from Industry. The University of Ottawa policy draws on the policies of professional associations to be discussed later, including the 2007 CMA policy, “Guidelines for Physicians on Interactions with Industry.”

*Canada: University of Toronto Faculty of Medicine*

Several policies guide medical student, resident, and physician interaction with industry at the University of Toronto. The 1999 document on commercial support of CME events lacks a definitive statement, calling only for speakers to be approved of by the course director and that they not be paid directly by the sponsoring company; it does not mention indirect payments, for instance, in the form of travel vouchers or other gifts. It does require, however, that presentations be unbiased, that commercial displays not be in the same room as the CME event, that full disclosure of conflicts of interest (monetary or other affiliations) be made, and that sponsorship be only partial with attendees paying a registration fee<sup>13</sup>. Moreover, it requires that lodging and travel not be in excess of what would be provided without commercial funding. In theory, this prevents CME events from being held at resorts and golf courses, for instance<sup>14</sup>.

A second policy at the University of Toronto stresses the importance of ensuring the relationship between Industry and physician trainees further health care, and that any conflicts of interest be resolved in favour of the patient<sup>15</sup>. This policy also calls for a disclosure of any relationship between physician trainees and training program with industry, and requires that funds from industry be administered by the University training program<sup>16</sup>. It does not, however, stipulate that funds must be unrestricted.

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<sup>10</sup> Ibid.

<sup>11</sup> Ibid.

<sup>12</sup> University of Ottawa Faculty of Medicine, "Interacting with Industry and Outside Agencies in a Teaching Environment," *Faculty Policies & Procedures*, 2008, [http://www.medicine.uottawa.ca/assets/documents/policies\\_procedures/Policy\\_Interacting\\_Industry\\_Septembre2008.pdf](http://www.medicine.uottawa.ca/assets/documents/policies_procedures/Policy_Interacting_Industry_Septembre2008.pdf) (accessed March 2009).

<sup>13</sup> University of Toronto Faculty of Medicine, "Policy on Support of University of Toronto Sponsored Continuing Education Activities from Commercial Sources," *Ethics Policies and Guidelines*, 1999, [http://www.facmed.utoronto.ca/Assets/staff/Commercial\\_Support.pdf?method=1](http://www.facmed.utoronto.ca/Assets/staff/Commercial_Support.pdf?method=1) (accessed April 2009).

<sup>14</sup> Ibid.

<sup>15</sup> University of Toronto Faculty of Medicine, *Guidelines: Relationships Between Physician Trainees, Postgraduate Training Programs and Industry*, 2008, <http://www.facmed.utoronto.ca/PageFactory.aspx?PageID=1085> (accessed March 2009).

<sup>16</sup> Ibid.

The Department of Psychiatry at the University of Toronto developed its own report regarding interaction with industry<sup>17</sup>. It notes that industry may provide opportunities for beneficial partnerships in enhancing clinical care, but the ethical challenges stemming from the complex relationships between physicians and industry must be considered<sup>18</sup>. The policy also identifies that awareness of both perceived and real conflicts of interest as reflected by the media and social critics is important<sup>19</sup>. To this end, a Task Force within the Department recommended student training on understanding conflict of interest, marketing, and detecting bias. Furthermore, it recommends that funding of educational events or scholarships be centrally administered. Disclosure of potential conflict of interest to the Department, patients, and audiences of talks is strongly suggested under multiple clauses. The recommended guidelines also prohibit acceptance of any gifts by physicians and residents from Industry. The task force identifies that industry-sponsored events can fill gaps in curriculum for the students<sup>20</sup>. However, the interaction between Industry and trainees in the form of these events requires checks and controls to ensure quality and accuracy.

*Canada: University of Manitoba Medical Students Association (MMSA)*

The MMSA policy pertains to corporate sponsorship in general<sup>21</sup>. The goal of the policy is to ensure autonomy of the association. It requires all sponsorship funds be administered by the MMSA without restriction from sponsors, whether funds are for the Association or for student scholarships or travel bursaries. The policy document echoes a theme present in all the previously discussed policies, in that it is concerned about perceived and real influence related to conflicts of interest. The MMSA does not prohibit funding from any particular source, but it stipulates that each sponsorship agreement has to be passed by the executive as a resolution.

*Canada: McGill University Medical Students' Society*

The constitution of the McGill University Medical Students' Society is very clear about sponsorship from industry. Under its second bylaw on Sponsorship, it states "the proposed sponsor must not present a conflict of interest with respect to medical professionalism by being involved in the pharmaceutical industry<sup>22</sup>."

*North America: American Medical Student Association (AMSA)*

A campaign by the AMSA, PharmFree is a national initiative to reduce conflict of interest at medical schools and academic medical centres<sup>23</sup>. Since its inception in 2001, the PharmFree campaign has developed educational tools, encouraged medical students to engage in grassroots activism at their medical faculties, and developed a scorecard that ranked US medical faculties on their policies limiting conflict of interest<sup>24</sup>. In 2001, AMSA banned all sponsorship by pharmaceutical companies and medical equipment manufacturers in any form, whether through donations, or advertising at its conference, on its website, and in its publications.

The PharmFree campaign has established Best Practices guidelines in the areas of gifts and meals, pharmaceutical samples, the presence of drug representatives in academic medical centres, financial support of educational

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<sup>17</sup> University of Toronto Department of Psychiatry, "Interactions with the Pharmaceutical Industry: Task Force Report," *University of Toronto - Department of Psychiatry*, 2003 December, <http://www.utpsychiatry.ca/AdministrationAndOrganization/Relationship%20with%20Pharmaceutical%20Industry.pdf> (accessed April 2009).

<sup>18</sup> Ibid.

<sup>19</sup> Ibid.

<sup>20</sup> Ibid.

<sup>21</sup> Manitoba Medical Students' Association, "MMSA Sponsorship Policy," *2006-2007 MMSA Meeting Minutes*, April 2007, [http://www.umanitoba.ca/student/groups/MMSA/minutes/2006\\_2007\\_minutes/MMSASponsorshipPolicy.doc](http://www.umanitoba.ca/student/groups/MMSA/minutes/2006_2007_minutes/MMSASponsorshipPolicy.doc) (accessed April 2009).

<sup>22</sup> Medical Students' Society of McGill University/l'Association Étudiante de Médecine de l'Université McGill, "The Constitution of the Medical Students' Society of McGill University/Charte de l'Association Étudiante de Médecine de l'Université McGill" (Montreal, April 20, 2009).

<sup>23</sup> AMSA, *PharmFree*, 2008, <http://pharmfree.org/> (accessed March 2009)

<sup>24</sup> Further details on how medical faculties were scored can be found at <http://www.amsascorecard.org/methodology>



events, industry-funded speaking relationships, disclosure, and purchasing, and in formularies<sup>25</sup>. In general, the PharmFree campaign recommends against the acceptance of any gifts, meals, samples, or funding of any medical education or research activity, except where unrestricted funding can be distributed through a central pool. These guidelines apply to medical education events both on-site and off-site<sup>26</sup>.

*International: International Federation of Medical Student Associations Pharma-Free Alliance*

The Pharma-Free Alliance was formed in 2008 and consists of National Member Organizations (NMOs) committed to procuring funding sources for the IFMSA central budget. As a result, the IFMSA does not rely on industry sponsorship. In March 2009, the Pharma-Free Alliance proposed a policy statement to the IFMSA March Meeting emphasizing the inherent conflict between the for-profit nature of the pharmaceutical industry and the duty of physicians to their patients. Based on this premise, the statement calls for the IFMSA to analyze the ethical implications of health care professionals' and students' material relationship with the pharmaceutical industry, oppose influence by the pharmaceutical industry in research and scrutinize the organization's relationship with for-profit companies that could result in a conflict of interest<sup>27</sup>.

The language of the 2009 document is considerably less assertive than that of the original 2008 document written when the Pharma-Free Alliance first formed<sup>28</sup>. In 2008, the Alliance called for signatory IFMSA NMOs to limit the funding in their budgets that comes from pharmaceutical companies and support leadership candidates within the IFMSA who support limited financial interaction with the pharmaceutical industry. By 2009, the wording of the Alliance document asked for dialogue and scrutiny. However, the policy statement was accompanied by a resolution to change an IFMSA bylaw to prohibit funding of IFMSA by pharmaceutical companies; NMOs would still be permitted to receive funding as they choose. However, neither document was passed by the IFMSA General Assembly for reasons including insufficient time to review the documents, a desire for partnerships between medical student organizations and the pharmaceutical industry, and a lack of other funding options<sup>29</sup>.

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<sup>25</sup> AMSA, "Key Policy Recommendations," *Policy Guidance*, 2008, [http://www.pharmfree.org/tools/resources\\_documents/files/0016.pdf](http://www.pharmfree.org/tools/resources_documents/files/0016.pdf) (accessed March 2009).

<sup>26</sup> A list of resources used in the PharmFree campaign can be found at <http://www.pharmfree.org/resources?id=0002>

<sup>27</sup> IFMSA Pharma-Free Alliance, "Tunisia Pharma Policy Statement" (Hammamet, March 2009).

<sup>28</sup> IFMSA Pharma-Free Alliance, "Pharma-Free Alliance Declaration on Access to Essential Medicines and Pharma-Funding" (Monterrey, March 2008).

<sup>29</sup> CFMS Global Health Program, "Update: IFMSA March Meeting" (Hammamet, March 2009).

### III.II Existing Professional Medical Association Policies

Professional medical associations bring together practitioners of a given specialty, and serve a critical role in continuing education and information sharing. They are influential, in that they issue guidelines and shape ethical norms.<sup>30</sup> In a self-regulating profession, it is professional associations that can make decisions that alter practice. The leadership within these associations has the opportunity to set the precedent of responsible interaction with industry. The CFMS, a representative body of Canadian medical students, also has the capability to alter the practice of future physicians. An assessment of the strengths and weaknesses of the guidelines of professional organizations can provide context for CFMS guidelines.

#### *Canada: Canadian Medical Association (CMA)*

The CMA struck a working group in 2007 to address all issues pertaining to pharmaceuticals, their marketing, and their provision.<sup>31</sup> Policies and resolutions submitted on the topic have included recommendations on direct-to-consumer advertising, internet prescribing, the National Pharmaceutical Strategy, post-market surveillance of pharmaceutical products, and physician interactions with industry.

In 2007, the CMA updated the 2001 guidelines (Physicians and the Pharmaceutical Industry).<sup>32</sup> The current guidelines are intended to apply to physicians, residents, medical students, and medical organizations, in their interactions with industry. The CMA Guidelines call for physicians to resolve conflicts of interest between their own financial interests and the wellbeing of their patients, in favour of their patients' wellbeing. Of particular relevance to this discussion are the CMA's policies on continuing medical education, gifts, and medical students.

With respect to CME, the guidelines stipulate that funds from commercial sources should be unrestricted, and that industry representatives should not be involved in content planning but they may provide logistical support in the organization of events. Like the University of Toronto policy on CME, lodgings and travel should not be in excess of that possible without commercial support. Organizers of CME events and presenters are to disclose ties to companies mentioned at the event, or ties to their competitors. Generic names are supposed to be used in presentations, and presentations should provide a balanced overview of the available scientific literature.

On the topic of gifts from industry, the CMA guidelines state that: physicians should not accept gifts of "any significant monetary or other value." They do allow, however, for physicians to be employed by industry in an advisory capacity. The guidelines allow for physicians to serve as advisors or consultants to industry and receive remuneration that is "reasonable" and "take[s] into consideration the extent and complexity of the physician's involvement."<sup>33</sup> There is considerable room for interpretation in this clause. The guidelines do prohibit physicians from receiving payment for seeing pharmaceutical company representatives in a promotional capacity, but, by definition, most pharmaceutical representatives are involved in sales, so it is questionable how these guidelines are actually implemented in practice.

With respect to medical students and residents specifically, the policy notes that the guidelines are equally applicable to trainees as they are to physicians. It also stipulates that students should receive training on the presented guidelines.

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<sup>30</sup> Rothman *et al.* (2009): 1367.

<sup>31</sup> Canadian Medical Association, "CMA Working Group on Pharmaceutical Issues," *CMA - Policy/Advocacy*, February 2007, [http://www.cma.ca/index.cfm/ci\\_id/53408/la\\_id/1.htm](http://www.cma.ca/index.cfm/ci_id/53408/la_id/1.htm) (accessed April 2009).

<sup>32</sup> Canadian Medical Association, *Guidelines for Physicians in Interactions with Industry*, (Ottawa: CMA, 2007).

<sup>33</sup> Canadian Medical Association (2007): 4.

*United States: American Medical Association (AMA)*

The AMA Code of Medical Ethics specifically addresses gifts from industry to physicians.<sup>34</sup> Acceptable gifts are those described as “not having substantial value” and as having “benefit to the patient.” The next sentence allows for the provision of “modest” meals, and the next clause clarifies that items of relevance to a physicians work are permitted, such as pens and notepads. However, with respect to “consulting,” the AMA guidelines are clear that payment – either financial or in the form of travel and accommodations – for “token” services is unacceptable. Specifically, physicians should not be compensated for information sessions with pharmaceutical representatives. Yet, even with recognition that “the giving of a subsidy directly to a physician by a company’s representative may create a relationship that could influence the use of the company’s products,” the guidelines inconsistently permit reimbursement by industry for conference faculty, for travel and other expenses, as well as similar reimbursement for physicians participating in focus groups.

The AMA guidelines were based on a 1991 report by the Council on Ethical and Judicial Affairs.<sup>35</sup> The purpose of the report was to distinguish between appropriate and inappropriate gifts; this clarifies the report’s assumption that there is such thing as an appropriate gift from industry to physicians, and the issue is learning how to identify them as such. A fundamental problem with gifts is highlighted, namely that receipt of a gift elicits a social obligation to express thanks and reciprocate. This does not necessarily lead to reciprocation in the form of an equivalent gift, but, as the report posits, a physician “be more responsive in granting interviews to sales representatives and may, on the basis of the information presented, decide to use a new drug or device on a trial basis with his or her patients.”<sup>36</sup> The report goes on to emphasize that physicians need to be aware of all evidence pertaining to new and established drugs, and gifts should not play a role in medical decisions. Furthermore, it is noted that the perceived effect of gifts on physicians’ medical decision making is as important to consider as the actual effect. In terms of social responsibility, this report is the only one from a professional association reviewed in this document that acknowledged the cost of gifts for physicians is transmitted to the public, in the cost of prescription drugs.<sup>37</sup>

Despite these principles, the recommendations that follow in the report allow for continued gift-giving, as long as the gifts are not exorbitant. However, it appears contradictory that the report at once accepts the principle of gift-giving yet acknowledges that this act can promote a sense of obligatory reciprocity between donor and recipient. Research on the effects of gift-giving is presented in more detail in the “Effects of Relationships with Industry” section.

*United States: American Psychiatric Association (APA)*

The APA has eliminated a considerable portion of industry funding from its annual activities. Under the policy voted on in March 2009, the Association will no longer accept industry funding of its symposia, nor will it accept meals at annual meetings.<sup>38</sup> Executive members of the APA noted, “the only way to totally eliminate the risk is to have the symposia supported by the APA alone,” including the risk that “accepting meals provided by pharmaceutical companies may have a subtle influence on doctors’ prescribing habits.”

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<sup>34</sup> American Medical Association, “Opinion 8.061 - Gifts to Physicians from Industry,” *AMA Code of Medical Ethics*, June 1992, <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml> (accessed April 2009).

<sup>35</sup> Council on Ethical and Judicial Affairs, “Gifts to Physicians from Industry,” *AMA Code of Medical Ethics*, December 1990, <http://www.ama-assn.org/ama1/pub/upload/mm/code-medical-ethics/8061a.pdf> (accessed April 2009).

<sup>36</sup> *Ibid.*: 2.

<sup>37</sup> *Ibid.*: 4.

<sup>38</sup> American Psychiatric Association, “The American Psychiatric Association Phases Out Industry-Supported Symposia,” *2009 News Releases*, March 2009, <http://www.psych.org/MainMenu/Newsroom/NewsReleases/2009NewsReleases/APAphasesOutISS.aspx> (accessed April 2009).

### III.III Industry Policies

Pharmaceutical companies and device manufacturers have responded to ethical concerns regarding their marketing, education, and gift-giving practices, with statements through PhRMA, the organization that represents leading American pharmaceutical companies. This section explores the defense of industry, and how it describes its own efforts to self-regulate.

#### *PhRMA*

The Code of Conduct connects marketing and patient care, noting “appropriate marketing ensures that patients have access to the products they need.”<sup>39</sup> In relationships with health care professionals, the industry guidelines suggest the role of pharmaceutical companies is as educator, informer, and researcher. With respect to the quality of information provided by industry to physicians, the Code requires it be accurate and not misleading, make claims about a product only when properly substantiated, and reflect the balance between risks and benefits. As to the context in which this information is delivered to health care professionals, the Code notes that meals are appropriate as a professional courtesy when taking up someone’s time, and that they are acceptable as long as they are modest; entertainment beyond meals is prohibited. In line with the policies of professional medical associations, CME funding is to be given to the organizer, and the Code is adamant that sponsoring companies should not influence content. Paid consultancy by physicians is acceptable under the Code, although gifts are strictly prohibited, including office stationary such as pens, mugs and notepads. The only exception is that some educational items less than \$100 are permitted. With the elimination of gifts as an acceptable practice, the PhRMA Code of Conduct actually goes beyond what some of the professional medical association guidelines have recommended.

Recently, the organization published a press release, categorically disagreeing with the proposal of Rothman *et al.* in a recent issue of JAMA, arguing that stringent restrictions on industry contributions to CME would limit activities that “improve public health and protect patient safety.”<sup>40</sup> Rothman *et al.* had made ten recommendations for professional medical associations to limit the influence of industry. These included reducing industry funding to 25% of their total budget with a goal of eventually receiving no funding from those sources; putting safeguards in place to ensure that conference and CME event organization truly is free of industry influence and prohibiting paraphernalia with company logos from conferences; requiring that research funds from industry go to a central, unrestricted pot and that research data belong to researchers not companies; prohibiting industry influence in the formulation of professional guidelines; eliminating the practice of product endorsement by professional associations; and requiring that the executive and staff of a professional association have no financial ties to industry.<sup>41</sup> These recommendations represent a significant swing from current practice. Despite some overlap between these recommendations and the PhRMA Code of Conduct, it is not surprising that the organization which represents the American pharmaceutical industry would object to potentially losing the ability to sponsor CME activities in the future.

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<sup>39</sup> Pharmaceutical Research and Manufacturers of America, “Code on Interactions with Healthcare Professionals,” *PhRMA*, January 2009, <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf> (accessed April 2009).

<sup>40</sup> Pharmaceutical Research and Manufacturers of America, “PhRMA Stat

### III.IV The Effects of Relationships With Industry

Restrictions on physician interaction with industry rest on the premise that physicians are influenced by that interaction, and that patient care may suffer as a result. A considerable body of research has tackled this question. Most of it focuses on changes in prescribing habits following the receipt of gifts or travel reimbursement for individual physicians, but the results provide an overview of the consequences of the relationships between industry and physicians that may be more broadly applicable. At the very least, the CFMS should consider the pitfalls highlighted by this literature in considering a policy regarding its own relationships with industry.

#### *Influences on Behaviour*

Numerous studies have indicated that receiving gifts, travel, and advertising by pharmaceutical companies change the way physicians behave. A 1988 study examined the prescribing practices of physicians before and after several CME events. Each event focused on a class of drugs, with several drugs being discussed, but each had a single major pharmaceutical sponsor. Investigators found prescriptions of all the drugs increased after the CME event, with the drug of the sponsoring company increasing the most<sup>42</sup>. A survey of physicians in Ohio determined that those who had interacted with pharmaceutical representatives were thirteen times more likely to include a drug made by the company of those representatives in the hospital formulary; this increased to twenty-one times more likely for physicians who had received payment from a company for a speaking engagement<sup>43</sup>. One study found that prescribing habits of physicians who attended a company-sponsored symposium in a warm vacation destination for a drug made by that company actually increased above the national average<sup>44</sup>.

Claims are sometimes made that without advertising and “education” by pharmaceutical companies, patient care would suffer through lack of physician awareness of the latest treatment options. There is no evidence to support this, and in fact, a 1982 study found that physicians were more likely to believe the efficacy of drugs as reported by commercial sources, instead of what was supported by the literature.<sup>45</sup>

It would seem, intuitively, that a pen is different from an all-expenses paid trip to a symposium in the Bahamas. However, the social rule of reciprocity referred to by Katz, Caplan and Mertz<sup>46</sup> suggests that regardless of the size of the gift, it is human nature to feel an obligation to return the favour as much as possible.

Perhaps more subtle than objective changes in prescription behaviours, but no less problematic, is the bias physicians exhibit, consciously or otherwise, in presentations on pharmacological treatment. Dr. Kassirer reported cases of physicians with financial ties to companies making presentations with subtle bias to undermine the competition’s medicines while promoting their own.<sup>47</sup> Simply having physicians consult for pharmaceutical companies, and speak on various topics, sways them and their audience toward a practice of medicine that prefers specific medications, whether or not they are in fact the best treatment option as demonstrated by evidence. This type of bias may be especially problematic for medical students, who often are educated by physicians participating in pharmaceutical industry sponsored research. Physician-educators may unconsciously incorporate their biases into their didactic teaching, which may then be accepted by medical students as fact.

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<sup>42</sup> M.A. Bowman and D.L. Pearle, "Changes in drug prescribing patterns related to commercial company funding of Continuing Medical Education.," *Continuing Education Health Professions* 8 (1988): 13-20 cited in Council on Ethical and Judicial Affairs (1991): 2.

<sup>43</sup> M.M. Chen and Landefeld S., "Physicians' behaviour and their interactions with drug companies," *Journal of the American Medical Association* 271 (1994): 684-689.

<sup>44</sup> James P. Orłowski and Leon Wateska, "The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns," *Chest* 102 (1992): 270-273

<sup>45</sup> J. Avorn, M. Chen and R. Hartley, "Scientific versus commercial sources of influence on the prescribing behaviour of physicians," *American Journal of Medicine* 73 (1982): 4-8 cited in Council on Ethical and Judicial Affairs (1991): 3.

<sup>46</sup> Dana Katz, Arthur L. Caplan and Jon F. Merz, "All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving," *American Journal of Bioethics* 3, no. 3 (2003): 41

<sup>47</sup> Kassirer (2005): 30

### *Self-Regulation*

Even if gifts can influence physician behaviour, arguably, professionals might be able to mitigate the effects through self-awareness. The research, however, suggests that physicians frequently underestimate the effect their relationship with industry can have. Studies indicating an increase in prescribing practices in favour of the drug of a sponsoring company following receipt of a gift or travel opportunity show that those same physicians were confident their behaviour would not change.<sup>48</sup>

### *Medical Students & Industry*

A survey of fourth year medical students found that receiving a textbook from pharmaceutical representatives did not improve recall of the company names, from which the students received the books. However, students did report appreciating the attention from company representatives. The authors concluded that although, in the long term, students did not remember specific companies they interacted with, in the short term, there was a perceived obligation to listen to the sales pitch that came with the gift.<sup>49</sup> Yet, a survey of residents, interns, and clerks at the University of Toronto in the Department of Psychiatry found that the more gifts the trainees received, the more likely they were to believe that this action would not have any influence on their behaviour<sup>50</sup>. This would indicate that those students and professionals most at risk for being biased by the pharmaceutical industry are the least able to self-regulate. As students, we are not immune to the effects of interactions with industry, and we need to be aware of the potential outcomes.

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<sup>48</sup> Orłowski and Wateska (1992).

<sup>49</sup> Warren S. Sandberg, Ruth Carlos, Elisabeth H. Sandberg and Michael F. Roizen, "The Effect of Educational Gifts from Pharmaceutical Firms on Medical Students' Recall of Company Names or Products," *Academic Medicine* 72 (1997): 916-918.

<sup>50</sup> B. Hodges, "Interaction with the pharmaceutical industry," *Canadian Medical Association Journal* 153 (1995): 553-559

#### **IV. Conclusion**

The goal of this document is not to suggest eliminating all relationships between physicians and industry. Rather our goal is to develop a framework to ensure that responsible relationships can take place between industry and medical students.

The CFMS, as the association representing medical students in Canada, is in a position to take a leadership role in the future direction of physician-industry relationships.

We call on the CFMS member schools to implement the following recommendations:

1. Schools have a responsibility to prepare medical students for real-world practice by educating them about appropriate relationships with industry.
  - a. Schools will provide an environment in which medical students can learn about industry relationships ethically and responsibly, for example through:
    - i. Lectures;
    - ii. Seminars; and/or
    - iii. Workshops.
  - b. Complete isolation from industry is neither feasible nor helpful in this process.
  - c. Exposure to industry relationships and topics on conflict of interest should occur early in training.
2. School administrations will develop policies together with their respective medical student societies to monitor any industry involvement in educational and extra-curricular activities in accordance with the principles referenced in this document.
3. Schools will make a requirement for lecturers and educators to disclose conflicts of interest with industry as defined by their home institution.
4. Student societies and students will not accept gifts of any kind from pharmaceutical companies or their representatives.
5. Student societies will not accept funding for any events from pharmaceutical companies or their representatives.

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