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## PHYSICIANS AND THE PHARMACEUTICAL INDUSTRY (UPDATE 2001)

The history of health care delivery in Canada has been marked by collaboration between physicians and the pharmaceutical and health supply industries; this collaboration extends to research as well as to education. Because medicine is a self-governing profession, physicians have a responsibility to ensure that their participation in such collaborative efforts is in keeping with their duties to their patients and society. The following guidelines have been developed by the CMA to assist physicians in determining when a relationship with industry is appropriate. Although directed primarily to individual physicians, including residents, and medical students, the guidelines also apply to relationships between industry and medical organizations. These guidelines focus on the pharmaceutical companies; however, the CMA considers that the same principles apply to relationships between physicians and all commercial organizations, including manufacturers and suppliers of medical devices, infant formulas, health care products and informatics, and other service suppliers. These guidelines reflect a national consensus of medical organizations and are meant to serve as an educational resource for physicians throughout Canada.

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### General principles

1. The primary objective of professional interactions between physicians and industry should be the advancement of the health of Canadians rather than the private good of either physicians or industry.
2. Relationships between physicians and industry should be guided by the CMA's Code of Ethics.
3. The practising physician's primary obligation is to the patient. Relationships with industry are appropriate only insofar as they do not negatively affect the fiduciary nature of the patient-physician relationship.
4. Physicians should resolve any conflict of interest between themselves and their patients resulting from interactions with industry in favour of their patients. In particular, they should avoid any self-interest in their prescribing and referral practices.
5. In any relationship between a physician who is not an employee of the pharmaceutical industry and the industry itself the physician should always maintain professional autonomy, independence and commitment to the scientific method.

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## Industry-sponsored research

6. A prerequisite for physician participation in industry-sponsored research activities is evidence that these activities are ethically defensible, socially responsible and scientifically valid. The physician's primary responsibility is the well-being of the patient.
7. The participation of physicians in industry-sponsored research activities should always be preceded by formal approval of the project by an appropriate ethics review body. Such research should be conducted according to the standards and procedures set out in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada) as interpreted by the National Council on Ethics in Human Research.
8. Patient enrolment and participation in research studies shall occur only with the full, informed, competent and voluntary consent of the patient or his or her proxy, unless the research ethics board authorizes an exemption to the requirement for consent. The standards and procedures set out in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans should be utilized for structuring and obtaining the relevant consent or for determining that the requirement for consent can be waived. The enrolling physician is responsible for implementing these standards and procedures. In particular, the CMA Code of Ethics requires the enrolling physician to inform the potential research subject, or proxy, about the purpose of the study, its source of funding, the nature and relative probability of harms and benefits, and the nature of the physician's participation and to advise prospective subjects that they have the right to decline to participate or to withdraw from the study at any time, without prejudice to their ongoing care. Because the prospective research subject is in a dependent relationship to the physician and might be susceptible to consenting under duress, it is preferable that the informed consent be obtained by a qualified person who is independent of the patient-physician relationship. However, the responsibility of assuring that proper consent has been obtained remains with the enrolling physician.
9. The physician who enrolls a patient in a research study has an obligation to ensure the protection of the patient's privacy, in accordance with the provisions of CMA's Health Information Privacy Code. If this protection cannot be guaranteed, the physician must disclose this as part of the informed consent process.
10. Practising physicians should not participate in research studies unless they are assured by the sponsors that the results will be made public within a reasonable period.
11. It is acceptable for physicians to receive remuneration for enrolling patients or participating in approved research studies only if such activity exceeds their normal practice pattern. This remuneration should not constitute enticement. It may, however, replace income lost as a result of participating in a study. Parameters such as time expenditure and complexity of the study may also be relevant considerations. The amount of the remuneration should be approved by the relevant review board, agency or body mentioned previously. Research subjects must be informed if their physician will receive a fee for enrolling them in a study.
12. Incremental costs (additional costs that are directly related to the research study) should not be paid by health care institutions or

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provincial or other insurance agencies regardless of whether these costs involve diagnostic procedures or patient services. Instead, they must be assumed by the industry sponsor or its agent.

13. When submitting articles to medical journals, physicians should state any relationship they have to companies providing funding for the studies or that make the products that are the subject of the study whether or not the journals require such disclosure.

### **Industry-sponsored surveillance studies**

14. Physicians should participate only in postmarketing surveillance studies that are scientifically appropriate for drugs or devices relevant to their area of practice.
15. Physicians considering participation in surveillance studies should avail themselves of appropriate resources to assist them in their decision-making. Research ethics boards that already exist in their community may serve in this capacity. The National Council on Ethics in Human Research is an additional source of advice.
16. When institutionally based research ethics boards are unavailable, participation in research and surveillance studies should be through national, regional, provincial or territorial coordinating agencies or bodies that can function as a resource for physicians in assessing the study's ethical acceptability and scientific value. Although these boards, agencies and bodies may be partially or completely funded at arm's length by industry, they should be under the direction of appropriately qualified health care professionals and researchers working independently from industry.

### **Continuing medical education / continuing professional development (CME/CPD)**

17. The primary purpose of CME/CPD activities is to address the educational needs of physicians and other health care providers in order to improve the health care of patients. Activities that are primarily promotional in nature should be identified as such to faculty and attendees and should not be considered as CME/CPD.
18. The ultimate decision on the organization, content and choice of CME/CPD activities for physicians shall be made by the physician-organizers.
19. CME/CPD organizers are responsible for ensuring the scientific validity, objectivity and completeness of CME/CPD activities. Organizers must disclose to the participants at their CME/CPD events any financial affiliations with manufacturers of products mentioned at the event or with manufacturers of competing products.
20. The ultimate decision on funding arrangements for CME/CPD activities is the responsibility of the physician-organizers. Although the CME/CPD publicity and written materials should acknowledge the financial or other aid received, they must not identify the products of the company(ies) that fund the activities.
21. All funds from a commercial source should be in the form of an unrestricted educational grant payable to the institution or organization sponsoring the CME/CPD activity. Upon conclusion of the activity, the physician-organizers should be prepared to present a statement of account for the activity to the funding organizations and other relevant parties.
22. Whenever possible, generic names should be used rather than trade names in the course of CME/CPD activities. In particular, physicians should not engage in peer selling.\* If specific products or services are mentioned, there should be a balanced presentation of the

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prevailing body of scientific information on the product or service and of reasonable, alternative treatment options. If unapproved uses of a product or service are discussed, presenters must inform the audience of this fact. Faculty must disclose to the participants at CME/CPD events any financial affiliations with manufacturers of products or service providers mentioned at the event or with manufacturers of competing products or providers of competing services.

23. Negotiations for promotional displays at CME/CPD functions should not be influenced by industry sponsorship of the activity. It is preferable that promotional displays not be in the same room as the educational activity.
24. Travel and accommodation arrangements, social events and venues for industry-sponsored CME/CPD activities should be in keeping with the arrangements that would normally be made without industry sponsorship. For example, the industry sponsor should not pay for travel or lodging costs or for other personal expenses of physicians attending a CME/CPD event. Subsidies for hospitality should not be accepted outside of modest meals or social events that are held as part of a conference or meeting. However, faculty at CME/CPD events may accept reasonable honoraria and reimbursement for travel, lodging and meal expenses. Scholarships or other special funds to permit medical students, residents and fellows to attend educational events are permissible as long as the selection of recipients of these funds is made by their academic institution.

### **Clinical evaluation packages (samples)**

25. The distribution of samples should not involve any form of material gain for the physician or for the practice with which he or she is associated.
26. Physicians who accept clinical evaluation packages (samples) and other health care products are responsible for ensuring their age-related quality and security. They are also responsible for the proper disposal of unused samples.

### **Other considerations**

27. These guidelines apply to relationships between physicians and all commercial organizations, including manufacturers of medical devices, infant formulas and health care products as well as service suppliers.
28. Physicians should not dispense pharmaceuticals or other products unless they can demonstrate that these cannot be provided within a reasonable time frame by an appropriate other party, and then only on a cost-recovery basis.
29. Physicians should not invest in pharmaceutical manufacturing companies or related undertakings if knowledge about the success of the company or undertaking might inappropriately affect the manner of their practice or their prescribing behaviour.
30. Practising physicians affiliated with pharmaceutical companies should not allow their affiliation to influence their medical practice inappropriately.
31. Practising physicians should not accept a fee or equivalent consideration from pharmaceutical manufacturers or distributors in exchange for seeing them in a promotional or similar capacity.
32. Practising physicians should not accept personal gifts from the pharmaceutical industry or similar bodies.

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33. Practising physicians may accept patient-teaching aids appropriate to their area of practice provided these aids carry only the logo of the donor company and do not refer to specific therapeutic agents, services or other products (e.g., baby formula).

**Medical students and residents**

34. These guidelines apply to physicians-in-training as well as to practising physicians. Medical curricula should deal explicitly with the guidelines.

\*Peer selling occurs when a pharmaceutical or medical device manufacturer or service provider directly or through a third party sponsors a seminar or similar event that focuses on its own products and is designed to enhance the sale of those products. The company directly or through a third party engages a physician to conduct the session:

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. Peer selling, as understood in this sense, differs from the sort of situation in which a pharmaceutical or medical device manufacturer or service provider provides funds to CME/CPD organizers to sponsor a bona fide educational event on a specific condition or on a specific product or service. In the latter event the control and structure of the CME/CPD event lies in the hands of the CME/CPD organizers. Even though the product or service may be the focus of such a bona fide event the arm's-length nature of the sponsorship by the manufacturer and the fact that the control and structure of the event lie in the hands of the CME/CPD organizers remove it from the realm of advertising and the event does not constitute an endorsement of the product or service in question.