Background and Context

The UBC Faculty of Medicine (FoM) is already bound by the UBC Policy [97] on Conflict of Interest and Commitment. In order to provide more specific direction with respect to alignment with policies such as the FoM CME guidelines in relationships with Industry; evolving North American standards in the role of Industry in Education overall, the following policy elaborates principles that support the intent and content of policies and codes of ethics as adopted by the Canadian Medical Association, The Canadian Association of Occupational Therapists, the Canadian Physiotherapy Association, and the Canadian Association of Speech Language Pathologists and Audiologists.

The following is an elaboration of the principles:

1. It is the responsibility of health professionals to employ unbiased, evidence-based skills and knowledge in the care of their patients and to serve as their health care advocate.

2. The primary objective of professional interactions between health professionals and industry should be the advancement of the health of patients rather than the private good of health professionals, industry or any other third party.

3. Health professional researchers must have the freedom to perform and report unbiased research

4. Industry has many activities and values that are beneficial to society. Specifically, producers of pharmaceuticals, medical devices, instruments and equipment, have always played an important role in health and health care. They save lives, prevent the spread of disease, help in diagnosis, improve the quality of life for many, and control pain and suffering. Nevertheless, within the structures of our society, the primary goal of industry is to make a profit. This primary motive influences all aspects of industry behaviour. The industries producing pharmaceuticals, medical devices and equipment are somewhat unique, compared to other industries in the following ways:

   - drugs, devices and equipment are “inputs” for health care, not “consumer goods”;
   - the pharmaceutical and medical devices manufacturing industry is highly research-intensive;
significant economies of scale exist in the discovery and production of drugs, medical devices and equipment;

manufacturers are granted legally protected monopolies over their discoveries;

fully understanding the indications for, and understanding the effects of pharmaceuticals and medical devices often requires significant clinical and pharmacologic knowledge;

the choice of drug therapy or medical device is often influenced or made by a health professional, not the consumer and should not be made or influenced by industry;

when a drug or medical device is needed, its purchase can seldom be deferred; and

a significant portion of the population does not consider price when making drug purchases because public or private insurance usually covers the cost. In addition, a substantial portion of the population would consider a more expensive medical device better, particularly when influenced by direct to consumer marketing.

4. Physicians and other health professionals are in a unique position in relation to patients and the industries that supply drugs and other health care devices including sports medicine products, assistive devices, and infant formula. In many important respects the health professional stands interposed between the patients who seek the benefits and the industries that supply those benefits. The health professional thus has a fiduciary responsibility towards the patient, i.e., he/she is in a position of trust. These fiduciary responsibilities must be met through health professionals accepting responsibility to be as educated as possible about the risks and benefits of any therapeutic intervention while at the same time recognizing their own limitations in some areas of therapeutics. In the real world in which decisions must be made, and prescriptions written, this is not always a comfortable balance. The sources of information and advice must be constantly assessed for potential biases. The marketing practices of pharmaceutical and medical device manufacturers tend to blur the distinction between education and persuasion while focusing on the benefits and downplaying the risks of their product. While in the general market place, this is a legitimate action on the part of business, health professionals have a clear responsibility to recognize and respond to this bias on behalf of the patients under their care.

An additional responsibility for health professionals in the current system is to assist in the maintenance of the system while maintaining responsibility for the care of individual patients. This means that some attention must be paid to the cost of pharmaceuticals and devices, whether those costs are borne by the patient individually or by the system as a whole. There is a danger that health professionals may prescribe the newest and most expensive drugs or devices without clinical evidence that they are superior to existing treatments. In addition, it is understood that many medical devices offer equivalent results, but may differ in price. It is the health professional’s responsibility to help the payer achieve the lowest possible price as long as products are considered equivalent in terms of safety and efficacy. In addition, in the current era whereby patients often ask for a certain device based on direct to consumer marketing by industry, it is the health professional’s responsibility to educate the patient about the true merit of the device that they request and similar yet more economical devices that are available.
5. It is recognized that industry has produced, in addition to promotional material, some educational materials that may be appropriate to health professional training.

6. There is evidence that industry influences research, medical education, prescribing patterns and CME. A database of 2700 articles (available at www.drugpromo.info) summarizes that most doctors think that information from pharmaceutical companies is biased, but many think it useful. Moreover, while most doctors consider themselves immune to manipulation by drug representatives and their gifts, they do consider that it will influence other doctors. www.who.int/medicines/areas/rational_use/drugPromodhai.pdf

7. It may be reasonable to consider obtaining some support from industry in moving toward unbiased, evidence-based educational endeavours and research.

8. The Faculty is committed to promoting the development of practitioners who are independent critical thinkers, evidence-based practitioners and are life-long learners. This commitment extends across the entire educational spectrum involving undergraduate, postgraduate, graduate and Continuing Professional Education/Development.

9. Trainees should be facilitated to take a broad view of their practice, the influences on their practice, and the relation between their practice and society as a whole.

10. There will be no posting of corporate logos or links to corporate websites on the Faculty of Medicine or Faculty of Medicine Department websites.

Research

As a result of cuts to public funding, medical research relies more on industry funding. The industry’s need to develop marketable products may skew the direction of health research in Canada. Heavy financial dependence on the pharmaceutical industry could jeopardize academic freedom, unless this is carefully managed.

It is the intent of the Faculty that donations and grants from industry and other sources to Departments within the Faculty would be used in an unrestricted manner that is consistent with the stated goals and needs of the Faculty and its Departments. Such unrestricted funds shall not be used, under any circumstances, for the personal gain of any faculty member. No stipends, honoraria or the like shall be paid to individual faculty members from such grants.

1. A prerequisite for participation in industry-sponsored research in the Faculty of Medicine is evidence that these activities are ethically defensible, socially responsible and scientifically valid.

2. The participation of members of the Faculty of Medicine in industry-sponsored research activities should always be preceded by formal approval of the project by the (University of British Columbia Ethics) review body. Such research should be conducted according to the standards and procedures set out in the “Tri-Council Policy Statement on the 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 elaborated by the National Council on Ethics in Human Research.
3. Withholding research results is common for a variety of reasons (patent, to protect scientific priority, publication delays and industry support requirements of intellectual property protection). No faculty member should enter into an agreement with industry where the power to publish study results is relinquished. While it is acceptable for an industry sponsor to review the data or a paper prior to publication, the industry sponsor shall not have the right to prevent a study from being published regardless of whether the results are complimentary or otherwise.

**Education**

The industry’s need to develop marketable products may skew the direction of health education in Canada. Heavy financial dependence on the pharmaceutical industry could jeopardize academic freedom, unless this is carefully managed.

1. All teachers must disclose conflicts of interest to learners in the Faculty of Medicine before beginning the educational interaction.

2. For University sponsored or accredited courses, the ultimate decision on the organization, content and choice of educational activities shall lie in the hands of the educational organizers within the Faculty and its Departments, regardless of the source of funding of the course.

3. Educational organizers must not be in a position of conflict of interest by virtue of any relationship with the company or companies that fund educational activities.

4. Industry sponsorship for educational events must be in the form of an unrestricted grant and the Departments of the Faculty are free to establish their own educational priorities uninfluenced by the availability of funds for any particular event. These funds must not bias the educational event.

5. Any funding from industry can be acknowledged with a statement at the beginning or end of the session that support comes from a particular company, or that materials have been produced with the help of industry funding. Generic names of drugs should be used rather than trade names in the course of the educational activities. Where specific products or services are mentioned, there should be a balanced presentation of the prevailing body of scientific information on the product or service and of reasonable alternative treatment options. All evaluation forms shall contain a specific question pertaining to real or perceived commercial bias in a presentation.

6. A registration fee must be charged for all accredited Continuing Education activities that would normally have a registration fee associated with them. Commercial support may help reduce the cost of registration but a registration fee should be paid by the participants in order to avoid a perceived or real influence on learning.

7. For CME accredited Continuing Education Activities, Faculty and Visiting Speaker payments must be the same as if there were no commercial sponsorship. Any payment to faculty or visiting speakers may not be made directly by commercial sponsors. All funds from the commercial sponsors must be in the form of unrestricted educational grants made payable to the UBC Department.

8. Financial contributions to post-graduate and graduate program activities should not result in special or increased access to the trainees by industry representatives.
9. Pharmaceutical and medical device displays – if pharmaceutical or medical device displays are permitted at an educational event, every manufacturer who is willing to pay for such space should be given an equal opportunity for displaying their material. Different levels of sponsorship are permissible provided the process is transparent and all manufacturers are made aware of the arrangements.

10. Promotional literature will not be distributed except in the context of the pharmaceutical and medical device displays in item #8.

11. The learner includes any of the following: undergraduate students, post-graduate students, graduate students, fellows and faculty who are affiliated with the UBC Faculty of Medicine.

**Educational Resources**

We understand that drug and device promotion is not necessarily education. By definition, drug and device promotion aims to increase product sales. The World Health Organization defines it as: “all information and persuasive activities by manufacturers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.”

1. Industry representatives may be invited by the Postgraduate/Graduate Program Director to submit educational materials (such as films, videos, CD-ROMs, audiotapes, anatomic models, textbooks, etc). These materials will be critically appraised by the office of the Director to determine if they are evidence-based. If judged suitable, the materials could be kept as a resource in a central location. Particularly valuable material may be incorporated into educational sessions.

2. If it is known that the industry has a particular evidence-based educational resource that would help fulfill an independently derived educational goal, the resource should be sought.

3. Industry-developed handout materials for entry to practice classroom educational purposes cannot be distributed without prior approval by the appropriate academic unit.

4. Practicing clinicians may accept patient-teaching aids appropriate to their discipline provided these aids carry only the logo of the donor company and do not refer to specific therapeutic agents, services or other products.

**Gifts**

1. Gifts from industry to individual faculty members should not be accepted. Social science research demonstrates that the impulse to reciprocate for even small gifts is a powerful influence on people’s behavior.

2. Travel and accommodation arrangements, social events and venues for industry-sponsored educational 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 health professional attending an accredited Continuing Educational 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 presenters at educational events may accept reasonable honoraria and reimbursement for travel, lodging and meal expenses, as defined in UBC policy 97. Scholarships or other special funds to permit residents to attend educational events are permissible as long as the selection of participants for these funds is made by their academic institution.
Samples

Where a clinician within a Faculty of Medicine Department chooses to accept samples, the following precautions and teaching venues should be considered. The clinician is serving as a powerful role model to ensure that the trainee prescribes cost-effective medications (and devices, etc) based on sound evidence. Graduate students, residents and undergraduate students should be exposed to the ethical issues surrounding samples so as to formulate an opinion for their own future practice. Ideally, the health professional should not accept samples for a drug or device that (s) he would not otherwise have prescribed.

Due to the concerns addressed above, the Faculty remains unconvinced about the desirability of using samples. Since this is common practice in Canada presently, and to be consistent with the Canadian Medical Association Policy, it is the expectation that the following guidelines should take place in each teaching venue.

1. The distribution of samples should not involve any form of material gain for the health professional or for the practice with which he or she is associated.

2. Health Professionals 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. If a sample is given to a patient it must be labeled with the patient’s name, date, name of drug and instructions as to use.

Detailing

Industry activities to promote products and increase sales do not always reflect what is in the patient’s best interest. If salespeople could be expected to provide objective information on their product, their interaction could be most beneficial. Such an expectation would be naive. Despite regulatory constraints, medical representatives continue to mislead prescribers knowingly. Strong evidence indicates that interaction with the pharmaceutical industry influences physicians’ prescribing behaviour and that physicians’ use of detailers could lead to inappropriate prescribing. Market research indicates that pharmaceutical sales representatives effectively promote sales of their products. Formal training sessions may help guide learners in their interactions with industry representatives. For medical devices, any information provided by the sales representative should be independently corroborated from the literature if present. The role of the representative is to guide the health professional in the proper use of a product and in ensuring availability of stock and supplies. Evidence regarding interaction with respect to new medical and other devices should be sought prior to their use.

1. Neither faculty nor learners are required to see industry representatives.

2. Meetings between learners and pharmaceutical company (industry) representatives should be arranged in advance with faculty members who agree to see representatives.

3. Meetings should be supervised by a faculty member and learners/trainees/residents should be debriefed afterwards focusing on the role of industry representatives, the communication techniques used and the critical appraisal of promotional material provided by the representative.

4. Industry representatives should not be invited to closed sessions for trainees such as the resident rounds or other required curricular activities.
5. The residency program will not facilitate access of representatives to the residents. Distributing lists of names and rotations of residents to industry representatives is prohibited.

These guidelines apply to all health profession programs in the FoM, including undergraduate medical and other graduate entry to practice students, residents, and other practitioners who are affiliated with the UBC Faculty of Medicine.

(This policy is adapted from UBC Department of Family Practice Policy, with permission and acknowledgement. Additional references are available in that policy)

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