



**INTERACTIONS WITH THE PHARMACEUTICAL INDUSTRY**

**TASK FORCE REPORT**

**DEPARTMENT OF PSYCHIATRY**

**UNIVERSITY OF TORONTO**

**December 2003**

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## Preamble

This report resulted from a growing recognition and concern within our own department and more broadly across the profession of medicine of the perceived and real conflict of interest in the complex relationship between physicians and the pharmaceutical industry. The realities that underpin this relationship – that physicians often need to prescribe medications to achieve desired therapeutic goals for their patients; that industry often generates research-based medications to improve treatment; that industry views physicians as the rate limiting step in the prescription of their medications; and that industry is, *primus inter pares*, a business that must profit to survive – establish the potential for both confluence of and conflict of interest. At the same time, as a research-focused and productive academic department, we have enjoyed high-level collaborations with industry in both basic and clinical science that have been investigator-initiated and governed by stringent research ethics requirements. In addition, at the level of the Faculty of Medicine, recently harmonized research ethics guidelines regulate this research interaction with industry.

The confusion and concern experienced by physicians, students and the public in the context of this relationship is well reflected by the simultaneous emergence nationally and internationally of multiple guidelines for these interactions by both physician organizations and by industry. In Appendix III of this report, three of these sets of guidelines are applied to common situations in relation to industry. In Appendix IV, references to various guidelines are provided as well as references to selected articles in this field. Overall, the similarities outweigh the differences among these guidelines but problems remain:

- ❖ they are never complete or prescriptive enough to cover every situation;
- ❖ promulgation is not the same as acceptance or adherence. Indeed, the research literature on clinical practice guidelines reflects tremendous difficulties in getting physicians to adopt new therapeutic behaviours based on research evidence; imposing a code of professional behaviour related to interaction with industry may be even more challenging;
- ❖ accountability around these interactions is not structured or transparent within our academic or professional community;
- ❖ consequences for non-adherence have yet to be established. The College of Physicians and Surgeons of Ontario (CPSO) advised us that while there have been occasional complaints to them about physician violation of the guidelines generated by the Canadian Medical Association and approved by the CPSO, these have never reached the level of the Discipline Committee.

The Department convened a Faculty Development Half Day on interactions with industry in September 2002 that was extremely well attended. We learned, not surprisingly, of a divergence of views within our faculty regarding such interactions, as well as a lack of

familiarity with existing guidelines that theoretically govern all physicians. In the next section of this report, we reflect upon the mission, values and principles of our department in relation to interactions with the pharmaceutical industry.

### **Mission, Values and Principles**

The Department of Psychiatry has as its mission the provision of educational programs, the promotion of research activities, and the delivery of clinical care. The Department is part of the Faculty of Medicine at the University of Toronto and also recognizes its important role in a broader society.

With regard to education, the Department values pedagogical excellence. Several key principles follow. Students and residents must be provided with education regarding the principles of conflict of interest, as is mandated by the Faculty of Medicine. Education must also be provided about the role of industry broadly – research, marketing and ethics. It is essential that faculty members model ideal conduct in this area for residents and students. There should be reasonable regulation during training of interactions by students and residents with industry. Evaluation of attitudes among students, residents and faculty members regarding interaction with industry should be gauged regularly. When industry-sponsored teaching does occur, careful consideration must be given as to whether such teaching is filling a void in our own curriculum.

In the area of research we are committed to scientific achievement. This means that investigator autonomy must be maintained as outlined by Faculty of Medicine requirements for participation in research. Scientific objectivity must be ensured according to the principles and processes of ethics review. In relation to industry, product promotion must be avoided in the dissemination of research findings, adherence to ethical standards must be maintained at all times, and, in presenting research findings, faculty members must disclose all industry affiliations.

We are committed to the highest standards of clinical care. This requires that we ensure that all of our clinical activities promote good and minimize harm. Each faculty member and resident needs to reflect upon the potential impact of interactions with industry on his/her primary responsibility to care for patients. It is recognized that industry may provide opportunities for beneficial partnerships in enhancing clinical care, but which may carry ethical challenges, which must be considered carefully. Patients should be made aware that faculty members may have a professional relationship with industry and consent for participation by patients in industry-related activities must be informed, capable and voluntary as outlined in the Health Care Consent Act.

As a University department, we are committed to academic freedom. This requires recognizing and addressing potential and real conflicts of interest, insisting on proper contracts, protecting intellectual property and adhering to the highest standards of objectivity and reliance upon sound evidence. Academic freedom also requires the promotion of a departmental culture that facilitates free discussion and debate in relation to all aspects of our relation to industry.

We also are committed to social responsibility and responsiveness. This requires awareness of both perceived and real conflicts of interest as reflected by the media and social critics. It also entails the avoidance of excessive remuneration and/or benefits in various relationships with industry that are likely to create real or perceived conflicts of interest. Protection of the reputation of the profession and the University is essential and requires every faculty member, student and/or resident to reflect upon the implications of his/her activities for the profession and/or University as a whole. Finally, there must be a commitment to the reporting of unacceptable practices so as to enable regulatory and other responsible groups to enforce appropriate standards.

All physicians must consider the implications for their primary obligation in the provision of care for their patients, as well as for trust and the therapeutic alliance, of interactions with industry. Psychiatry may best meet the complex needs of its patients through a variety of collaborations – with patients’ families and friends, with multidisciplinary colleagues, with government, with the employment sector, and with other groups. Industry may provide opportunities for beneficial partnerships in enhancing clinical care. All of these collaborations carry ethical challenges that must be confronted individually.

The above statements of mission, values and principles serve as a framework for the recommendations outlined in the next section of this report.

## **Recommendations**

### **A. *Education***

1. Formal teaching on conflict of interest will be introduced into the core curriculum for residents. This will be led by the bioethicist of the Centre for Addiction and Mental Health together with other Faculty members with interest and expertise in the area and is mandated by the Faculty of Medicine in its education guidelines.
2. The development of simulated encounters with pharmaceutical company representatives for training residents in understanding marketing and detecting bias will be explored. There is evidence of effectiveness of this teaching intervention in the academic literature. This will be an opportunity for academic collaboration with the Faculty of Pharmacy, which has a similar interest in this area.
3. Exploration also will begin with the Faculty of Pharmacy of local replication of the province-wide “academic detailing” project in Nova Scotia. Academic detailing involves the use of University faculty to provide new drug information to community-based physicians in their offices.
4. Faculty development will be undertaken through dissemination of this report, dissemination of CMA guidelines, and devotion of one educational event/year/teaching hospital to an element of this interaction.
5. Faculty/resident discussion of these issues will be promoted at each teaching hospital. This may occur through a variety of formats, ranging from individual supervision to seminars and rounds.
6. Sponsorship of speakers and their topics selected by industry will be prohibited. Industry may contribute to centralized funds at the academic health sciences centres and the Department of Psychiatry to support teaching activities where our faculty and residents exclusively select the speakers and topic areas. Support of industry will be acknowledged appropriately as well as the arm’s length nature of the support. Support from multiple sources is preferred. When a potential external speaker is in Toronto in the context of industry sponsorship, the invitation to the speaker from an academic health sciences centre or the Department of Psychiatry must occur directly between those parties and must include the following requirements:
  - a. there must be no industry honorarium for the presentation;
  - b. the presence of industry representatives or promotional material at the presentation is prohibited;
  - c. the content of the presentation must not be promotional;
  - d. disclosure statements will be required as per A8.

At the end of the academic year, each academic health sciences centre and University program will provide through its Psychiatrist-in-Chief or Program

Head an accounting of industry-sponsored educational activities to the Chair. There will be no product marketing or displays at rounds, seminars and special lectures and the presence of industry marketing/sales representatives is prohibited at internal academic events. Formal conferences with industry sponsorship may, as per the University of Toronto Faculty of Medicine continuing education guidelines, include industry booths where these are physically separate from the area where education is being provided.

7. Sponsorship of retreats for faculty and residents by industry is prohibited.
8. Speakers at teaching hospital Grand Rounds and seminars should provide disclosure statements at the outset regarding potential conflict of interest with the subject matter (e.g., honoraria, consultancies, advisory boards).
9. It is sometimes argued that industry-sponsored events fill gaps in the curriculum for our students, residents, and Faculty. Given their popularity, the appropriate Departmental curriculum committee should examine their content and determine whether these events indeed fill a void in our undergraduate, postgraduate and continuing education curricula in order to develop balanced and valued alternatives.
10. With regard to educational events targeted specifically to our residents and/or faculty and consistent with University requirements, our faculty members may not receive honoraria specifically for such teaching within our academic community.
11. Direct individual sponsorship (i.e., covering travel costs, registration, hotels, and meals) by industry of individual residents and faculty (other than faculty speaking at industry-sponsored symposia) to attend local, national and international conferences (such as the Canadian Psychiatric Association and American Psychiatric Association annual meetings) is prohibited. Industry-sponsored travel awards for residents and fellows, awarded competitively through a process determined and controlled entirely by the Department of Psychiatry, will be allowed. However, these travel awards must be consistent with the ethos of this document.

**B. *Research***

1. Each Psychiatrist-in-Chief of a teaching hospital shall report annually to the Vice-Chair, Research on total research funding and the proportions that reflect industry and other non-peer-reviewed support versus peer-reviewed funding.
2. The presentation of research findings at the hospital or Departmental level (including Research Day) should include disclosure of potential conflict of interest as would be required at some scientific meetings and in peer-reviewed publications.

3. Faculty must bring any request from industry to participate in post-marketing surveillance studies to the attention of the individual responsible for research in his/her teaching hospital for ethical and research evaluation.
4. All faculty and residents conducting research will read, consider and adhere to the Tricouncil Policy Statement (TCPS) governing the ethical conduct of research, and will also adhere to policies promulgated by the University, the Faculty of Medicine and /or individual teaching hospitals. The goal of this is the protection of human subjects, investigator autonomy, and academic freedom.

**C**     *Clinical Care*

1. Faculty and residents must read, consider and adhere to the guidelines of the Canadian Medical Association that govern this interaction for all Canadian physicians. The Chair of the Department will ensure this set of guidelines is distributed annually electronically to all residents and faculty.
2. Physicians should disclose to their patients any significant conflicts of interest in recommending a treatment. This will require personal judgment but some examples include holding a patent or significant financial interest (e.g., stock market shares, ownership in a technology or company providing the treatment) or recruiting subjects for a study in which the physician is also an investigator.

**D.**     *The University*

1. All physicians holding University appointments shall disclose annually to their Psychiatrist-in-Chief and University Program/Division Head potential sources of conflict of interest related to industry (honoraria, consultancies, advisory boards). This information will also be available to the Chair. It will allow determination of the nature and extent of this interaction as well as provide an opportunity for discussion in the context of performance appraisal. All Program/Division Heads and hospital Chiefs shall disclose their own potential sources of conflict of interest related to industry to the Chair of the Department of Psychiatry. The Chair of the Department shall disclose his/her own potential conflicts of interest to the Dean of the Faculty of Medicine.
2. Faculty members invited to participate in industry-sponsored events as organizers or speakers must ensure that the purpose of the event is not primarily promotional. Faculty members should satisfy themselves that the event is primarily educational and that the content is scientifically valid and objective. Consistent with the guidelines of the Canadian Medical Association (CMA), generic rather than trade names of drugs should be used where appropriate. Faculty members should not engage in peer selling, as defined in the CMA guidelines.

3. The Department shall establish a sub-committee of the Senior Advisory Committee to both consider and monitor issues related to interaction with industry on an ongoing basis and to report annually to the Senior Advisory Committee. This committee shall include representation from education and research as well as residents and Fellows.
4. Academic trust funds shall include appropriate weighting mechanisms for the acknowledgement of industry-sponsored research grants that reflect intellectual contribution to the design and/or analysis. A research grant sponsored by industry will be rewarded only if the applicant can demonstrate that he/she has made a contribution to the scientific aspects of the study.
5. The Promotions Committee of the Department will consider only industry-sponsored grants that reflect significant intellectual contribution to the scientific aspects of the study by the applicant.
6. The Department supports the position that all gifts from industry directly to individual faculty and residents, regardless of financial value, should be prohibited. This prohibition exceeds the restrictions recommended in the guidelines of the Canadian Medical Association but reflects recent advocacy as well as research challenging the belief that gifts of minimal value have no influence on physician behaviour. With regard to medication samples for patient use, faculty must adhere to the rules of the Canadian Medical Association in this regard as well as the requirements of their hospitals regarding acceptance and safe storage of samples.
7. Following acceptance and promulgation of this report, the Department will regularly survey its Faculty and students to gauge attitudes related to this issue as well as to evaluate the content and impact of these recommendations.
8. Contributions to the University in the form of endowments from industry (e.g., endowed chairs) must be consistent with the University of Toronto guidelines and supported by clear memoranda of agreement. All such endowments will be subject to internal review by the subcommittee on industry interactions to advise the Chair of the Department.
9. The issue of adherence to these guidelines should be a component of annual performance appraisal as well as promotion, and concerns in that regard should be directed to the subcommittee on industry interactions to advise the Chair of the Department.

**E. *Society***

1. Faculty members involved in relationships with industry should accept remuneration and/or benefits that are commensurate with regular professional fees and/or benefits. Fees and/or benefits substantially in excess of regular



professional earnings are most likely to create real or perceived conflicts of interest.

2. In undertaking activities in association with industry, physicians must feel assured that public disclosure of such activities would not result in any harm to personal, professional or university reputation.
3. Faculty members, students or residents who have concerns about academic or professional activities in relation to industry should bring these concerns to the attention of the sub-committee described in section D2 of this report.

### Future Directions

This will be a living document, responsive to feedback as well as the changing climate of science, the University, and society.

# **APPENDIX I**

## **TERMS OF REFERENCE**

### **Membership**

David Goldbloom, Physician-in-Chief, CAMH, (Chair)  
Sidney Kennedy, Psychiatrist-in-Chief, UHN  
Anthony Levitt, Psychiatrist-in-Chief, SWCHSC  
Allan Kaplan, Director, Postgraduate Education, Department of Psychiatry  
Trevor Young, Head, Mood Disorders Program, Department of Psychiatry  
Gary Remington, Deputy Clinical Director, Education, Schizophrenia Program, CAMH  
Padraig Darby, Co-Chair, Research Ethics Committee, CAMH/Department of Psychiatry  
Susan Abbey, Chair, Continuing Professional Development Committee, Canadian  
Psychiatric Association  
Sagar Parikh, Head, General Psychiatry Division; CME Director, CAMH  
Brian Hodges, Vice Chair, Education, Department of Psychiatry  
Don Wasylenki, Chair, Department of Psychiatry (*ex officio*)  
PRAT representatives: Justin Geagea and Kevin Chopra, Residents in Psychiatry

### **Reporting**

To the Executive Committee, Department of Psychiatry

### **Scheduling**

At the call of the Chair

### **Mandate**

1. To review existing guidelines that govern interaction with industry.
2. To consider formal adoption of existing guidelines versus creation of modified guidelines for the Department of Psychiatry staff, residents, and students.
3. To develop an education mandate related to interaction with industry for staff, residents and students.
4. To consider monitoring and complaint mechanisms
5. To consider enforcement and consequence mechanisms related to guideline adherence.
6. To complete a final report by the end of the academic year 2002-2003.

## **APPENDIX II**

### **WORK OF THE TASK FORCE**

#### **November 2002**

The committee first met, considered its terms of reference and membership, and debated its mandate. It was agreed that our deliberations would not include formal research interactions with industry as that was receiving separate scrutiny by the Faculty of Medicine for all its faculty and academic health sciences centres. We reviewed existing guidelines on industry interaction from the Faculty of Medicine, the Canadian Medical Association, and multiple other professional and industry organizations. We agreed to generate multiple “real-life” scenarios of interaction to look at the applicability of the guidelines. Other identified issues included the apparently growing participation of the faculty in industry-sponsored symposia at professional meetings where promotional and educational mandates co-exist. The role of psychiatrists as consultants and/or advisory board members to industry raised additional challenges. Relevant peer-reviewed literature addressing the issue of interactions with industry was circulated (see reference list).

#### **December 2002**

We reviewed over 20 scenarios generated by members of the committee that included educational, business, and personal interactions with industry. The CMA guidelines were considered “the floor” for governing our behaviour in relation to these since we are already obliged to adhere to those. Whether we would apply a higher standard than those guidelines was the subject of some discussion. Because the issue of industry-sponsored educational symposia at the Canadian and American Psychiatric Association annual meetings had been a focus of concern, we discussed the CPA credentialing process of these in some detail. All of the slide material must be pre-submitted to CPA and approved for lack of scientific bias by an independent auditor picked by the CPA; there is a substantial fee charged to industry for this requirement to achieve Maintenance of Certification eligibility, and the CPA is one of only two Canadian medical specialty organizations that insists on this credentialing for its annual meeting. In addition, delegates from the CPA attend the actual symposium to scrutinize the presentations for adherence to the submissions and for bias. However, the dependency of CPA and other medical specialty organizations on the revenues from industry for permission to hold these symposia at the annual meeting was also acknowledged. We also reviewed the Faculty of Medicine guidelines from the University of Toronto and recognized that our Department was not adhering to the requirement that teaching about conflict of interest be an essential component of our core curriculum for residents.

## **January 2003**

Gordon DuVal, Bioethicist at the Centre for Addiction and Mental Health, gave a presentation on conflict of interest and led a discussion. The residents emphasized that the perception of the faculty as pushing the limits of or violating the guidelines was a major issue of concern in terms of modeling behaviour. This led to a discussion of both disclosure and prohibition. It was felt that disclosure by faculty of interactions with industry to both the Psychiatrist-in-Chief of the relevant academic health sciences centre as well as to the relevant University Program Head in terms of honoraria, consultancies and advisory boards was an important first step in accountability and transparency – and no different than what is required for academic participation in peer-reviewed literature and scientific meetings. It was noted that neither the academic trust funds in teaching hospitals nor the Promotions Committee at the Department gave much credit to participation in industry-sponsored clinical trials that did not involve our faculty in either design or analysis. As for prohibition, it was felt that there should be rules for the sponsorship of in-hospital rounds and seminars. A radical approach was suggested of a one-year moratorium on any interactions whatsoever with industry in the teaching hospitals – no individual contacts with pharmaceutical representatives, no sponsored presentations, and no attendance at or presentations by our faculty by industry sponsored events. It was pointed out that this well exceeded the existing guidelines where we still do not have compliance. It was conceded that peer pressure among academic colleagues was likely to have the greatest leverage. The scenarios were amended to include not only the CMA and Canadian industry guidelines in response to each individual scenario but also the American College of Physicians guidelines, which appear to be the most detailed and research-based.



Adobe Acrobat  
Document

## **April 2003**

The task force held its final meeting in an effort to generate the foundations of a final report. Divergent views remained among colleagues and likely reflected a range of legitimate views among residents and faculty on an issue that continues to challenge our profession. Despite this, there was consensus that:

Conflict of interest is ubiquitous in our profession and not limited to our relations with the pharmaceutical industry

Perception of conflict of interest is as large a challenge as the reality of it

Given the ubiquity of conflict of interest, the goal is not absolute avoidance but rather education, acknowledgement, and regulation

There are potential benefits both to our profession and to industry in our interaction that relate to improving care, education and research; there are also risks to our professional

integrity, to the trust we hold with our patients, students, and colleagues, and to our goals as a University Department.

**October 2003**

The Task Force, based on extensive input from the bioethicist at the Centre for Addiction and Mental Health and by the Executive Committee of the Department of Psychiatry, made further revisions to the document in preparation for its presentation to the Senior Advisory Committee of the Department.

## APPENDIX III

### SCENARIOS REGARDING INTERACTION WITH INDUSTRY

Responses based on CMA Policy on Physicians and the Pharmaceutical Industry  
(2001) in blue - {⌚}

Responses based on Code of Marketing Practices of Canada's Research-Based  
Pharmaceutical Companies (revised 2003) in red - {📄}

Responses based the American College of Physicians Position Paper on Physician-  
Industry Relations (2002) in purple - {🔔}

Additional commentary by Task Force (2003) in green - {🕒}

### EDUCATION EVENTS

**1.0 A pharmaceutical company sends an invitation for a weekend at a resort. There are 4 hours of talks Saturday morning by Ontario psychiatrists and the rest of the weekend is free. "It's just a chance for people to get away and have a little treat."**

{⌚}-24. Travel and accommodation arrangements, social events and venues for 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 part of a conference or meeting.

{📄}-4A.3.4 Social functions which are part of a Continuing Health Education (CHE) program may enhance the learning process. However, such functions must not compete with or seem more important than the educational aspect of the program. In fact, social functions should be set up so participants have a chance to reflect on and discuss their learning experience. The CHE partners who sponsor a CHE program will share responsibility for deciding what is appropriate when it comes to social functions. The use of good judgment will ensure that educational content is the primary focus of the CHE program. The costs for social events (other than meals) must be paid for by the participants.

{📖}-4A.3.5 Grants and honoraria may be provided to healthcare practitioners who speak at or moderate CHE programs. Such grants and/or honoraria do not apply to other healthcare practitioners attending the program or to the spouses or family members of those attending the program.

{📖}-4A.3.7 For events that have not been accredited, or which do not meet the principles of adult learning described in section 4A.2.3, but which involve the presentation of medical/scientific information, organizers must conform to the spirit of Section 4 and, in particular, must adhere to Sections 4A.3.4 and 4A.3.5.

{🔔}-Generally acceptable industry gifts include modest hospitality (such as a reception or other food and drink) that is connected with a legitimate educational program.

2.0 **A pharmaceutical company invites you to an event at a luxury spa in the US to "join with your US colleagues" to learn about their new and improved drug which is in fact a tweaking of their old, soon-to-go-off patent drug.**

{🕒}-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.

{📖}-4A.2. Rx and D members are committed to separating CHE from other types of activities. CHE programs must be accredited or they must meet the principles for CHE described in section 4.2.3. Only those programs that meet and follow these criteria are considered CHE events under this code.

{📖}-4a.2.1 CHE consists of those educational programs which serve to maintain, develop, or increase the knowledge, skills, and competence which a healthcare practitioner uses to provide care to patients, or service to the professions.

{📖}-4A.2.2 The content of CHE programs must reflect that body of knowledge and skills which is accepted by the professions as constituting the basic health sciences, clinical sciences, and clinical practice of the profession.

{📖}-4A2.3 A CHE program must adhere to the following principles of adult learning:

- A learning needs assessment must be conducted;
- A member of the target audience must help to design and develop the program;
- Clear learning objectives must be identified based on the needs assessment and the objectives must be reflected in the program;

- The program must be interactive;
- A final evaluation which outlines how the learning objectives were achieved must be conducted.

If these five principles are not met, the program cannot be promoted as “educational”.

{🍷}-4A.3.4 Social functions which are part of a Continuing Health Education (CHE) program may enhance the learning process. However, such functions must not compete with or seem more important than the educational aspect of the program. In fact, social functions should be set up so participants have a chance to reflect on and discuss their learning experience. The CHE partners who sponsor a CHE program will share responsibility for deciding what is appropriate when it comes to social functions. The use of good judgment will ensure that educational content is the primary focus of the CHE program. The costs for social events (other than meals) must be paid for by the participants.

{👤}-4A.3.5 Grants and honoraria may be provided to healthcare practitioners who speak at or moderate CHE programs. Such grants and/or honoraria do not apply to other healthcare practitioners attending the program or to the spouses or family members of those attending the program.

{📖}-4A.3.7 For events that have not been accredited, or which do not meet the principles of adult learning described in section 4A.2.3, but which involve the presentation of medical/scientific information, organizers must conform to the spirit of Section 4 and, in particular, must adhere to Sections 4A.3.4 and 4A.3.5.

{🍷}-Generally acceptable industry gifts include modest hospitality (such as a reception or other food and drink) that is connected with a legitimate educational program.

{⌚}-24. Travel and accommodation arrangements, social events and venues for 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 part of a conference or meeting.

**3.0 A pharmaceutical company wants your advice on speakers to include in an event that they are organizing for residents apart from the U of T program "because we can never get contact with them and we want to get to know them".**



{⌚}-34. These guidelines apply to physicians-in-training as well as to practicing physicians.

{⌚}-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.

{📄}-6.1 Companies must never pay a fee or make a donation in order to have access to a healthcare practitioner.

{🔔}-Physicians should be circumspect if asked to deliver educational programming developed by a medical education and communication company. Such companies, which are largely financed through the pharmaceutical industry, are for-profit developers and vendors of continuing medical education. It is important that physicians retained as lecturers in such settings control the content of the educational modules they deliver rather than allow their presentations to be scripted by the company.

{🔔}-Faculty, deans and program directors should promote sensitivity to potential biases by providing specific education to help their students, physician trainees, and medical fellows evaluate industry-provided information.

{🔔}-For education and sensitivity training to be successful, however, faculty must act as positive role models. Chief residents and medical school faculty members should set ethical examples to students by conducting their relationships with industry in a highly principled manner and disclosing their own commercial ties.

{🔔}-It is unethical for academic institutions and educational organizations to accept any support that is explicitly or implicitly conditioned on industry's opportunity to influence the selection of instructors, speakers, invitees, topics, or content and materials of educational sessions. To reflect this position, medical education providers should adopt and enforce specific organizational policies about acceptable and unacceptable interactions with industry.

**4.0 You are invited to a weekend workshop at a resort paid for by a pharmaceutical company, with spouse/family.**

{⌚}-24. Travel and accommodation arrangements, social events and venues for 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 part of a conference or meeting. However, faculty at CME/CPD events may accept reasonable honoraria and reimbursement for travel, lodging and meal expenses.

{⚖}-The CMA guidelines (as opposed to industry) are silent on spouses/partners/children – but why would they be allowed things that attendee physicians are not?

{👉}-4A.3.5 Grants and honoraria may be provided to healthcare practitioners who speak at or moderate CHE programs. Such grants and/or honoraria do not apply to other healthcare practitioners attending the program or to the spouses or family members of those attending the program.

{🔔}-Physicians frequently do not recognize that their decisions have been affected by commercial gifts and services and in fact deny industry's influence, even when such enticements as all-expenses paid trips to luxury resorts are provided. Research, however, shows a strong correlation between receiving industry benefits and favouring their products.

**5.0 A pharmaceutical company invites you to a dinner talk at a very expensive restaurant.**

{⌚}-24. Travel and accommodation arrangements, social events and venues for 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 part of a conference or meeting.

{⚖}-The policy refers to “modest meals.” Think public perception of modesty.

{👉}-4A.3.4 Social functions which are part of a Continuing Health Education (CHE) program may enhance the learning process. However, such functions must not compete with or seem more important than the educational aspect of the program. In fact, social functions should be set up so participants have a chance to reflect on and discuss their learning experience. The CHE partners who sponsor a

CHE program will share responsibility for deciding what is appropriate when it comes to social functions. The use of good judgment will ensure that educational content is the primary focus of the CHE program. The costs for social events (other than meals) must be paid for by the participants.

{🍷}-7.1 Social interaction, including hospitality and entertainment, is part of doing business in the world today. When member companies provide entertainment or other forms of hospitality outside the scope of educational events, the kind of entertainment or hospitality should be appropriate and reasonable. Its costs should not exceed that which the guests would normally expect to pay for similar entertainment. In deciding what form of entertainment should be offered, member companies should think about the impression that will be left in the minds of both guests and others who may learn about the event or activity.

## 6.0 A pharmaceutical company asks you to participate in a satellite symposium at a professional meeting.

{🕒}-24. Travel and accommodation arrangements, social events and venues for 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 part of a conference or meeting.

{🕒}-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.

{🕒}-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. 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 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.

{☞}-4A.2. Rx and D members are committed to separating CHE from other types of activities. CHE programs must be accredited or they must meet the principles for CHE described in section 4.2.3. Only those programs that meet and follow these criteria are considered CHE events under this code.

{☞}-4a.2.1 CHE consists of those educational programs which serve to maintain, develop, or increase the knowledge, skills, and competence which a healthcare practitioner uses to provide care to patients, or service to the professions.

{☞}-4A.2.2 The content of CHE programs must reflect that body of knowledge and skills which is accepted by the professions as constituting the basic health sciences, clinical sciences, and clinical practice of the profession.

{☞}-4A2.3 A CHE program must adhere to the following principles of adult learning:

- A learning needs assessment must be conducted
- A member of the target audience must help to design and develop the program
- Clear learning objectives must be identified based on the needs assessment and the objectives must be reflected in the program
- The program must be interactive
- A final evaluation which outlines how the learning objectives were achieved must be conducted

If these five principles are not met, the program cannot be promoted as “educational.”

{☞}-4A.3.4 Social functions which are part of a Continuing Health Education (CHE) program may enhance the learning process. However, such functions must not compete with or seem more important than the educational aspect of the program. In fact, social functions should be set up so participants have a chance to reflect on and discuss their learning experience. The CHE partners who sponsor a CHE program will share responsibility for deciding what is appropriate when it comes to social functions. The use of good judgment will ensure that educational content is the primary focus of the CHE program. The costs for social events (other than meals) must be paid for by the participants.

{☞}-4A.3.5 Grants and honoraria may be provided to healthcare practitioners who speak at or moderate CHE programs. Such grants and/or honoraria do not

apply to other healthcare practitioners attending the program or to the spouses or family members of those attending the program.

{📖}-4A.3.7 For events that have not been accredited, or which do not meet the principles of adult learning described in section 4A.2.3, but which involve the presentation of medical/scientific information, organizers must conform to the spirit of Section 4 and, in particular, must adhere to Sections 4A.3.4 and 4A.3.5.

**7.0 A pharmaceutical company offers you travel and accommodation costs to attend a professional meeting.**

{⌚}-24. Travel and accommodation arrangements, social events and venues for 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 part of a conference or meeting.

{📖}-4A.3.5 Grants and honoraria may be provided to healthcare practitioners who speak at or moderate CHE programs. Such grants and/or honoraria do not apply to other healthcare practitioners attending the program or to the spouses or family members of those attending the program.

**8.0 A pharmaceutical company offers to sponsor grand rounds.**

{⌚}-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.

**9.0 Residents are sent an email by a faculty member inviting them to a talk on "Advances in the treatment of bipolar disorder" at a university hospital. On arrival, the residents see a room full of food, with two drug reps. The real title of the talk is flashed up, "Olanzapine and bipolar disorder."**

{⌚}-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.

{⌚}-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.

{⌚}-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. 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 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.

**10. A pharmaceutical company wishes to sponsor an invited speaker.**

{⌚}-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.

{⌚}-21. All funds from a commercial source should be in the form of an unrestricted educational grant payable to the institution or the 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.

**11. Pharmaceutical companies wish to sponsor other educational events.**

{⌚}-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.

{⌚}-21. All funds from a commercial source should be in the form of an unrestricted educational grant payable to the institution or the 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.

**12. Your psychotherapy supervisor is very pleased with the work you are doing. One day, you tell him/her you will be attending a conference. Your supervisor states that he/she will attempt to get some industry funding funneled through the appropriate channels to allow for your trip to be significantly subsidized.**

{⌚}-24....Scholarships and other special funds to permit medical students, residents and fellows to attend educational events are permissible as long as the selection of the recipients of these funds is made by their academic institution.

**13. The marketing arm of a pharmaceutical company in consultation with the CME provider company requests that material included in an academic presentation be removed or material not originally included be added.**

{⌚}-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.

14. **The Research and Development arm of a pharmaceutical company has provided material for a scientific presentation about a compound that is in early drug development. The physician presenter wishes to “oversell” the clinical potential for this compound, while the pharmaceutical company wishes to maintain a cautious and scientific approach, which can sometimes go against the wishes of their own marketing organization.**

{⌘}-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. 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 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.

15. **A psychotherapy treatment has been languishing for more than a decade as a relatively unknown modification of cognitive behavioural therapy. Its adoption into a large multi-centre comparative clinical trial developed by a single pharmaceutical sponsor results in a favourable outcome for the psychotherapy which is delivered under conditions of meticulous research rigor. The treatment has now attained international recognition. Workshops have been held across major North American centres including Toronto.**

{⌘}-A treatment that has been demonstrated to be efficacious (as opposed to effective) in research that, regardless of funding source, has been approved by an ethics committee and published in the peer-reviewed literature) is legitimate fodder for knowledge transfer.



## GIFTS AND MATERIALS

### 1.0 A pharmaceutical representative offers to supply you with free 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.

{🔔}-Drug samples may be characterized as “gifts”. Because physicians can distribute such medications to patients at no apparent cost, the practice may seem to promote the profession’s core principle of equitable access and justice in health care. The practice does allow the patient to try out a new medication before being committed to an expense. However, the sample mainly serves to encourage physicians to prescribe the new product. Research shows that once a patient exhausts a free supply of medication, the physician typically writes a prescription for the same brand. Because few samples are for older or less expensive products, higher patient costs generally result. Moreover, physicians and their families and staff use approximately one third of the samples, which illustrates how the practice fosters access to physicians’ offices and encourages a gift relationship.

### 2.0 A pharmaceutical representative offers to supply educational material for a waiting area.

{⌚}-33. Practicing 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).

{📦}-11. SERVICE-ORIENTED ITEMS {🔔}-(the term “Gifts” does not appear in this code of marketing practices)

General principle: Member companies must not distribute service-oriented items or conduct “special promotions,” which cannot be justified if subjected to scrutiny by members of the health professions and the public.

{📦}-11.2 Acceptable service-oriented items are defined as those items whose primary goal is to enhance the practitioner’s/patient’s understanding of a condition or its treatment.

{🔔}-It is understandable that, in a busy practice, physicians would welcome industry’s materials and technologies to keep themselves and their patients current with the latest developments in the medical field. Physicians must keep in mind,

however, that industry-supported medical information, although neutrally packaged, is in fact promotional.

**3.0 A pharmaceutical representative offers to provide subsidized internet access to information and/or software.**

{⌚}-32. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies.

**4.0 A pharmaceutical representative invites you to play golf with him/her free of charge.**

{⌚}-32. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies.

**5.0 A pharmaceutical representative offers you tickets to sporting or entertainment events with or without dinner with or without a talk.**

{⌚}-32. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies.

{⌚}-24.... Subsidies for hospitality should not be accepted outside of modest meals or social events that are part of a conference or meeting.

**7. ENTERTAINMENT (PROMOTIONAL ACTIVITIES) - {⌚}-Note that entertainment is viewed by industry as a promotional activity.**

{🎪}-Social interaction, including hospitality and entertainment, is a part of doing business in the world today.

{🎪}-When the member companies provide entertainment or other forms of hospitality {⌚}-(outside the scope of educational events), {🎪}-the kind of entertainment or hospitality should be appropriate or reasonable. Its cost should not exceed that which guests would normally expect to pay for similar entertainment. In thinking about what forms of entertainment should be offered, member companies should think about the impression that will be left in the minds of both guests and others who may learn about the event or activity.

**6.0 A pharmaceutical company offers residents a free meal with or without a talk.**

{⌚}-24 Subsidies for hospitality should not be accepted outside of modest meals or social events that are part of a conference or meeting.

{⌚}-32. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies

{⌚}-34. These guidelines apply to physicians-in-training as well as to practicing physicians.

## 7.0 A pharmaceutical representative offers you a gift.

{⌚}-32. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies

{🔔}-Physicians do not always agree about the appropriateness of gifts. Ideally, physicians should not accept any promotional gifts or amenities, whatever their value or utility, if they have the potential to cloud professional judgment and compromise patient care. As a practical matter, many physicians are comfortable with limiting their acceptance of gifts to items that enhance medical practice or knowledge and that are of modest value. Differences in opinion will undoubtedly arise because of the ways in which an item or service is valued in different practice environments and communities.

{🔔}-Nonetheless, debates are important because they remind physicians of the need to gauge regularly whether a gift relationship is ethically appropriate.

{🔔}-The inherent difficulty in defining what makes a gift appropriate has, to an extent, contributed to lapses in judgment by otherwise ethical persons. It is difficult to set with any precision a monetary value that would render a gift unacceptable. There is no consensus model for determining relative value, and one will not be recommended here. Instead, some specific guidance is offered in the following examples of generally acceptable industry gifts: inexpensive gifts for office use (such as pens and calendars), low-cost gifts of an educational or patient care nature (such as medical books), and modest hospitality (such as a reception or other food or drink) that is connected with a legitimate educational program.

## 8.0 A pharmaceutical company offers to sponsor a resident retreat.

{⌚}-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 the 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.

{⌚}-30. Practicing 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. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies

{⌚}-34. These guidelines apply to physicians-in-training as well as to practicing physicians.

**9.0 A pharmaceutical company wishes to endow a Chair in the Department of Psychiatry.**

{⌚}-These are organizational/institutional ethics issues rather than individual physician ethics issues and are not addressed by the CMA policy. Nevertheless, our Department has already established a precedent of returning endowments to donors for Chairs when the donors sought to violate the required arm's length relationship regarding the selection of a Chair and his/her academic activities in that role.

**PROFESSIONAL NON-TEACHING INTERACTION**

**1.0 You are asked to appear as a witness for a pharmaceutical company in a law suit.**

{⌚}-3. The practicing 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.

{⌚}-30. Practicing physicians affiliated with pharmaceutical companies should not allow their affiliation to influence their medical practice inappropriately.

**2.0 You are asked to consult to an independent third party (Friends of Schizophrenia; Mood Disorders Association) when their funding for that project comes from industry.**

{⌚}-3. The practicing 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.

{⌚}-30. Practicing physicians affiliated with pharmaceutical companies should not allow their affiliation to influence their medical practice inappropriately.

### 3.0 You are asked to consult to a pharmaceutical company.

Under the category of 'consulting' to industry, there are several levels--consulting on a study design, teaching industry staff themselves, as well as serving on an advisory board. Under the teaching industry staff, you may recall that the Clarke had a policy for teaching sales reps, etc approved through the MAC /Pharmacy and Therapeutics committee, to allow patients to be involved in the teaching of pharmaceutical employees and others. (Perhaps we were too expensive, since as far as I know, we haven't done that at CAMH for the past couple of years!).

{⌚}-3. The practicing 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.

{⌚}-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.

{⌚}-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.

{⌚}-30. Practicing physicians affiliated with pharmaceutical companies should not allow their affiliation to influence their medical practice inappropriately.

## 13. ADVISORY BOARDS/CONSULTANTS

{📖}-13.1 General Principle: It is recognized that Rx and D members will seek advice and guidance from healthcare practitioners in the conduct of various aspects of their business. On such occasions, healthcare practitioners assume the role of a consultant providing advice, knowledge, expertise and services to the company.

{📖}-13.2 When entering into such arrangements, Rx and D members must be guided by the following:

- There must be a written contractual agreement outlining the nature of the services to be provided;
- The purpose and objectives of the interaction must be clearly defined by the company in its initial correspondence on the event;
- Remuneration must be in the form of an honorarium. Travel and accommodation expenses, where warranted, should be reimbursed.

**4.0 You are asked to participate on an advisory committee to a pharmaceutical company.**

{⌚}-3. The practicing 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.

{⌚}-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. Practicing physicians affiliated with pharmaceutical companies should not allow their affiliation to influence their medical practice inappropriately.

{📁}-13.1 It is recognized that Rx and D members will seek advice and guidance from healthcare practitioners in the conduct of various aspects of their business. On such occasions, healthcare practitioners assume the role of a consultant providing advice, knowledge, expertise and services to the company.

{📁}-13.2 When entering into such arrangements, Rx and D members must be guided by the following:

- There must be a written contractual agreement outlining the nature of the services to be provided;
- The purpose and objectives of the interaction must be clearly defined by the Company in its initial correspondence on the event;
- Remuneration must be in the form of an honorarium. Travel and accommodation expenses, where warranted, should be reimbursed.

**5.0 You are offered an honorarium to participate in a focus group.**

{⌚}-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.

{📁}-12.1 Market research links the consumer, customer and public to the marketer through information – information that points out and defines marketing

opportunities and problems; information that generates, refines and evaluates marketing programs; information that monitors marketing performance; and information that improves understanding of marketing as a process....This section applies to market research carried out within the framework of various fora , including studies, individual and group interviews, and focus groups.

{📄}-12.2.1 The purpose of an individual or group interview must be made clear to the participant(s). Market research must not be a disguise for selling or developing sales contacts. Nor should it deliberately sway the opinion(s) of the participant(s).

{📄}-12.2.2 Honoraria offered to healthcare practitioners who gather or provide market research information should be based on rates similar to (and not higher than) their usual rate of pay.

{📄}-12.2.3 Even when a consent form is not signed, the confidentiality of participant(s) must be preserved. The identity of the participant(s) must not be revealed for purposes of promoting company products to them in the future.

## **6.0 You are asked to participate in an industry sponsored clinical trial.**

{⌚}-6. A pre-requisite 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.

{⌚}-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.

## **9. POST-REGISTRATION CLINICAL STUDIES**

{📄}-9.2.3 All post-registration clinical studies must have a clearly defined goal, which is amenable to scientific review and testing.

{☞}-9.2.5 Post-registration clinical studies must be carried out in accordance with...the Tri-Council Policy Statement: Ethical Conduct for Research involving Humans.

{☞}-9.2.8 After the data is collected but before the study is published, the researchers and the medical/scientific department of the company must jointly review the scientific evaluation of the data.

{☞}-9.2.9 Researchers' pay must reflect costs incurred in conducting the study, such as practitioner fees, salaries of study staff, laboratory tests. Payment may be in the form of a monetary grant, travel to attend scientific and medical meetings, or equipment, provided the latter is needed for and relevant to the study.

{☞}-9.2.10 Payment to researchers must not be based on continuing administration of the medicine under study to patients after the researcher has completed the study protocol.

**7.0 You are asked to contribute as an author to an industry-sponsored publication such as a monograph or journal supplement.**

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

**8.0 Physicians have attended a working meeting for which their travel and accommodation were covered by the industry sponsor. One physician opts to stay an extra one or two days and insists that this be covered by industry. Industry organizers are under clear instructions that the cost for the time during the meeting is provided and not more, yet they do not wish to "offend" their "esteemed colleague."**

{☞}-32. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies

**9.0 A physician participates in a sporting event that has been arranged after a working meeting. The physician lacks appropriate sports clothing and charges the cost of this clothing to the sponsoring company. This again placed the sponsoring organization in the awkward position of not wishing to offend a "valued client," but there are clear guidelines that this is not an acceptable arrangement.**

{☞}-32. Practicing physicians should not accept personal gifts from the pharmaceutical industry or similar bodies.



## APPENDIX IV

### SELECTED REFERENCES

#### **On-Line Sources of Policy on Industry Interaction**

Canadian Medical Association/College of Physicians and Surgeons of Ontario (2001):  
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Faculty of Medicine, University of Toronto:  
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Accreditation Council on Graduate Medical Education (USA) (2002):  
<http://www.acgme.org/New/GMEGuide.pdf>

The American Medical Student Association (2003): <http://www.amsa.org/prof/policy.cfm>

#### **Clarke Institute of Psychiatry Guidelines for Resident Interactions with Pharmaceutical Companies – March 21, 1994**

While it is recognized that the pharmaceutical industry makes a valid contribution to the development of new treatments and the education of health professions, the market orientation of the pharmaceutical industry can result in ethical conflicts with physicians in training.

The following are meant as guidelines for the interaction of residents and the pharmaceutical industry.

Formal training in critical appraisal of pharmaceutical material and discussions about potential ethical conflicts must be incorporated into the resident teaching program.

Residents should receive specific training in understanding and anticipating potential conflicts that arise from meeting individually with pharmaceutical representatives. Samples of medications are not to be accepted by residents, nor are medications to be kept in offices. Indigent patients can be provided medication by the Institute pharmacy when this is appropriate.

Educational material (slides, videos, presentations, texts) should be pre-approved by the Clarke Resident Education Committee before it can be presented to house staff.

Residents may not accept funds to attend conferences unless they are presenting, or the funds are awarded by the Institute.

Efforts will be made to utilize pharmaceutical donations through Institute educational funds such as – Associates Resident Fund, Grand Rounds Prize, Library Fund, Sponsored Lectureships, for redistribution as prizes, bursaries, conference money, etc. Funds will be awarded at the discretion of Faculty.

These guidelines also included an Educational Material Review form to determine the educational value, accuracy, and promotion/bias of pharmaceutical company-sponsored educational material.

### **Coordinators of Psychiatric Education (COPE) Pharmaceutical Company Sponsored Fellowships Draft Guidelines**

Preamble: Pharmaceutical companies have an interest in sponsoring residents to attend international scientific meetings. This interest is predicated on the belief that supervised attendance at these meetings will facilitate the development of clinical and academic psychiatrists with special expertise in many aspects of psychiatric practice and education.

COPE is a volunteer organization of psychiatric coordinators and resident representatives from each of 16 [Canadian] medical schools. COPE has an interest in facilitating and developing educational opportunities for residents both within and outside of the traditional training program.

COPE, along with various members of the pharmaceutical industry, propose to offer jointly sponsored resident education programs along the following guidelines:

CMA guidelines on the relationship between physicians and industry must be followed.

Independent sponsorship of individual residents by industry is not allowed.

Program themes must be developed with a set of educational goals and objectives.

COPE must approve all program goals and objectives.

Programs must afford equal exposure to each of the biopsychosocial aspects of the topic.

Financial sponsorship must be reasonable and not excessive.

All programs must have clearly identified mentors.

All mentors should be approved of by COPE.

Mentors should be aware of their roles, and may be supported to a reasonable degree by industry.

At least one of the mentors should be a COPE member.

Clear criteria for the selection of residents should be made available to all residents and Program Directors well in advance of the deadlines.

Resident selection should be transparent and based on the above criteria.

All residents, irrespective of program, will be expected to provide a formal summary of their educational accomplishments to residents in their home program on return. In order to facilitate the development of educational opportunities outside of industry interest, yet highly relevant to the practice of psychiatry, industry will be strongly encouraged to contribute an additional \$250.00 per funded resident to a COPE Education Fund that will be used to sponsor other educational pursuits of COPE.

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