GUIDELINES PAPER

HISTORICAL DOCUMENT

Canadian Psychiatric Association Guidelines in Relating to the Pharmaceutical Industry

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This guidelines paper was reviewed and delisted as an official position of the Canadian Psychiatric Association in November 2007. It is being made available for historical purposes only. The paper was originally developed by the Canadian Psychiatric Association's Professional Standards and Practice Council and approved by the CPA's Board of Directors on May 21, 1986.

The pharmaceutical industry and practicing physicians coexist in a state of dynamic tension created by their mutual involvement in the business of treating patients.

This close intertwining of interests and livelihoods is bound to result in genuine misunderstandings and legitimate conflicts of interest. This guidelines paper is an attempt to delineate and further promote an ethical and constructive relationship between psychiatrists and the pharmaceutical industry for the ultimate benefit of the patients we serve.

Components of the dilemma

a) *Advertising and critical thinking*

Concerns regarding the advertising of pharmaceutical products are well stated by Blank (I) who quotes a speech to the Promotion Clinic of the Pharmaceutical Advertising club in 1966 by a specialist in motivational research: ". . . doctors are human beings, . . . medical men are subject to the same kind of stresses. the same emotional influences as affect the layman. Physicians have as part of their self-image a determined feeling that they are rational and logical, particularly in their choice of pharmaceuticals, The advertiser must appeal to this rational self-image and at the same time make a deeper appeal to the emotional factors which really influence sales." In support of this view Parish (2) comments that "it is well to remember that prescription drugs are directed consumer goods, and for this reason, prescribing doctors constitute a market. They are, therefore, subjected to the same factors which affect consumer purchase patterns." Wilson et al. (3) noted that vulnerability to advertising increased with age in the population of general practitioners they studied. These physicians when prescribing, relied increasingly on the pharmaceutical industry as a source of knowledge as time since graduation increased. Relying only on the pharmaceutical industry in this way for Continuing Medical Education is unwise and Wade (4) comments that some doctors appear to be too easily persuaded by drug promotion and may use "the latest drug" despite having little knowledge of the pharmacology and effects. It is worth remembering that the bulk of psychotropic medication is not prescribed by psychiatrists (5-7).

O'Connor (8) draws attention to the need for critical thinking in our relationship with the pharmaceutical industry. He hesitates to contemplate how often the average clinician when reading asks important questions such as: "were both statistical and clinical significance considered in this paper? What kind of study is this that I am reading (randomized clinical, cohort analytic or descriptive study, etc.)?" "Failure to make such a critical effort means the giving up of a crucial professional decision. A doctor who lets someone else decide what is best for his patient has lost a large degree of his professionalism." The best method to learn or maintain the ability to think critically is of course involvement in actual research no matter how simple. Here again, however, there are traps for the unwary: an honorarium to prescribe a brand name drug and simply describe its effectiveness (9) is certainly not rigorous research, yet has the superficial trappings of respectability.

b) *Financial Sponsorship*

In 1980, Woods (10) reminded us that the CMA Journal maintained a ratio of editorial to advertising pages of roughly 55:45 and that without that level of sponsorship the Journal, which is distributed free of charge, would cost each of its 35,000 readers about $40.00 a year. With other journals the figures may vary but this message remains the same. On the other hand, editorial independence of all information media supplied by industry advertising is and must remain staunchly intact.

An evolving phenomenon of the 1980s is the emergence of brief publications (11-14) which scan the literature to present abstracts or editorials on topics of current interest in the psychiatric field, often collecting articles

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on a common theme culled from diverse journals. These publications are distributed free of charge, are supported by educational grants from single pharmaceutical companies and have independent editors.

The financial importance of sponsorship is recognized in other areas like C.M.E. programmes and our own C.P.A. Annual Conference.

c) *Contributions to health care*

Stetler (15), President of the Pharmaceutical Manufacturers Association (1973), in defending the industry, proposed that the medicines reduce the cost of health care by reducing the need for more costly services, reducing mortality and morbidity as well as reducing the patient's discomfort. He also draws attention to studies by Balter and Levine (16) of the N.I.M.H, psychopharmacology research branch which showed that between 1964 and 1970 prescriptions for psychopharmaceuticals increased less than the overall prescription growth rate. He also stated that, in 1971, expenditures per product advertised average out at 49 cents per product per physician (1971) which appears less dramatic than the $3,000.00 per doctor per year quoted at that time by other sources. Finally, he emphasized the service which the industry provides as a source of information about new drugs and cites Coleman et al. (17) who found that detailmen or drug firm mail constituted the physician's first source of information about a new drug 74 per cent of the time. To this one should add the service to physicians (and to the industry) provided by the Compendium of Pharmaceuticals and Specialties (CPS) published yearly by the Canadian Pharmaceutical Association and the sponsoring of the Physicians Reference Manuals. The effectiveness of pharmaceuticals in containing health care costs in Canada has recently been reviewed (18).

d) *Pharmaceutical research pressures*

A thorough look at the activities of the pharmaceutical industry with particular reference to research is provided by Gray (19,20) who draws attention to the haphazard nature of new discovery, and the difficult road to the retail pharmacy; only one in 10,000 new compounds actually makes it all the way to the market. This and other pressures make for a high risk and extremely costly investment and thus increase the pressure to "hard sell." For example, increasingly complex drugs and increasingly stringent safety testing have increased the time lag between discovery and distribution from a few months in the 1950s to a current 10-12 years. This increasing time lag cut into a product's patent life which prior to 1969 in general covered a product for 17 years, but if research and development took about 12 years then the manufacturer had only 5 years to recoup his costs. In 1969, Bill C-102 made revisions to the Patent Act that allowed granting of compulsory licences to import low-cost, generic drugs into Canada and this was soon followed by substitution legislation. Finally came the provincial "formularies" such as Ontario's Parcost with the policy of reimbursement for only the lowest-cost product listed in each category, This has led, Gray states, to the research-based companies pulling resources out of Canada to commercially healthier climes whilst continuing to sell their drugs and make good profits, a situation which leaves us relatively exposed to the market pressures without the apparent compensations of the basic research component of industry.

e) *Contact points*

Our concern now is how does all of this affect our daily professional lives and what if anything can we or should we do about it. The main points of contact between the psychiatrist and the industry are through prescribing procedures, promotional mail, company representatives, professional journals, sponsorship of professional activities and joint research.

Interfacing between the Pharmaceutical Industry and the Psychiatric Profession

a) Ethical responsibility

Physicians must recognize that we are the guardians of our own mortality and of our own professionalism and cannot shift the burden of responsibility for this to regulatory bodies nor to the industry to monitor itself. We must develop and sustain the faculty of critical thinking, and university teaching programmes must not only teach this to our students but should also teach them to be more acutely aware of the marketing techniques which will assail them for the rest of their professional lives, If necessary they should engage experts marketing strategy to teach in pharmacology programmes at undergraduate and post-graduate levels. Awareness of the ethical principles designed by the Pharmaceutical Industry itself regarding drug promotion and marketing practices is equally important (21).

b) Ethics of prescribing

i) Promotions by the pharmaceutical industry include the provision of prescription pads to physicians free of charge and here one must be careful about the wording and its effects. McAdam (22) in an Ontario Medical Association newsletter, drew attention to the fact that some physicians had been provided with prescription pads which contain the directive "NO SUBSTITUTION" as part of the printed format. The use of such prescription pads is strongly discouraged: if a physician wishes a specific product to be dispensed, then he should indicate so by writing "no sub" immediately following the name of the product.

ii) Prescription should be by generic name, not proprietary name and if there are advantages in bio-availability of a particular product then that product should be specified. Foulks (23), points out that a useful guide for physicians is the programme for the quality assessment of drugs (QUAD), operated by the health protection branch of the Department

of National Health and Welfare. By means of spot-check chemical analyses for purity, periodic inspections of manufacturing facilities, quality control procedures and, when important, analyses for bio-availability, this programme attempts to ensure that all approved products meet appropriate standards. QUAD provides a minimum acceptable standard, which brand name manufacturers most often exceed in order to protect their reputation for consistent quality (24).

iii) The choice of a particular brand of medication should never be determined only by the availability of samples.

c) *Pharmaceutical information sources*

These sources should primarily be the scientific literature in pharmacology not promotional literature: however the value of the CPS manual (25), with an independent editorial board, is recognized as a source for brand names of available pharmaceuticals. In this context the Physicians Reference Manuals (25) are recommended as a format through which the Pharmaceutical Industry should inform physicians of its products. The editor being an independent physician should increase the objectivity of the presentation. Much promotion is aimed at the physician in his office but ideally this area should be free from promotional material. No convincing economic case can be made for accepting free prescription pads, note pads, history sheets, calendars, pens, paperweights and the like.

Visits from pharmaceutical company representatives, if encouraged, should be business-like and should include important questions about the study design, identify the investigators and their source of funding, establish whether both statistical and clinical significance were considered and similar questions which would help to establish the reliability of the findings of studies which are used to support promotional statements (27). Pharmaceutical companies should be encouraged to include this information in their promotional mail.

Some teaching hospitals, recognizing the important contribution made by the pharmaceutical industry in providing valuable products for patient care, have established a policy for visits from pharmaceutical company representatives and have developed guidelines for both they and hospital staff to follow, which will shape this relationship appropriately (28). Psychiatrists in private offices similarly need to instruct staff in managing offers of promotional materials.

It should be noted that pharmaceutical company representatives are frequently obliging in responding to requests by psychiatrists to search out and provide reprints of scientific papers.

d) *Ethics of advertising*

It has already been noted that professional journals are supported in large part by advertising revenue and of course control is exercised on advertising copy. The Canadian Journal of Psychiatry along with most other medical journals use the Pharmaceutical Advertising Advisory Board (CCPP) in screening advertisements that appear in these journals and approved advertising carries the logo PAAB/CCPP which certifies that it has met the following general guidelines of the PAAB code of Advertising Acceptance (29):

2.1 All pharmaceutical advertising must be accurate, complete and clear and designed to promote credibility and trust. Statements or illustrations must not mislead.

2.4 Advertising must reflect an attitude of caution with respect to drug usage, with emphasis on *rational drug therapy* (12.1.3). It should provide sufficient information to permit assessment of risk/benefit.

2.5 Advertising which is prejudicial to any sex, race, occupation or age group, or contravenes the ethical values of the health professions, is not acceptable.

2.6 No advertisement may state or imply in absolute terms, either in company generated copy or quotation(s) from references that any product is "safe", "ideal", "non-toxic", has "guaranteed efficacy", is "uniformly well-tolerated", is "acceptable to children", has "totally predictable action or effect".

5.3 Statements claiming or implying that a pharmaceutical product has a superlative feature or function, e.g. most effective, least toxic, best tolerated; or is accorded special status, e.g. the standard, the drug of choice, unique, most frequently prescribed; in general, should not be used in pharmaceutical advertisements unless they can be substantiated.

5.4 Statements claiming or implying a special status for, or comparative superiority of, a company, its personnel or services, must not be used in an advertisement unless they can be substantiated.

The full PAAB Code of Advertising Acceptance should be read by all physicians and it is recommended that any advertisement which is felt to be incorrect as to fact, misleading in effect, discriminating or in poor taste, should be reported to the Commissioner of the PAAB/CCPP, to the Editor of the journal in question and to the manufacturer. Procedures exist, we must be the administrators.

e) *Sponsorship of Continuing Medical Education activities*

Guidelines also exist for managing sponsorship of professional activities. The Committee on Fellowship Affairs of the Royal College of Physicians and Surgeons of Canada requested that all Regional Advisory Committees discuss the question of CME support by the pharmaceutical industry (30). Similarly, the Board of Directors of the CMA recognized with appreciation the contribution of the pharmaceutical industry to CME activities. In order to preserve and appropriately manage this valuable funding the following guidelines were approved by both CMA and PMAC (31):

1. The organization, content and choice of speakers must be determined by the physician organizers. The organizers may be CME directors at medical schools, CME physician organizers in community hospitals, or CME representatives for specialty and professional societies.
2. Disposal of the funds should be the responsibility of the physician organizers. While the program should acknowledge the financial aid received, it should not designate the sponsor's product. It is appropriate to acknowledge the assistance of the sponsoring pharmaceutical company.
3. As a principle, the use of generic names is preferred in presentations and discussions.
4. Large scientific congresses frequently attract commercial exhibits of pharmaceutical companies. If this is the case, and it coincides with a CME session, negotiations for space or display should be conducted separately from discussions for CME sponsorship.
5. The value of social functions at CME meetings is recognized. However, they should neither compete with, nor take precedence over, central events.

As noted in these guidelines, large scientific congresses frequently attract commercial exhibits of pharmaceutical companies, yet these exhibits and events are limited as regards to real scientific or professional value. It has been suggested (32,33) to remedy this situation that CPA sponsors an ANNUAL COMBINED PSYCHOPHARMACOLOGICAL WORKSHOP held at the CPA Annual meeting with some form of financial participation from the pharmaceutical industry. The best authorities should be encouraged to present at this workshop and all efforts be made to minimize the possibility of partiality.

f) *Research activities*

Another contact area between the industry and physicians is research, and again care must be taken to avoid partiality. Drug research in Canada is controlled by the Food and Drug Act, a special department looks after drugs that act on the Central Nervous System, which includes the psychopharmacological agents. All new drugs have to be approved under this Act, as do the clinical research protocols and methods. A code for good monitoring practice for clinic investigations has been drafted recently (34). However these trials are carried out by the industry itself and may therefore be seen to have a conflict of interest. It may be that as O'Connor (8) has said "vehicles to allow early consultation with groups that have research expertise might guarantee better quality in the research studies that the companies do promote. In exchange these companies might then fund more physician-controlled research completely divorced from their own goals. In this way both the profession and the company would meet some of their objectives." Furthermore, when research involvement is solicited then those research projects should be approved by Research and Ethics Committees of local hospitals or universities.

It seems appropriate to conclude by quoting once more from O'Connor (8) "Those persons in the world with the most clearly defined objectives seem most likely to achieve their ends. The medical profession must allow the pharmaceutical companies their legitimate and very necessary profit, while clearly defining its own objectives of preserving the scientific method and providing quality care."

Summary of Recommendations

In view of the fact that the Pharmaceutical Industry and the Medical Profession must relate to each other ethically, the Canadian Psychiatric Association makes the following recommendations:

Ethical responsibility

1. That psychiatrists recognize and accept responsibility for monitoring their role in this relationship and teaching this to their students.

Ethics of prescribing

2. The use of prescription pads which include promotional material or "no substitution" as part of the printed format is strongly discouraged.
3. Prescribing should be by generic name with specific recognition of a particular brand added by the prescribing psychiatrist only when appropriate.
4. Samples should be used with discrimination and choice of drugs should be made on clinical grounds not on availability of samples.

Pharmaceutical information sources

5. Independent journals, books and reference manuals should ensure increased objectivity of information presented and their use is encouraged.
6. Psychiatrists should conduct interviews with pharmaceutical company representatives in a professional and scientific manner.
7. Hospitals are encouraged to establish guidelines for the visits of pharmaceutical company representatives. Psychiatrists in private practice should similarly instruct their support staff.
8. Psychiatrists should question promotional materials which do not attain scientific journal standards.

Ethics of advertising

9. Advertising copy which does not meet the guidelines of the PAAB Code of Advertising Acceptance should be reported to the commissioner of the PAAB/CCPP, and to the Editor of the Journal and to the manufacturer.

Sponsorship of Continuing Medical Education activities

10. The CPA endorses the CMA Guidelines for acceptance of pharmaceutical company financing of Continuing Medical Education courses and meetings.

11. The establishment of a Combined Psychopharmacological Workshop as a regular event at its annual CPA meeting is encouraged. This should be sponsored by the CPA with financial support from the pharmaceutical industry.

Research activity

12. Uncontrolled promotion of a specific product under the disguise of research is unacceptable.
13. University research departments are encouraged to consider the establishment of collaborative consultation with the industry in return for sponsorship of independent psychopharmacological research.
14. As with all research, activities involving pharmacological agents should be approved by Hospital or University Research and Ethics Committees.

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