

Guidelines for ethical relationships between physicians and industry

The Royal Australasian College of Physicians

**Third Edition
2006**

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Foreword

As relationships between the health professions and industry become more complex, so are there changing views of that relationship by both the community and professionals. This is the third edition since 1994 of a document which evolved from previous statements and publications of The Royal Australasian College of Physicians.

This work recognises that health care related industries provide a valuable and legitimate component of society but that relationships between industry and health professionals may lead to dualities, and possibly conflicts of interest. Therefore there is a need for practical guidance for clinicians, researchers, educators and managers about how to understand and manage their interactions with industry.

The recommendations are strongly worded, but remain advisory. Matters as complex as the ones discussed, about which there are varied views, are appropriately regulated through voluntary codes, with individuals taking responsibility for their actions after considering the evidence, the arguments and the issues.

In order to support individuals, it is suggested that institutions and professional societies establish their own policies regarding relationships with relevant industries and this document describes ways in which they may do so. There are other new features including a section on students and trainees.

The objective is to focus on the interests of the broad community. The production of this document has involved wide consultation with other Colleges and interested parties, including industry and community groups. Following this consultation, these guidelines have been designed to reflect the experiences and views of the health professional community as a whole, not just those of physicians.

I would like to thank the working party for their hard work and professionalism in developing this document about ethical guidance, relevant to, practical for, and useable by the health community.



Jill Sewell AM, PRACP
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Executive summary

Health care professionals and industry work together when conducting research, within organisations, when providing health care to the community and in education and training. Industry has a valuable and legitimate role in the health care sector. However The Royal Australasian College of Physicians (RACP) acknowledges that in working with industry, health care professionals may experience ethical dilemmas or conflict of interest situations.

These guidelines aim to assist health care professionals in managing their relationships with industry. It is vital that patient care and science are unaffected by industry affiliations of health care professionals. The guidelines recommend that health care organisations develop procedures for managing dualities or potential conflicts of interest situation before they escalate into major ethical issues.

Some health care professionals may be unaware they are being influenced or argue that it could happen to others but never to them. The guidelines recognise that everyone can be influenced and that health care professionals need constantly to evaluate their relationships with industry.

This is the third version of the guidelines since 1994. This version includes new information and evidence and a new section dealing specifically with issues affecting medical students and postgraduate trainees, and some practical tools to assist health professionals in managing their relationships with industry. In developing the guidelines there was wide consultation involving medical and other health professionals, consumers, and representatives from industry and other relevant organisations. The resulting text therefore reflects the experiences and views of the wider community of health professionals and not just physicians.

The guidelines are advisory. The RACP acknowledges that there are many different opinions about ethics in the medical community and that judgement often depends on the details of individual cases.

The guidelines make a number of recommendations for individual practitioners, including promotions of products by industry, use of therapeutic devices, support for meetings and educational activities, employment and remuneration and research and development.

The majority of health professionals are also members of a range of health care organisations and the guidelines examine the roles of institutions and professional societies, including sponsorship issues, educational activity support, membership of disease specific community health organisations and the roles of officers in societies.

Industry has a very important role in medical research in Australia and New Zealand and the guidelines make recommendations regarding clinical trials, payment and publication of results. The final section on medical students and trainees examines their interactions with industry, meetings and education issues.

The guidelines provide practical advice for health care professionals working with industry in an ethical environment. Every health care professional will work with industry at some stage of his or her career. It is a responsibility of health care professionals to ensure that the relationship does not affect their clinical practice.

Summary of main recommendations

Implementation of the guidelines and Conflict of Interests committees

- In every organisational or practice setting a group of individuals should be identified with responsibility for ensuring that processes exist for identifying issues and developing policies relevant to relations with industry in that particular setting. This function may be taken on by a pre-existing body such as an Ethics Committee or a Conflict of Interests Committee may need to be established.
- Details of membership of this group and the outcomes of its deliberations should be publicly available.
- The group, or those delegated by it, should have responsibility for deciding how to respond to complaints, inquiries and changing circumstances.

Issues affecting individual clinical practitioners

- Medical practitioners should not accept a fee or equivalent consideration from representatives of industry for seeing them in a promotional capacity.
- Acceptance of drug samples from pharmaceutical representatives should be avoided in most cases.
- Gifts and offers of entertainment should be rejected.
- Offers of industry sponsorship to attend conferences, scientific meetings and other gatherings should be considered carefully before being accepted. Acceptance usually should be restricted to those in which the professional is to make a formal contribution. In other cases, steps should be taken to reduce the risk of perceived impropriety by obtaining agreement from institutional committees and making appropriate public declarations.
- Accepting sponsorship to cover the cost of travel, attendance or meals at conferences or meetings for family or friends, is inappropriate.
- Remuneration for services provided to industry should be appropriate and transparent. It should be declared to employers and to patients, where relevant.
- Endorsement of specific products and advertorials should be avoided.
- Obtaining benefit from the sale of a medical device to one's own patients is inappropriate.
- Where a conflict of interest could arise through recommending the use of a particular device, such a recommendation should be made by the clinician at arm's length from the sale or distribution of the device.

Issues arising in relation to institutions and professional societies

- The planning, content, speaker selection and subject matter of any conference of a society, or of any meetings arranged under its auspices, should not be influenced by commercial interests of industry sponsors.
- Industry sponsorship of meetings should be provided independently of their scientific and clinical content.

- The organising group of an educational meeting should comprise a majority of individuals without conflicts of interest that relate to the meeting. Possible conflicts should be managed within the operation of the committee.
- Industry sponsorship of a meeting organised under the auspices of an institution or professional society should be untied and fully disclosed.
- Speakers at a meeting planned by any organisation should be required to disclose dualities of interest at the time of their presentations.
- Payments to individuals at an independent meeting should be made through the meeting organisers and not by industry sponsors.
- If a company selects and sponsors speakers at a scientific or educational meeting, it should take full responsibility for the organisation and promotion of the meeting.
- Meetings organised directly by industry should be critically scrutinised in relation to the possibility of bias or incomplete information by health care professionals attending them.
- It is the responsibility of the institution accrediting an educational activity to ensure that the activity is free of bias related to industry sponsorship or representation. Wherever possible medical grand rounds should be funded separately from industry. If industry sponsorship is accepted, the sponsor should have no part in determining the speakers, subject or content.
- Industry advisory boards should be formally constituted with terms of reference, meetings should be conducted according to accepted standards and there should be evidence that decisions have an impact on the companies involved.
- Policies and processes are needed to ensure that statements or guidelines drawn up by Institutions or Societies with industry support are based on relevant evidence. Dualities and conflicts of interests must be appropriately managed. The guidelines and statements must not be influenced by industry interests.

Issues relating to researchers

- Dualities involving researchers with a direct interest in the research should be managed on a case-by-case basis with specific strategies where necessary to protect the integrity of the research process.
- In general, it is undesirable for medical practitioners engaged in research involving their own patients to be primarily responsible for the process of seeking consent. Information should be provided and discussion about the pros and cons of involvement undertaken through third parties who do not have direct contact with the patients involved.
- Financial compensation for participating as an investigator in a clinical trial should be commensurate with work performed.
- The benefits gained by a clinician from the conduct of an industry sponsored clinical trial should be subject to review and approval by an appropriately constituted ethics committee.
- Research grants from industry should be made to the institution and not to individuals and should be appropriately acknowledged in research and other publications.
- Any research project conducted by private practitioners should include an investigator with an institutional affiliation and be assessed by an ethics committee associated with that institution or some other arrangement must be made to ensure

ethics committee review and oversight occurs, and that there are clearly defined and transparent processes for the management of funds.

- It should be a condition of both agreements to participate by researchers and approval by ethics committees that there is a commitment to make publicly available all results, negative as well as positive, which are potentially relevant to clinical practice.
- Responsibility for decisions concerning publication of results should rest with disinterested investigators and not solely with the sponsoring company.

Issues arising in relation to students and trainees

- Training programs should include discussions about the role of industry, dualities and conflicts of interests, and the evaluation and interpretation of industry material.
- The role of institutional policies and the practices of individual clinicians, teachers and mentors in shaping the behaviour of students and trainees should be recognised in the development of curricula.

Definitions

In this document *industry* is understood broadly to refer to the full range of for-profit enterprises associated with health care. These include, but are not restricted to, the pharmaceutical industry, the biotechnology industry, the medical device industry and commercial providers of services related to clinical practice, research and education.

The term *health care professionals* is taken to include: medical practitioners in all specialities, those working in private practice and those in institutions such as hospitals, universities and research institutes; practitioners in other health professions; representatives, employees and administrators of institutions, such as universities and research institutes; fellows, members and employees of professional organisations; members and employees of community organisations with an interest in the management of a particular medical condition or aspect of research; and members of these various groups during the course of their undergraduate or postgraduate training.

An *interest* is a commitment, goal or value arising out of a social relationship or practice.

A *duality of interest* arises when two or more interests coexist.

A duality may become a *conflict of interest* when a particular relationship or practice gives rise to two or more conflicting interests.

A *pecuniary interest* refers to the possibility of financial or other material gain arising in connection with professional decision making. Examples of pecuniary interests include: share holdings or board memberships; paid employment, including consultancies and commissioned fee-paid work, speaker fees and fees provided in return for an expert opinion; fellowships, research and educational grants; and travel grants, conference expenses, gifts and hospitality.

Non-pecuniary interests refer to goals or benefits not linked directly with material gain, such as enhancement of career and the possibility of acquiring professional recognition, status or fame. In the medical setting such interests are often powerful drivers of decision making, although they may be hard to identify and impossible to quantify.

Chapter One

Introduction: The context, process and principles

1.1 The issue

The treatment of disease, the conduct of research directed toward improvements in prevention and treatment, and the production of therapeutic products are the result of contributions from medical practitioners and other health professionals, medical researchers, employees of industry, consumers, administrators of hospitals and professional and community organisations, and many others. The individuals and groups working in these different areas interact in various ways to facilitate the realisation of their own goals and purposes.

Although they share many common interests, however, each of the groups has its own specific objectives, which are not always consistent with each other. In particular, the for profit sector, which includes the pharmaceutical industry, the biotechnology industry, manufacturers of devices and providers of various services, is naturally concerned to generate profit for owners and shareholders, a goal which may potentially come into conflict with the primary goal of the health care system, which is to provide for the health care needs of the community.¹ Because of this potential for conflict, many health professionals feel uncomfortable in their relationships with industry, and uneasiness has also been expressed both in the community and by government agencies.^{2 3 4}

To respond to these concerns it is necessary to clarify the purposes and interests of each group, to identify potential conflicts or differences among these, to develop ways of averting or managing actual conflicts and to communicate openly with each of the constituencies. This is a complex task, not only because of the number and variety of participants but also because many clinicians and researchers today are themselves associated with industry, as researchers, advisers, or recipients of benefits in some other form. Further, industry contributes to health care and health care practices by supporting medical conferences and other meetings, medical and community education programs, and research. Many health care professionals are involved at all stages of the development and conduct of research projects, including identification of key issues to be addressed, study design, conduct of clinical trials and dissemination of results, and at each of these stages diverging interests may arise which could influence the goal of providing enhanced health care to the community. Universities, research institutes and professional and community organisations enter into partnerships with industry to achieve their purposes of health care delivery and research and in some cases rely heavily on income derived from these relationships to conduct their day to day business.

A particular concern of health care professionals and the wider community which has been frequently emphasised is the promotional activities of the pharmaceutical industry. These activities take many forms, including overt advertising, the provision of gifts to individual doctors or to their employing institutions, travel assistance, support for meetings and

educational programs and dissemination of information to the community.⁵ In this case, the concern is heightened by the fact that the targets for these advertising and promotional activities – usually medical practitioners - are not the consumers of the products. Rather, medical practitioners act as the agents of both their patients and the wider community, with the protection and promotion of whose welfare they are entrusted. While health care professionals of all kinds often assume that they are immune from skilled advertising techniques^{6 7 8} evidence shows that both health care decision making and the conduct of research are profoundly affected by all the influences, in ways that are not always beneficial to the wider community.^{9 10 11} For this reason, concern has arisen that health professionals may unwittingly become agents of industry and a need has been identified for the development of techniques for recognising sources of influence and the kinds of effects these may have, and developing effective and transparent strategies for responding to them.^{12 13}

Similar issues are raised by other aspects of the relationships involving those working within the health care system and industry, including educational and research activities, and the management of hospitals and professional organisations.^{14 15 16 17 18} These guidelines are intended to contribute to the process of clarifying these issues and developing ways of responding to these issues that protect and preserve the interests of patients and the wider community.

1.2 Responsibilities of health professionals in relation to industry

Health professionals have a range of responsibilities in relation to the development and use of pharmaceutical agents and other therapeutic devices. Medical practitioners have specific responsibilities to their patients, researchers have responsibilities to the community of scientists, and administrators have responsibilities to those who set the policies they are appointed to execute. Depending on the professional roles involved, these responsibilities may include:

- using existing, approved drugs and devices in the most effective and appropriate way as part of treatment and care;
- monitoring their use and reporting adverse reactions;
- participating in clinical trials of new drugs and in company sponsored trials of marketed drugs;
- participating in post-marketing surveillance of new drugs and therapeutic devices;
- keeping up to date with scientific developments in their fields and with available information about new drugs and changed information about established ones;
- considering the implications of new technologies and pharmaceutical agents for the community as a whole and contributing to discussion about the most appropriate use of resources; and,
- engaging directly in research or contributing to or supporting such research.

These responsibilities substantially overlap with the objectives of many aspects of industry, with which health professionals develop and maintain many fruitful relationships. It is important to acknowledge these constructive engagements, which are often beneficial both to the participants and to the community as a whole. Medical practitioners and researchers can provide knowledge and experience which can enhance the outcomes of the work undertaken by industry. Conversely, industry can supply resources which facilitate the development of new therapeutic possibilities.¹⁹

While the interests of clinicians, researchers and health administrators on the one hand and representatives of industry on the other overlap, however, they are not identical and at times may diverge or come into conflict with each other.²⁰ The vast array of relationships, and the multiplicity of interests served, greatly exceed the possibilities that can be anticipated by legal structures and codes of conduct expressed at a high level of generality.²¹ In addition, actual decision making depends on the details of the contexts within which specific practices, such as clinical medicine and research, are embedded, and it is difficult to formulate rules that apply in all conceivable contexts. Indeed, it is the nature of professional practice that decisions are made in relation to the specific needs of the individuals involved.

1.3 Why the issue is important

It is important for health care professionals to exercise care in their relations with industry because contact with industry may lead to:

- a loss of commitment to or change in underlying goals or purposes;
- undermining of the processes of professional judgement;
- inappropriate outcomes or outcomes at variance with the underlying values of the health care professions or of the community; and,
- loss of trust by patients, government and the wider community.

In brief, inappropriate or poorly managed relationships between the health professions and industry can lead to an erosion of the integrity of these professions and an undermining of the trust between practitioners and the community on which the health care system depends.

1.4 Developing the guidelines

We offer guidance to individual practitioners in their interactions with industry, to researchers in the planning and execution of their work, and to institutions and professional organisations charged with the responsibility of delivering health care and overseeing educational activities and research practice. Individuals and organisations need to develop their own processes for identifying and managing issues relevant to them. We have suggested a framework to facilitate this.

The guidelines have evolved from guidelines developed by The RACP over a ten-year period. They are based on identifying and interpreting the best practice currently available. We did not undertake a systematic literature review but have relied heavily on published evidence to support the conclusions, which also arise out of argument and debate. The production of the document has involved extensive consultation with a wide range of contributors, from the medical and other health professions, industry and consumer groups. Following this consultation we have designed the guidelines to reflect the experiences and views of the health professional community as a whole and not just those of physicians.

1.5 Advisory nature of the guidelines

We stress that these guidelines are advisory. There is no universal consensus about how to assess the influence of industry on health care and research or about optimal courses of action to respond to issues arising in specific settings. It is recognised that there are often differing views about the most appropriate course of action: indeed such diversity of views is encouraged and welcomed. In addition, it is emphasised that judgements must be made in

relation to the specific details of individual cases, which may be infinitely variable. Together, these factors impose limitations on the extent to which effective guidance can be provided in the form of general principles and summary formulations.

We consider that matters as complex and varied as those discussed here should be regulated on a voluntary basis, according to local conditions and needs, by individuals who are themselves engaged in practice and administration. Accordingly, we accept that not everyone will agree with our recommendations and that on occasion individuals and organisations may choose other courses of action. We suggest that, in the interests of the communities we serve, we all reflect on dualities and possible conflicts at the start of and during every professional interaction we have with our colleagues in industry.

1.6 General principles

The overriding general principle on which these guidelines are based is that the values of clinical care, of the welfare of society and of science should prevail over commercial imperatives and monetary values. This means that benefits received as a result of relationships between health professionals and industry – whether pecuniary or non-pecuniary, in cash or kind, as gifts, hospitality or subsidies - must leave the independence of professional judgement unimpaired. Arrangements between health professionals and pharmaceutical companies should be open and transparent. Where the possibility of a conflict of interest could be raised, regardless of the context, this should be declared openly to all relevant parties. However, openness in itself is not sufficient: additional steps need to be taken to circumvent the conflicts and to prevent distortion of the relationships involved. The nature of these steps is the basis of this document.

It is recognised that the array of issues and problems may be extensive, that judgements may be difficult and at times controversial, and that the process of arriving at decisions must itself be subject to the principles of independence and transparency. For this reason it is appropriate for health professionals and institutions to give careful consideration to the development of processes to define policies and strategies and, where appropriate, arrangements to ensure monitoring and enforcement. (See Chapter 3)

1.7 The evidence

Medical practitioners, researchers and other health professionals often believe that they are unaffected by their interactions with industry.^{22 23 24} A great deal of evidence has now been accumulated which shows that this is often not the case. It is now recognised that any interaction involving health professionals, professional societies, researchers and industry may be associated with changes in behaviour in favour of industry. In particular, the effectiveness of pharmaceutical promotion, sponsorship of meetings and support for educational programs and research in altering the behaviour of clinicians and researchers is now well established.^{25 26 27}

The available evidence is useful for the identification of issues and problems affecting the relations between health care professionals and industry and for the development of strategies to address them.²⁸ However, because the issues involved often require ethical judgements the data themselves must be interpreted through a process of critical reflection and public debate. As both the evidence and community standards change over time it is likely that conclusions will also evolve.

It is one of the purposes of guidelines, and ethical codes in general, to influence behaviour. It is important that strategies be devised to evaluate the effectiveness of such forms of guidance, both to permit assessment of their impact and to contribute to their further development. Despite its importance, this need is beyond the scope of the present text.

1.8 Consumer participation

In the process of revising this document the views of consumers have been sought in various ways. This is in recognition of the fact that increasing involvement of health consumers in a variety of roles, such as those of patient, carer, advocate, voluntary worker or administrator, leads to better health outcomes and improved patient satisfaction.^{29 30} It also reflects the view that such participation has ethical value in its own right and facilitates the development of constructive partnerships that further improve health care.

The consumer feedback obtained so far has provided great assistance in the development and refinement of the text. Because the need for such feedback is ongoing, additional suggestions and critical comments from members of the community are specifically invited and welcomed at any time.

Chapter Two

Dualities and conflicts of interest

2.1 Theoretical framework

One of the key issues arising in the context of relationships with industry is that of the possibility of conflicts of interests (COI). It is important to define this concept carefully and to clarify the kinds of strategies that are available to deal with such conflicts. To do this it is first necessary to define the concepts of “interest” and “duality of interests”.

These concepts may be defined in the following terms:

- An “interest” is a commitment, goal or value arising out of a social relationship or practice;
- A “duality of interest” arises when two or more interests coexist. These interests may or may not conflict, depending on the specific circumstances; and,
- A duality may become a “conflict of interest” when a particular relationship or practice gives rise to two or more contradictory interests.

These definitions emphasise certain important points:

- The existence of dualities of interest is a fact of modern life. It reflects the diversity of modern societies and the plurality of individual roles. Inevitably, different roles may give rise to varying obligations, and therefore multiple dualities, some of which may, on occasion, erupt into conflicts; and,
- Whereas in common usage, the term “conflict of interest” is often taken to imply the existence of unethical behaviour, conflicts generally arise in the absence of unethical behaviour. The COIs arise out of the facts and not from malign motivations. Furthermore, neither dualities nor COIs in themselves inevitably cause harm; it is the ambiguity about goals and values and the possibility for harm that arouse concern. In these situations it is sometimes difficult for the individual concerned to perceive that there is a conflict, and sometimes the conflict may be irresolvable if both roles are maintained.

The decision about whether a duality constitutes a conflict should not rest with the individual concerned but with the affected community. If a conflict is judged to exist, some action needs to be taken to separate the conflicting duties, as explained below.

2.2 Pecuniary and non-pecuniary interests

Conflicts and dualities of interests include both pecuniary and non-pecuniary issues. In medical and research settings, the latter are often the most important and subtle.

A pecuniary interest refers to the possibility of financial or other material gain arising in connection with professional decision making. Examples of pecuniary interests include:

- share holdings or board membership;
- paid employment, including consultancies, commissioned fee-paid work, speaker fees, fees provided in return for an expert opinion;
- fellowships, research and education grants; and,
- travel grants, conference expenses, gifts and hospitality.

Non-pecuniary interests refer to goals or benefits not linked directly with material gain, such as enhancement of career and the possibility of acquiring professional recognition, status or fame. In the medical setting such interests are often powerful drivers of decision making, although they may be hard to identify and impossible to quantify.

2.3 Examples of dualities and conflicts of interests

Dualities of interest arise whenever there are two interests that arise simultaneously within the same relationship or social role. Dualities may or may not constitute a conflict, depending on the context. Whether a conflict does exist should be decided by the community or group that is potentially affected, wherever possible, or by an institutional Conflict of Interests Committee. Examples of settings in which conflicts of interest may arise are as follows:

- A medical practitioner or a member of his or her family holds shares in a pharmaceutical company the products of which the practitioner may prescribe;
- An active clinician is a member of a pharmaceutical company's Board of Directors;
- A health professional is a member of the advisory board of a company that provides health care services;
- A health care practitioner undertakes paid employment, including commissioned and non-commissioned fees for work as a speaker, author or expert adviser on behalf of a pharmaceutical company;
- A clinician, researcher or office holder in a professional organisation holds a fellowship or an endowed position supported directly or indirectly by a pharmaceutical company;
- A researcher receives support from a pharmaceutical company for carrying out research;
- A clinician accepts gifts or hospitality expenses from a company whose products he or she prescribes; or,
- A clinician or researcher receives support from industry for travel and conference expenses.

2.4 Practical strategies

Effective management of conflicts of interests lies in identifying them, making clear declarations, maintaining openness and transparency, and developing appropriate structures to deal with specific issues. While it is essential that dualities and conflicts should be dealt with in an open and transparent manner it is important to recognise that in many cases this will not be sufficient. In these cases specific action will need to be taken to separate activities or functions. Specifically, it is suggested that the following sequence of events may prove helpful:

- individuals in identified areas of activity declare dualities of interest, whether financial or non-financial;
- these are considered by the relevant community – e.g. a committee or council or group of individuals directly affected;
- an assessment is made concerning whether the dualities constitute a potential or actual conflict;
- if it appears that a conflict of interest is present or likely, practical strategies are devised to separate the pursuit of the conflicting interests; in some cases, this may entail withdrawal from or curtailing of a particular activity, while in others, it may

- be sufficient to delegate functions or roles to an individual, a group of individuals or a committee; and,
- the decisions and practical outcomes are communicated to the constituency affected.

The details associated with each of these steps will, of course, vary according to the circumstances and the context.

For example, in the case of presentations at meetings, policies should be developed by the organising committee. In general these should include open and complete disclosure in a manner that will permit audience members to interpret the content of the talk appropriately. Similar considerations apply to contributions to journals or other publications, teaching, and in other settings.

Key points

- Dualities and conflicts of interest are a common feature of modern life, reflect objective conditions and do not imply moral error.
- Interests can be pecuniary or non-pecuniary.
- It is necessary to distinguish between “dualities” and “conflicts” of interests in relation to actual circumstances.
- Dualities need to be disclosed to the relevant community - e.g. a committee or council - which considers whether they are sufficient to constitute a conflict and whether further action needs to be taken.
- Disclosure may need to be linked to a strategy to manage conflicts of interest in order to disengage the two sets of contending values.

Chapter Three

Implementation of the recommendations: the establishment of Conflict of Interests Committees (COIs)

This document raises issues regarding a wide variety of clinical, research and institutional contexts. These relate to diverse settings and often complex circumstances which themselves may be subject to change or evolution over time. Because of this variation any rules provided as guidance must be formulated at a high level of generality that permits application in a wide range of settings. The process of application itself, however, requires detailed analysis of the circumstances of an individual case and an interpretation of the needs of the relevant affected community. Often this will necessitate reflection, discussion and debate within that community.

As has been mentioned previously, the recommendations in this document are proposed as advisory only. They are not linked to a prescribed, formal method of enforcement. This is appropriate because ethical decision making requires constant scrutiny of issues and principles and cannot be replaced by a system of legislative imperatives. Indeed, clinical practice requires that ethical decisions are taken in a setting of dynamic negotiation and compromise among participants who often have different value perspectives. Furthermore, appropriate methods of surveillance and monitoring are likely to vary across institutional and clinical settings.

On the other hand, it is clearly important that the principles of transparency and disinterestedness of judgement that have been recommended for the management of dualities and conflicts of interest are also observed in the implementation of the guidelines themselves. The various affected communities are entitled to expect that adequate due process and consultation have been followed not only in the development of the broad generalisations that constitute the recommendations but also in their interpretation and application. Accordingly, it is appropriate that in each individual setting a process be established to elaborate the specific content of the guidelines that is relevant for that context and, according to the needs of that setting, to supervise their implementation.

It is therefore recommended that in each relevant organisational setting a committee of individuals (a “Conflict of Interests committee” or “COI Committee”) be established which has responsibility for ensuring that processes exist for:

- identifying the main issues relevant to relations between the health care setting and industry;
- developing policies regarding relationships with industry covering the specific issues relevant to that particular setting;
- developing methods for assessing the impact and appropriateness of policies;
- ensuring adequate communication with the relevant local community;
- responding to new circumstances as they arise;
- responding to questions or complaints;
- assessing and managing dualities and conflicts of interest within that specific health care setting; and,

- keeping records of declared dualities and identified conflicts and how they were managed.

COI Committees may conduct the above functions themselves or delegate them to a range of bodies with appropriate skill and experience. In many cases, the latter will be existing committees, such as ethics committees, or they may be groups which come together only as needed according to circumstances; they could be made up of elected members of an organisation or a committee of colleagues identified for this purpose; it would often also be appropriate to include community representatives. Details of the membership of the Conflict of Interests Committee and the outcomes of their discussions should be publicly available.

It is emphasised that the Conflict of Interests Committee is itself not necessarily responsible for developing policies or carrying out disciplinary action. Rather, the role of this committee is primarily to ensure that mechanisms are available within the institution or organisation to ensure that an adequate range of policies and processes relevant to its goals and activities are developed and subject to some form of assessment and review. In many cases responsibility for these various functions is likely already to be spread among a number of existing committees, in which case the Conflict of Interests Committee can assist by coordinating their activities and ensuring that the policies are both consistent and cover all the relevant issues.

The functions carried out by Conflict of Interests Committees cover important aspects of quality assurance that should be a part of the routine practice of all practitioners and institutions.

Key points

- In every organisational or practice setting a group of individuals, known as a Conflict of Interests Committee, should be identified which has the responsibility for ensuring that processes exist for identifying issues and developing policies relevant to relations with industry in that particular setting. Details of the membership of this Conflict of Interests Committee and the outcomes of its deliberations should be publicly available.
- Such groups, or those delegated by them, should have responsibility for deciding how to respond to complaints, inquiries or new circumstances.

Chapter Four

Issues affecting individual clinical practitioners

4.1 Introduction

Individual clinical practitioners come into daily contact with organisations which provide assistance to them but whose primary objective in the market economy is to make a profit. Such organisations cover a wide range of activities, such as the pharmaceutical industry and manufacturers of devices.

Clinicians often need to make decisions rapidly, sometimes under pressure. They may command control of substantial resources because of their ability to call on the social wealth allocated by governments. Because of this influential position, industry applies significant resources to the task of influencing the behaviour of practitioners. Practitioners therefore have a responsibility to ensure that their decisions are not biased towards any particular drug, device or for-profit service provider.

Most of the evidence regarding the influence of industry on clinical practice relates to medical practitioners who are the largest users of the products of industry. Accordingly, the focus of the discussion will be on medical practitioners. It is likely, however, that similar considerations apply to nurses and allied health professionals.

This chapter considers the issues arising in the setting of clinical practice surrounding the promotion of pharmaceutical products, dualities and conflicts of interests, interactions with pharmaceutical representatives, gifts, entertainment, the use of drug samples, familiarisation programs and other promotion strategies, therapeutic devices, support for meetings and other educational activities, sponsorship of travel and meetings of various kinds, and employment and consultancies. It offers guidance in relation to each of these matters. In general, the view taken is that all interactions between clinical practitioners and industry should actively serve the interests of patient care. In those cases where a clear benefit to clinical practice is less certain, great caution should be exercised.

4.2 Evidence regarding the effects of promotional activities on clinical practice

There is extensive evidence that medical practitioners are influenced by their contact with industry. Advertising and other forms of drug promotion, including provision of gifts and entertainment, travel assistance to meetings, or sponsorship of scientific meetings and inclusion in advisory boards all increase demand for specific products.^{31 32}

Promotional material distributed by pharmaceutical companies is often biased, incomplete or unsupported by evidence and may promote unapproved uses.^{33 34 35 36} Contact with drug detailers and promotional materials erodes physicians' ability to identify wrong claims, increases non-rational prescribing^{37 38} and results in acceptance of commercial rather than scientific views.³⁹ Physicians deny or are unaware that promotional activities affect their behaviour.^{40 41 42}

While it is appropriate for a physician to interact with pharmaceutical representatives with educational benefits to doctor and patient, most clinicians develop procedures to maximise

this benefit. Such behaviour is important and should include critical evaluation and feedback on all unsubstantiated material including journal reprints if of poor quality. In some cases contacting the pharmaceutical company or Medicines Australia might be appropriate.

Choices of speakers and topics at meetings may have significant implications for industry. Biases can be introduced into any kind of event, including continuing professional development activities and departmental and other meetings.^{43 44 45 46} Sponsorship leads to bias in favour of a company's drug.^{47 48} Prescriptions for sponsors' drugs increase in the six months after an event.⁴⁹ These effects are observed even when no overt promotion of the sponsors' products occurs.⁵⁰

Financial relationships between industry, scientific investigators, and academic institutions are widespread.^{51 52 53 54} Sponsorship affects research outcomes. There is a significant association between source of funding and outcome of trial.^{55 56 57} Industry sponsorship is associated with pro-industry conclusions and restrictions on publication and data sharing.⁵⁸ Research funded by drug companies is less likely to be published than research funded by other sources and is more likely to have outcomes favouring the sponsor.^{60 61} Evidence regarding the activities of nurses and allied health professionals is more limited but is likely to raise similar issues.^{62 63}

4.3 Conflicts of interest within the clinical practice setting

Dualities and conflicts of interest in clinical settings may arise from the relationships of medical practitioners with industry in relation to clinical care and research, teaching and other professional and employment responsibilities. They include involvement of clinicians in and interactions with owners of private hospitals and pathology providers, educational opportunities funded by third parties and honoraria for participation in education programs. *The principle guiding the responses to dualities of interests relating to the clinical setting is that the relationship between clinician and patient should not be compromised by commercial or other interests that could subvert the principle that the interests of the patient should be primary.*

Arrangements between clinical practitioners and pharmaceutical and other for-profit companies should be open and transparent. Where the possibility of a conflict of could arise, regardless of the context, this should be declared openly to all relevant parties. In many cases this will require disclosure of financial or other arrangements to institutions, ethics committees, patients, potential research subjects and others. As emphasised, such disclosures of dualities do not in themselves imply the existence of conflicts of interest, but merely allow public scrutiny to ensure that such conflicts do not develop. The ultimate test for the effective management of conflicts of interest in this setting is that benefits received from industry – whether in cash or kind, or as gifts, hospitality or subsidies - leave practitioners' independence of judgement unimpaired and do not influence decisions they might make concerning the welfare of their patients.

Key point

- Relationships between clinicians and patients should not be compromised by commercial or other interests that could subvert the principle that the interests of patients are primary.

4.4 Promotion by and interactions with industry

Of particular concern to the public and to clinical practitioners are relationships between the pharmaceutical industry. Clinicians and industry share common goals in that they are engaged in the treatment of disease and the conduct of research directed toward improvements in treatment. However, there are also divergent interests, as a result of the fact that the primary responsibilities of those working in industry are to their shareholders, whereas the primary responsibility of clinical practitioners is to act in the wellbeing of their patients.

The promotional activities of the pharmaceutical industry attract special attention. These can take many forms, including overt advertising and the provision of gifts and perquisites to individual practitioners or to their employing institutions. These activities arouse concern because:

- they may utilise techniques of persuasion other than argument based on evidence;
- they target prescribers who are agents of both their patients and the community; and,
- it is increasingly recognised that the costs of pharmaceutical promotion significantly add to the cost of pharmaceutical products.

4.4.1 Gifts

There is compelling evidence that the giving of gifts to medical practitioners is an effective marketing activity which impacts on doctors' independence of judgement. Acceptance of gifts is associated with an increased likelihood that doctors will prescribe products produced by pharmaceutical companies, even in the absence of scientific data to support such clinical decisions.^{64 65} This includes not only discrete gift items, but also payment for dinners, entertainment or expenses associated with daily living. Often medical practitioners are unaware that they are subject to such influence: indeed, they often consider that there are not affected.^{66 67 68} There is increasing concern in the community about the effects of gifts and other techniques of persuasion used by industry, especially because it is recognised that to make a disinterested decision in the interests of a patient a health professional must be unencumbered by issues relating to his or her personal interest.⁶⁹

Individuals must judge for themselves what is and is not acceptable but, to avoid impairment of their judgement, should reject gifts. There are in fact only rare occasions on which acceptance of gifts could be considered to be in the interests of patient care. These generally involve provision of service-oriented items – for example, patient counselling or teaching aids – which are not otherwise readily available. Even in these cases caution should be exercised because of the risk of undermining the assumption of independence of health professionals from industry, and therefore the trust on which clinical relationships depend.

Non-service oriented items should in general not be accepted. Health professionals should recognise that even items of small value which superficially appear to be innocuous are intended to sway doctors' judgements and at the least, may suggest to patients that the proper distance between the medical practitioner and for-profit industry has been transgressed. For this reason many practitioners today decline to accept even items of trivial value such as pens or message pads.

Key point

- Although individuals must judge for themselves what is acceptable, to avoid impairment of their judgement gifts should be rejected. This includes items of small value.

4.4.2 Entertainment and hospitality (See also 5.6)

Hospitality is the provision of food and beverages by industry in association with a professional education meeting. Entertainment is the provision by industry of tickets to cultural, sporting or artistic events i.e. with no associated professional education. It is current practice nowadays for doctors to reject pharmaceutical company entertainment invitations, and this response is appropriate and expected.

For some doctors, hospitality provides an attractive and enjoyable context within which information about pharmaceutical products can be presented. Information sessions may be held in the evening after a day's work and it may be appropriate for them to be combined with provision of food and drink. If the content of the meeting is of significant educational value the acceptance of such perquisites might be considered acceptable. The appearance of impropriety however, should be considered before accepting lavish dinners and entertainment, even if accompanied by a scientific presentation.

Food and drink may be offered by industry to make grand rounds or similar meetings within hospital settings more attractive. Here too, although this practice seems innocuous it arouses concerns within the community, where it is recognised as a device to influence doctors by means other than argument and presentation of evidence.⁷⁰

It is recognised that judgement on these matters may sometimes be difficult. In specific cases it may be helpful and appropriate to discuss issues that arise with colleagues, with institutional representatives, with the employing authority or an ethics committee.

Key point

- Acceptance of hospitality in connection with a professional educational meeting may be acceptable. Acceptance of entertainment and entertainment expenses not connected with education is undesirable and such offers should be declined.

4.4.3 Drug samples

Drug samples are pharmaceutical products distributed by manufacturers or their agents to doctors. These samples are commonly starter packs that may be provided to patients who need to commence treatment promptly. In some cases the provision of free samples may be sought by a clinician in order to obtain a drug unavailable on the Pharmaceutical Benefit Scheme. In other cases clinicians may utilise such samples to provide immediate access to drugs in emergency circumstances or to assess patient acceptability of medications in short-term trials.

The provision of a sample or a free supply of a drug or other product which appears to be a service is in most circumstances a marketing exercise. It is intended to accustom the clinician to prescribing a particular product, or to establish a cohort of patients on long-term

treatment with a particular drug.⁷¹ In general, if the use of a particular medication is clinically indicated there are often measures whereby that medication can be legitimately obtained without the potential drawbacks of free samples.

Accordingly, apart from exceptional circumstances, the acceptance of drug samples from manufacturers or their representatives is not recommended.

Key point

- Acceptance of drug samples from pharmaceutical representatives is usually inappropriate.

4.4.4 Familiarisation programs, support programs and other promotional strategies

Some manufacturers have introduced “support” programs that offer patients enrolled in those services such as telephone help-lines, educational literature, access to web sites and even additional medical treatments. Although such programs may occasionally provide useful and accurate information and a measure of genuine support to patients, clinicians should bear in mind that they are essentially “brand loyalty” devices that may influence the attitudes of patients and their doctors to the use of medications and that pharmaceutical companies provide no guarantee of continuity. Practitioners providing patients with information about these services should take care to ensure that information is accurate and relevant and an aid to patients prescribed the medicine.

4.4.5 Off-label prescribing

In some areas of medicine off-label prescribing is common. This is especially the case, for various reasons, in the treatment of HIV/AIDS, cancer, and psychiatric and paediatric illnesses.^{72 73} In particular in paediatrics, many commonly used drugs have not been specifically tested on children. Although the practice is officially discouraged, off-label prescribing is sometimes recommended in advertisements and related materials.

In many cases, prescribers will have personal knowledge or experience of use of medications in circumstances other than the registered indications, and consistent with agreed standards of practice. In other cases they will have scrutinised the medical literature in detail and arrived at informed judgements about the appropriate manner in which to use the medications. Apart from these circumstances, doctors should exercise caution about prescribing medicines for non-registered indications as the practice is associated with an increased risk to the patient.^{74 75}

4.4.6 Use of medical software containing advertising

Some software programs used by medical practitioners to assist with clinical functions include advertising of pharmaceutical and other products.⁷⁶ Where computers utilising these programs are positioned in such a way that they could be seen by patients during consultations two special issues arise. First, they are likely to raise in the minds of patients the possibility that their practitioners may be subject to influence from industry or bias as a result of their associations with it. Second, by allowing commercial values to intrude into the relationship between doctor and patient they risk undermining the key ethical assumption of the clinical encounter that it is the interests of the patient that are the paramount and overriding concern.⁷⁷

For these reasons it is recommended that, where possible, practitioners choose software that does not include industry advertising or, if they are already using such software, they should find a way to disable the advertising functions.

Key point

- Practitioners using software for clinical functions should choose programs that do not include industry advertising or should “disable” the advertising functions of their programs.

4.5 Use of therapeutic devices

Therapeutic devices are physical objects that are in general produced by industry for commercial gain and are employed by clinical practitioners for a therapeutic purpose. A very wide range of devices is available, covering many aspects of medical practice. They include, for example, devices to deliver asthma drugs, continuous positive air pressure devices for the treatment of sleep apnoea, cardiac pacemakers and stents, breast implants, artificial joint prostheses, blood pressure and glucose monitoring devices.

Because they are produced in a commercial setting the potential exists for dualities and conflicts of interest exactly as for medications. Issues are also raised in relation to advertising and promotion and sponsorship. Much that has been said about medications therefore also applies to devices.

Because the regulatory systems relating to drugs and devices vary slightly and because devices may also be promoted and used by non-medical practitioners, there are some additional issues that need to be considered. It is appropriate to draw attention in particular to three of these:

4.5.1 A clinical practitioner may have a personal or financial interest in the development, manufacture or sale of a device. Such interests are not exclusively financial. For example, practitioners may hold shares in or receive payment of royalties from a company that produces a device. There may be enhancement of a practitioner’s personal prestige or career if they had been personally involved in a product’s design, testing, refinement or commercialisation.

While the development of a new device with useful therapeutic potential may be laudable, a duality of interest exists where its use is recommended to the practitioner’s own patients. This must be managed in the same way as other dualities. If after disclosure it is concluded that a conflict of interests in fact exists, then remedial action is likely to be necessary. This may take the form of divestment by the practitioner of shares or an arrangement whereby discussion about whether to employ the device is undertaken with the assistance of a third party

4.5.2 A clinical practitioner may enter into a special arrangement with the manufacturer or distributor of a particular device or type of device. For example, the clinician may receive special benefits, either in cash or in kind, if he or she prescribes the device. Alternatively, he or she may come to an arrangement with a manufacturer to provide a device at a favourable cost to patients within a particular institution.

The former possibility is undesirable. At least a declaration of dualities is required, with careful scrutiny of the details by the body nominated by the Conflict of Interests committee. The latter possibility may produce benefits to the institution and to patients. However, here too disclosure is necessary, covering the relevant factual details, such as the nature of and the reasons for the arrangement and its consequences for patients, including the benefits claimed and potential drawbacks, such as limitation of choice and other options forgone.

- 4.5.3** A manufacturer or distributor of a device may advertise directly to the public or offer special benefits, such as free medical assessments, as an inducement to the use of their product.

While consumers are entitled to have access to reliable information about all the products they use, the presentation of information in the setting of commercial advertising or other promotional strategies rarely achieves this goal. In addition, while supporting services are sometimes of genuine clinical benefit, in most cases they contribute little beyond what is routinely available in clinical practice. Accordingly, apart from exceptional circumstances, such practices should be avoided.

Key points

- It is inappropriate to obtain a benefit from the sale of a medical device to one's own patients.
- Relationships between clinical practitioners and producers and suppliers of devices should be transparent.
- Where a conflict of interest is likely to arise, a recommendation to use a particular device should be made by a clinician at arm's length from the sale or distribution of the device.

4.6 Support for meetings and other educational activities

Both the pharmaceutical industry and, increasingly, the biotechnology industry provide sponsorship for the organisation of meetings and for practitioners to attend them. This sponsorship is provided with the expressed aim of contributing to continuing education. However, there is evidence that it affects the decisions clinicians make in their practices, with the result that these decisions are not always based on objective scientific data and may not contribute optimally to patient care.^{78 79 80} This evidence leads to the conclusion that sponsorship of meetings carries a clear risk of influencing the capacities of clinical practitioners to make disinterested decisions on behalf of their patients. In view of this, great care should be exercised before accepting travel sponsorship or gifts. The nature of sponsorship or gifts and any obligations associated with them should be declared openly to those who might have an interest in knowing. Where a meeting is organised directly by an industry sponsor the presentations should be critically scrutinised in relation to the possibility of bias or incomplete information.

The best way for industry to provide sponsorship of scientific meetings is through independent organising bodies which use the funds provided by industry to defray the costs of bringing in invited speakers and for other purposes. The costs of travelling to and attending such meetings should in general be met by those who attend them because of

their educational value. If they accept sponsorship outside these arrangements individuals need to determine that it is clearly linked to education, that it does not lead to loss of professional independence, and that public scrutiny of it would not raise concerns.

In addition clinical and scientific meetings organised by independent organising committees pharmaceutical companies sometimes provide sponsorship to clinicians to participate in a variety of other events, such as local meetings of specialist groups, hospital grand rounds, departmental scientific meetings, product launches and continuing professional development programs. While these meetings usually have a clearly defined primary educational aim, they may be open to the suspicion that they will result in clinical decisions being influenced by personal associations with industry. Practitioners involved in organising or attending such meetings need to have a high level of awareness of this risk. They should take deliberate steps to ensure that the source and extent of sponsorship are fully disclosed and that the primary educational purposes of the meetings are achieved.

Before any form of industry sponsorship is accepted the following questions should be considered:

- Will acceptance of sponsorship result in any actual or perceived loss of professional independence either during or after the period of sponsorship?
- Is the proffered sponsorship genuinely and clearly linked to further education or ongoing professional development which is likely to benefit the community?
- Do the potential sponsor's corporate history and business practices, either locally or internationally, raise concerns?
- Have the criteria used to select invited speakers and delegates to an industry-sponsored meeting been publicly disclosed?
- Have the scientific and promotional components of the meeting been sufficiently separated by the organisers?
- Are there any dualities of interest that need to be declared?
- Would patients and their families be concerned by such sponsorship?
- Will the propriety of the sponsorship stand up to scrutiny by colleagues and the public?
- After consideration of the above, do the potential benefits outweigh the risks?

The recommendations in this section may be useful when considering specific situations.

Key points

- Industry sponsorship of meetings should be provided independently of the scientific and clinical content.
- Meetings organised directly by industry should be critically scrutinised in relation to the possibility of bias or incomplete information.
- Payments to individuals should be made by the independent meeting organisers and not by for profit sponsors

4.6.1 Where sponsorship or an honorarium is offered in return for a formal contribution to a legitimate scientific meeting or conference program

A legitimate scientific meeting or conference may be defined as “a gathering [that] is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and the main incentive of bringing attendees together is to further their knowledge on the topic(s) being presented”.⁸¹ Industry sponsorship may be offered to individual medical practitioners to travel to such meetings in which they will be involved as speakers, chairpersons or in other significant capacities, such as contributors to the organisation of subsequent meetings. This form of sponsorship recognises the standing of the individuals and is very often appropriate. However, it is important that it is *indirect, untied* and *fully disclosed*.

Sponsorship should be indirect. Industry sponsorship for attendance at meetings should always be through a third party. It is legitimate for the independent organising committee of a meeting to use industry sponsorship to cover or defray the costs of invited speakers. To qualify as independent, an organising committee must be free of industry sponsor representation, and ensure that the relevant professional details of each committee member are placed in the public domain and dualities of interests are declared.

Where payments are to be made to individuals in return for participation at a meeting, such payments ought to be made by the independent meeting committee and not by the industry sponsor. Payments should be commensurate with the services provided and not excessive as judged by the independent organisers of the meeting or others.

It is not in general appropriate for physicians to accept sponsorship directly from industry and independently of the meeting organisers. It is never acceptable for physicians to accept sponsorship (either directly or indirectly) to cover the cost of travel, attendance or meals for family or friends.

Sponsorship should be untied. Sponsorship that is tied to the promotion of any commercial product should not be accepted, even if payments are received via an independent organising committee.

It is the responsibility of individual practitioners receiving sponsorship to ensure that any information or research presented at meetings is unbiased and in accordance with the accepted norms of scientific inquiry. It is important that such information or research does not lend itself to be interpreted (rightly or wrongly) as an endorsement of commercial products. For example, practitioners ought to be careful to use product non-specific terms when presenting (e.g. drug class rather than brand names). Where reference to a specific product is unavoidable the generic name should be used and both commercial trade names and mention of individual pharmaceutical and health technology companies should be avoided.

Before sponsorship or an honorarium is accepted in return for participation in a meeting it should be confirmed that the scientific and commercial elements of the meeting have been sufficiently separated. Speakers should declare dualities of interest at the beginnings of their presentations, including direct or indirect sponsorship they have received to attend the meeting.

Sponsorship should be fully disclosed. Industry sponsorship received and used by a meeting organising committee to pay clinicians for their contributions ought to be fully disclosed and placed in the public domain prior to the meeting. Such disclosures should include:

- the names and brief descriptions of the relevant activities of sponsors;
- statements of the nature and size of both monetary and in-kind contributions;
- declarations by sponsors attesting to the untied nature of their contributions;
- statements by the committee regarding promotional rights granted in return for sponsorship (e.g. advertising space); and,
- a list of criteria for selecting invited speakers or other participants who qualify for financial sponsorship or honoraria.

Practitioners need to be careful about accepting payments from organising committees that fail to meet high standards of public disclosure about industry sponsorship. Particular care must also be taken for meetings which are not regular meetings of recognised professional societies, especially if there is no independent organising committee and the meeting is organised by industry. In these cases, it must be recognised that invitations almost certainly arise from the fact that companies consider that clinicians' contributions will be to their benefit. In addition, the lack of an independent organising committee may call into question the independence of a speaker. If accepted, support for contributions to such events should always be declared in accordance with the criteria above to hospital, university or other bodies with which the practitioner is affiliated.

4.6.2 Where sponsorship or an honorarium is offered to a practitioner not making a formal contribution to a scientific meeting or conference

Offers of sponsorship to practitioners to attend conferences and meetings where they will not contribute formally as speakers, chairpersons or in other capacities are more problematic. The potential value of scientific and clinical meetings is indisputable, as is the responsibility of health professionals to attend them to update their skills.

The distinction familiar in educational settings between those presenting educational materials and those in the audience receiving them, furthermore, does not always apply exactly to scientific or clinical meetings, where audience members may often be actively engaged and contribute vigorously. However, the roles of presenters and of other attendees at a meeting are nonetheless different and in relation to questions of industry sponsorship they are associated with different levels of risk.

This is exacerbated by the fact that in cases where a formal contribution is not being made sponsorship is almost always provided directly by a company to an individual. Under these circumstances, even if the potential educational value of the meeting is unquestionable, acceptance of sponsorship to cover travel and attendance costs is very likely to lead to perceived or actual conflicts of interest in subsequent decisions regarding the sponsor's products. As a result, both the risk of compromising the personal and professional standing of practitioners and the level of community concern about their conduct are high.

Accordingly, in such cases practitioners must exercise extreme care. If, after having considered the questions listed above, a clinician believes that accepting sponsorship in a particular case is reasonable steps ought to be taken to reduce the risk of perceived impropriety. Agreement should be sought specifically from appropriate institutional

committees (e.g. hospital, university, professional society) prior to acceptance of the sponsorship. The necessary public declarations should always be made and be available for scrutiny.

As discussed above, it is always inappropriate for practitioners to accept sponsorship (either directly or indirectly) to cover the cost of travel, attendance or meals for family or friends. The principles for accepting group sponsorship for attendance at meetings and conferences are the same as for individuals. Group sponsorship in no way mitigates individual responsibility or ethical obligations.

Key points

- Industry sponsorship to attend conferences, scientific meetings and other gatherings should usually be restricted to those in which the professional anticipates active engagement, for example by making a formal contribution, and when attendance without support is not possible. Such sponsorship should be indirect, untied and fully disclosed.
- In other cases, if a clinician believes that accepting sponsorship is reasonable, steps ought to be taken to reduce the risk of perceived impropriety by obtaining agreement from appropriate institutional committees and making appropriate public declarations.
- Acceptance of sponsorship to cover the cost of travel, attendance or meals of family or friends is never acceptable.

4.6.3 Sponsorship for medical “grand rounds”

Medical grand rounds are a time-honoured and valued institution within medical training and ongoing professional development. Grand rounds may also be expensive to run. Not only may funds be required to provide remuneration for an invited specialist or expert speaker, but organisers often wish to provide attendees with free food and other incidentals in order to promote attendance.

Financial support for grand rounds should always be sought from institutions or from alternative sources, including attendees, before offers of sponsorship from industry are sought or accepted. This is especially important in teaching institutions because of the additional responsibilities to students and trainees.⁸²

If industry sponsorship is accepted it is imperative for organisers to minimise any real or perceived conflict of interest by:

- insisting that all sponsorship is untied and fully disclosed;
- ensuring that the industry sponsor has no part in determining the speaker, subject or content matter for the grand round;
- ensuring that all speaker dualities of interest are declared prior to the event;
- ensuring that all content is presented in accordance with the accepted norms of scientific practice, including that all information be presented in an unbiased and balanced manner, especially where any product of the industry sponsor is mentioned;
- ensuring that any free food and incidentals provided are standard fare and do not detract from the primary educational focus of the grand round; and
- ensuring that, when a display of industry materials and/or interactions with industry personnel are unavoidable, that these are kept to a minimum.

Key points

- Wherever possible, grand rounds should be funded independently of industry support.
- Where no alternative is available the industry sponsors should have no part in determining the speakers, subject or content.
- All sponsorship should be disclosed.

4.6.4 Sponsorship for local meetings of specialty groups and departmental scientific meetings

Given the relatively small size of such meetings combined with the risk of the appearance of impropriety, health professionals and meeting organisers should question whether industry sponsorship is necessary. Many of the costs for such meetings can be defrayed by nominal attendance fees and other non-commercial sources.

Where industry sponsorship is required for such meetings it is important for individual practitioners and meeting organisers to take steps to ensure there are no real or perceived conflicts of interest. As stated above, all effort should be made to ensure that sponsorship is indirect, untied and fully disclosed.

4.6.5 Product launches

The primary purpose of product launches is promotional rather than educational. This premise should always guide decisions concerning access to such events. In teaching institutions, decisions about access should also take into account the additional educational responsibilities to students and trainees.

4.6.6 Meetings at which support for a particular speaker or other benefits are provided by industry

In some cases a supporting company selects and sponsors both the speaker(s) and the meeting. Under these circumstances the company should send out invitations in its own name, provide the venue for the meeting, support the speaker and meet other costs. Such meetings should not be or purport to be under the auspices of independent practitioners or organisations. If the topic is likely to be of interest to a significant number of people, then professional bodies or other sources separate from the company may decide to advise their members.

A company may provide a speaker and support for a meeting primarily organised by practitioners. The overriding principle for acceptance of such offers should be that the program must be arranged by these practitioners independently of influence from industry. It is the responsibility of those involved in organising the meeting to provide evidence that this is the case.

Use can be made of visiting speakers, but care should always be exercised in acceptance of such offers to ensure that an unbiased presentation is to be made. Companies may be disinclined to sponsor speakers unless it is known that they are likely to support the objectives of the company. If areas are known to be contentious, care must be taken to ensure that there is an appropriate balance of speakers canvassing alternative views.

Companies may offer support for meetings by paying for venues, satchels, refreshments and exhibitions of pharmaceutical or scientific products etc. Professional societies may consider that, on balance, the risks of involvement are outweighed by the benefits. This is acceptable as long as the fact and extent of such support is made clear on all invitations and publicity and the guidelines for travel of individual practitioners are observed. In particular, it must not be contingent upon alterations in the program, speakers or other aspects of the format of the meeting. In these cases, contractual arrangements should be entered into with the agreement of all the bodies involved. The terms of the arrangement - e.g. the use of the names of the speakers for publicity purposes - should be fully understood by all parties.

Key points

- If a company selects and sponsors speakers it should take full responsibility for the organisation and promotion of the meeting.
- The conditions under which support for a meeting is provided should be disclosed.

4.6.7 Company support for continuing medical education (CME) or continuing professional development (CPD) programs

This subject is covered under 5.6.

4.7 Employment, consultancies and remuneration for services

Practitioners are entitled to remuneration for services provided to industry unless their conditions of employment exclude the right of private practice. Remuneration for services provided to industry should be disclosed to employers and patients. Medical practitioners should not accept a fee or equivalent consideration from companies in exchange for seeing them in a promotional or similar capacity.

4.7.1 Consultancies

Individual practitioners who act as consultants for, or provide other services to, pharmaceutical or other companies, including those in the investment industry,⁸³ are entitled to fair remuneration for the services they provide. However, such relationships with industry often create dualities of interests and may on occasion produce the impression of a conflict between duties to industry and to patients. For example, if a practitioner becomes publicly associated with the products of a particular company, the question may be raised as to whether his or her recommendations to patients are based on an unbiased assessment of all the products that are available.

If a clinician acts as a consultant to industry this information should be public knowledge and reported to relevant committees, heads of department, employing institutions and patients. Institutions should decide whether the duality constitutes a conflict of interests and if it does, what actions need to be taken to avoid compromise of the doctor's primary responsibility to patients.

4.7.2 Employment

Practitioners may be directly employed in industry or subject to contracts with other employers. In these circumstances, conflicts of interest may arise because of requirements imposed as conditions of employment. For example, industry may restrict communication of commercially sensitive information, and managed care organisations may impose limits

on the extent and kinds of treatments that are available or even actively intervene in clinical relationships to direct doctors' decisions.

The implications of such employment arrangements have been discussed elsewhere.⁸⁴ Where conflicts arise medical practitioners should inform their patients of the nature of the differences and their implications. In some cases, they may need to make decisions about whether it is ethical to continue to work in this setting.

4.7.3 Membership of advisory boards

Pharmaceutical companies and other industry often establish advisory boards to give advice about particular drugs or techniques or groups of products. Such advice may involve all aspects of product development, from preclinical studies to marketing. It is appropriate for individual practitioners to contribute to such boards. Indeed, this is one way in which they can use their clinical knowledge to ensure that pharmaceutical developments satisfy community needs.

To ensure that advisory boards facilitate appropriate product development, individual practitioners must ensure prior to acceptance of appointment to a board that it follows formal, defined terms of reference, that there is an agenda for each meeting and that minutes of the meeting are recorded. Members also should be satisfied that their involvement is meaningful rather than symbolic.

It is possible that membership of an advisory board will encourage feelings of commitment to products and sometimes to the pharmaceutical company and its representatives. While such feelings are common following any such collaboration, it is important that practitioners are meticulous in ensuring that product use and recommendations are always based on sound scientific and clinical principles. They must remain clear that there can be no obligation to prescribe a particular product or to recommend its use to other clinicians.

In view of the fact that membership of an advisory board always poses questions of duality of interest, advisory board members should declare such involvement. Examples include: when making presentations at meetings relevant to the company or its products, when teaching and training, when consulting with patients, in meetings and discussions in institutions, when prescribing in circumstances where questions might be raised about the independence of clinical decisions, and when ethics committees consider clinical trials of products of that particular company or of a competitor.

It is possible that in some circumstances the association with industry will be judged to lead to a conflict of interest and therefore to require that other activities of the practitioner involved are affected: for example, involvement in a committee of a professional or government body or engagement in research. Outcomes might range from withdrawing from a particular discussion to withdrawal from the activity itself.

Key Point

- Advisory boards should be formally constituted with terms of reference, meetings should be conducted according to accepted standards and there should be evidence that decisions have an impact on the companies involved.

4.7.4 Endorsements and “advertorials”

Clinical practitioners, particularly those who are regarded by members of industry as having particular influence within their professional community, may be asked to make public comments supporting particular products.

There is an assumption in the community and among the patient population that health professionals are trained to analyse scientific evidence and to provide advice about health practices and community health needs. It is important to avoid using one’s status as a health professional and the good faith associated with it to promote commercial interests.

It is necessary to distinguish between scientific comment and support for a particular product. The context in which the comments appear may be very important here. A paid advertisement from a company may legitimately quote comments made in a scientific publication. However, comments should not be provided for the express purpose of supporting the advertisement of a product. If a comment is intended as an educational contribution the appropriate procedures should be followed. The practice of providing endorsement of a product in the form of a public statement, sometimes called “advertorial”, clouds the boundary between professional responsibility and commercial interest and is generally unacceptable.

Companies promoting newer drugs sometimes arrange presentations by practitioners willing to suggest that the use of some older – and usually cheaper – agents may be undesirable due to their more severe side-effects. Clinicians taking part in industry-sponsored presentations should be discouraged from promoting such suggestions unless they are supported by robust evidence.

Key point

- Endorsements of specific products and “advertorials” should be avoided.

4.8 Research and development (See also Chapter 6)

New discoveries by physicians and the development of new drugs or interventions should be encouraged. Those involved should be able to be rewarded for this work, but conflicts of interest may arise in the setting of clinical research.

Such conflicts of interest have been addressed above. A particular issue for practising medical practitioners concerns the recruitment of patients under their care for research in which they are personally involved. This raises the possibility of a conflict between the interest in conducting the research most effectively and that of making clinical judgements in the best interests of one’s patients.

In general, it is undesirable for medical practitioners engaged in research involving their own patients to be primarily responsible for the process of seeking consent. Information should be provided and discussion about the pros and cons of involvement undertaken either through or with the help of third parties who do not have direct clinical relationships with the patient involved. In the event that a patient of a researcher is recruited for a study, the researcher should explain clearly the nature of his or her involvement in the study, links with third parties including industry and the risks involved, and personal views on the pros and cons of this patient’s participation.

Although it is recognised that the details may vary from setting to setting whichever approach is adopted should incorporate the following principles:

- (1) that patients should have an opportunity to discuss their participation in a project with someone not involved in their clinical care; and,
- (2) that the actual granting of consent should be to someone other than the clinician primarily responsible for their care.

Where, in a particular research project, a conflict could arise between the requirements of research and those of clinical decision making it is essential that a clear disclosure should be made to the patient, together with a presentation of the options available to him or her.

In many cases it will be best for the physician to cease to manage the patient clinically during the conduct of that project, at least in relation to the particular issues that are addressed in it.

Key points

- When clinicians suggest to patients the possibility of involvement in studies in which they are investigators, independent professionals should be available to discuss the benefits and risks and undertake formal recruitment into the study.
- When patients of researchers are recruited into studies involving the researcher, disclosure to patients and institutions is required so that conflicts of interest are avoided.
- In general, it is undesirable for medical practitioners engaged in research involving their own patients to be primarily responsible for the process of seeking consent. Information should be provided and the pros and cons of involvement undertaken through third parties who do not have direct clinical relationships with the patient involved.

4.9 Summary and conclusions

Strategies for dealing with issues arising in relation to individual practitioners are as follows:

- Financial and non-financial interests that could compete with patient care should be disclosed.
- Where the possibility of a conflict of interest arises special arrangements should be made to avoid the conflict or to separate the relevant functions: for example, either by refusing an offer of sponsorship or by the appointment of an independent researcher to approach potential participants in research.
- Health professionals should take great care with respect to the acceptance of gifts or other perquisites from industry, limiting them at the least to those of very direct relevance to patient care.
- Acceptance of travel sponsorship to a meeting should be limited to individuals anticipating active engagement and be provided through the independent organising committee.
- Adequate payments should be made for services provided, including reimbursement of practice expenses, and should be administered under a contractual arrangement open to scrutiny.

Chapter Five

Issues affecting institutions and professional societies¹

5.1. Responsibilities of institutions and societies: general

Professional societies and industry have a mutually beneficial relationship. From time to time, these societies may receive financial support and industry may have an opportunity to showcase its advances to a sophisticated and responsive audience. However, the question of relations between the professions and industry is a very sensitive one in the community, and it is acknowledged that there are many settings in which conflicts of interest arise and associations between societies and industry can lead to compromise of the societies' objectives and public standing.^{85 86}

Funding received from industry is often associated with an assumption that a reciprocal benefit will follow. For example, sponsorship of a society may provide opportunities for its members to benefit from marketing royalties on products (such as credit cards, insurance, and stationery), or from the sale of its membership list. A society may be approached to participate in the marketing of medical products as well. It is important to recognise that the mere fact of an association with private industry may lead to a duality between the interest in strengthening the financial base of the society and that of being publicly identified as an independent, disinterested contributor to debates about health and health policy.

Societies must not allow their objectivity to be influenced by corporate or other sources of income. Dualities of interest should be disclosed in a timely and comprehensive manner.

There are many settings in which dualities and conflicts of interest may arise in the conduct of the business of a society. These include the society's publications, dealings with industry, including sponsorships of meetings, and various programs. Personal interests, including shareholdings, of council and committee members and employees can also raise the potential for conflicts of interest.

5.2 Dualities of interests involving officers of a society

It is possible that officers of a society, including members of its council and committees and employees and volunteers, may have either pecuniary or non-pecuniary interests related to industry. These may take the form of shareholdings or paid consultancies or other commitments in the form of advisory positions or even scientific collaborations. In these cases, the general rules applying to dualities and conflicts of interest should be applied: namely, that the dual interests should be declared and that an appropriate body should assess whether a conflict exists, and if so, that appropriate actions should be taken.

If action is required in a particular case, the nature of this will depend on the circumstances. It may vary from the need for an individual to withdraw from a particular discussion to withdrawal from participation in the body in question. Although those who participate in the activities of a society are entitled to privacy, this must be balanced against the needs of

¹ The expression "societies" is used to refer to Colleges and other professional societies, universities, research institutes and other bodies involved in the activities relating to teaching and research

members of the society to be confident that their interests are being appropriately served. In many cases the matter should be referred to the Conflict of Interests Committee to consider the possibility of a conflict of interest and to manage questions of privacy and open disclosure.

5.3 Membership of disease-specific community health organisations

Many health professionals will belong to community based organisations that deal with specific diseases such as cancer, asthma, diabetes or heart disease. Since many of these organisations attract significant industry funds, the practitioners' obligations are the same as for institutions and societies in general (see 5.1). In particular, such organisations should publicly disclose all sponsorship and any community based educational programs with which they are associated must be free of bias.⁸⁷

5.4 Sponsorship of meetings

Full disclosure of sponsorship of meetings and maintenance of independence in determining scientific content (including selection of sessions and speakers) are necessary. Even with safeguards, the risk remains that meetings (and sessions) may appear to be influenced by commercial enterprises. Complete disclosure of commercial support is required for all sponsored activities, as well as a balanced and objective presentation of data related to commercial products. Speakers should be required to indicate any dualities of interest at the time of their presentations, including relationships with the sponsor. Speakers should be asked explicitly to ensure balanced presentations related to controversial issues, including presentation of advantages and disadvantages of specific therapies.

Although commercial sponsors may wish to pay the costs of individuals who attend a supported meeting this often creates serious dualities of interest.⁸⁸ On occasions this may, in the view of the independent organising committee, be acceptable, but recipients should be chosen and reimbursed by the organising committee and not by the for-profit organisation. It may be acceptable for students, other trainees or staff members to receive funds to cover the costs of attending educational conferences, provided that the selection of the recipient is made by the training institution. Travel support for speakers may be acceptable as part of their compensation.

Sources of commercial funding should not influence the scientific, educational or public policy decisions of societies. Commercial supporters should not be able to influence the planning, content, speaker selection or execution of any program of a society, and commercial sponsorships should not influence the subject matter of any meetings arranged under its auspices. It should be made clear that the display of commercial products or services at society meetings, advertisements in a society's journals or social event sponsorship are not to be taken to imply warranty, endorsement or approval of these products or services, or effectiveness, quality or safety.

Except where directly relevant to a scientific presentation, the display of commercial information and promotional materials should be restricted to designated areas separate from those within which the presentation is being made.

Key points

- Commercial support for all sponsored activities should be disclosed and presentation of data should be balanced and objective.
- Speakers should disclose any dualities of interest at the time of their presentations.
- Commercial supporters should not influence the planning, content, speaker selection or execution of a society's program or the subject matter of meetings arranged under its auspices.

5.5 Sponsorship of various kinds of conferences

There are various special settings in which particularly complex issues of sponsorship may arise. These include conferences convened to discuss specific clinical or scientific issues and meetings of experts to develop clinical and public policy guidelines. In some cases these are sponsored by a specific society while others are sponsored by a variety of groups which play different roles in their organisation and outcomes.

Despite the added complexity in these cases, the same general rules apply and each society should satisfy itself that the appropriate standards have been met. Outside funders of an event must have no influence over its content, selection of speakers or participants, or the content of reports or other documents, recommendations, guidelines etc. produced as a result. In general, individual societies should review, and accept responsibility for, any such documents.

Full and rigorous rules for disclosure should be established for all such meetings, and should be publicised in any relevant documentation. It is desirable for participants to include a majority with no conflict of interest in the matter under study. Individuals with conflicts of interest may participate in such events as long as the appropriate public disclosures are made and that these are appropriately managed by a planning committee which is independent of any influence of commercial sponsors.

Key point

- Outside funders of an event must have no influence over the content, selection of speakers or participation or the content of reports, recommendations or guidelines produced as a result.

5.6 Educational activities, including continuing professional development (CPD) programs (See also 4.4.2)

As with other activities that are sponsored by industry, in the case of educational programs including CPD programs (sometimes also referred to in the medical context as “continuing medical education” programs), there is convincing evidence that the fact of sponsorship alone often influences both the content of these programs and the effects that they have on the behaviour of those who undertake them.⁸⁹ Furthermore, because the conduct of educational activities is often a core responsibility of scientific and clinical societies, the independence of these programs is of profound importance both for the members of the societies and for the broader community.⁹⁰ Overseas, there has been a tendency for CPD to be delivered by for-profit companies having strong links with industry.⁹¹ In Australia, it is increasingly common for meetings of purported educational intent to be organised by commercial entities for the achievement of profit.

In general, special care should be taken that educational programs are free from the possibility of bias towards any commercial sponsor.

This means that for any such program:

- the group responsible for organising it should include a majority of individuals who do not have relevant conflicts of interest;
- strict rules of management of dualities and conflicts of interest should be observed within the organising committee;
- the scientific, clinical and educational content should in no way be affected by the presence or nature of commercial sponsorship;
- speakers should be meticulous about declaring dualities and conflicts and steps should be taken to ensure that their presentations are balanced; and,
- processes should be established to assess the outcomes of the programs, including provision for feedback regarding possible biases from course participants.

Various mechanisms are available for ensuring that the above conditions are met.⁹² It is desirable that educational programs sponsored by a society do not involve industry support at all. However, if this is not possible, such support should be paid into a fund that is available to the society to conduct these and other activities. The process of negotiating with industry sponsors should be separated from that of designing the program. It is inappropriate for receipt of sponsorship support to be made contingent on conditions of any kind regarding choice of speakers or topics or inclusion of particular content.

The organising committee should adopt procedures to ensure that individuals with conflicts of interest may provide input into discussion but should not participate in the actual decision-making process relevant to that issue. The committee should be able to provide a formal undertaking that the scientific, clinical and educational content are in no way affected by the presence or nature of commercial sponsorship, or, if this is not possible, to provide a written statement of the way in which such sponsorship did affect the program content.

Strict guidelines and clear disclosure statements should be provided to prospective speakers and other teachers. If a speaker has a conflict of interest, his or her presentation may be subjected to review in advance of the delivery of the program by a reviewer without a relevant conflict of interest to ensure that it is balanced.

The policies and practices that have been adopted for a particular program should be open to public scrutiny. Independent observers should be identified who can provide a disinterested assessment of the outcomes.

It is the responsibility of the institution accrediting an educational activity to ensure that accreditation of a particular activity implies that the activity was free of inappropriate biases related to industry sponsorship or representation.

Key points

- It is the responsibility of the institution accrediting an educational activity to ensure that the activity is free of biases related to industry sponsoring or presentation.
- Strict guidelines, which include requirements for clear disclosure statements, should be provided to speakers.
- The organising group should include a majority of individuals without conflict of interest and conflicts should be managed within the operation of the committee.
- Measures should be adopted to ensure that the scientific, clinical and educational content is in no way affected by the presence or nature of commercial sponsorship.
- Processes should be established to assess the outcome of the programs, including provision for feedback regarding possible biases from course participants.

5.7 Endorsements of clinical guidelines and specific treatments²

It is one of the roles of professional organisations to inform and educate the public and government regarding specific issues concerning medicine, science and clinical practice. From time to time this may require taking positions in relation to the nature and consequences of particular health problems and treatments. This could include support for specific therapeutic agents or endorsement of clinical guidelines that support particular therapies.

The development of statements of endorsement of guidelines or treatments must be undertaken with great care to avoid compromising the objectivity and credibility of the organisation in the eyes of the broader community. Rigorous policies are needed concerning the processes according to which such statements are generated and reviewed.

The policies and processes should ensure that in each case the statement is based on relevant evidence, that the conditions under which it was prepared included appropriate management of dualities and conflicts of interests, and that any contributions from industry in support of its preparation were provided through arrangements that ensured that the process was free of influence.

In the case of clinical guidelines it is also necessary to ensure that these conditions applied to the participants in any meetings arranged to generate the guidelines. Where endorsement of statements or policies developed by other societies is considered similar conditions should be satisfied.⁹³

Key point

- Policies and processes are needed that ensure that the preparation of statements of endorsement involves examination of the relevant evidence and includes appropriate management of dualities and conflicts of interest, and that their contents are not inappropriately influenced by industry contributions.

² In this section the term “endorsement” is used to include decisions by a society to sponsor, approve or participate in a particular activity or to provide public support for a particular product

5.8 Publications (See also 6.8)

Professional societies often contribute to the development of the understanding of medicine by sponsoring the publication of scientific journals or other newsletters. In these settings, like the others discussed above, it is possible that conflicts of interest may arise involving associations with industry. These include circumstances where editors, reviewers or others involved in the publication process have a personal interest in the content of an article submitted for publication: perhaps the commonest such example of this is where a reviewer is working in a similar area and could benefit from a delay in the publication of the article in question; a somewhat rarer example would be circumstances in which an editor could possibly benefit from promotion of his or her own work. Journals often obtain significant earnings from advertising and from reprints bought by sponsors for distribution to medical practitioners: the possibility of such payments also has the capacity to influence editorial decision making.

Authors' disclosures should be required in all cases and published together with the corresponding articles. Reviewers, editors and committee members associated with publications should be asked to declare dualities of interest and those with significant conflicts of interest should be excluded from consideration of the particular manuscripts involved. Journal editors should also excuse themselves from reviewing work in which a potential or actual conflict of interest exists and transfer responsibility to an alternative editor. Where a journal achieves substantial income from sale of reprints this should be disclosed to readers.

Additional comments regarding publications are found in 6.8.

5.9 Conclusions regarding issues arising in relation to societies and institutions

The independence of professional and scientific societies may be affected in a number of ways by relations with industry. These relations may involve individual members, employees or the society itself. In all cases, care should be taken to ensure that appropriate mechanisms are available to deal with the particular issues. Dualities and conflicts of interest in the conduct of the business of such societies should be approached in a systematic manner, which should at the least include the following steps:

- Establishment of a defined process for identifying dualities and assessing their potential to constitute conflicts and, if necessary, to develop strategies in response;
- Disclosure of financial and other interests to an appropriate forum within the society designated by the Conflict of Interests committee;
- Assessment of which interests are potentially relevant and examination of potential for conflict;
- In the case of conflict, development of strategies to avoid compromising either the individual involved or the work of the Society/Institution/College; and,
- Public communication of the outcomes of this process in an appropriate form.

Chapter Six

Issues affecting researchers

6.1 Introduction

There is an extensive literature dealing with the ways in which both the conduct and the outcomes of research may be affected by relations with industry.^{94 95} This includes the role of pharmaceutical companies in the development and funding of clinical and basic research, issues arising in relation to the design of clinical studies, the increasing involvement of individual researchers in the commercialisation of their own work, and increasing acceptance that researchers may retain intellectual property, hold patents and maintain shareholdings in biotechnology companies related to their research.⁹⁶ These circumstances raise particular questions about the independence of research and the reliability of data that are made available to the public.^{97 98}

The arguments about whether investigators with a direct interest in the outcomes of research should be permitted to participate in such research are complex, as indeed, are the organisation and structure of individual research projects. It is important that this complexity, and the full range of dualities and conflicts arising in relation to research, is appreciated and that a flexible, case-specific approach is maintained. In individual instances, it is often possible to identify specific pressure points at which dualities may erupt into conflicts and to devise specific strategies to protect the integrity of the research process.

These issues apply both to clinical and basic research. Clinical researchers may have financial interests in the conduct or outcome of clinical trials. Opportunities to profit from research financially or academically may affect - or appear to affect - researchers' judgements relating to the primary obligation to protect patients' interests. Clinical researchers may influence study design, patient selection, data collection and analysis, adverse event reporting, or the presentation and publication of research findings. Similarly, basic investigators may be paid for specific services or through a pharmaceutical or biotechnology company funding a project overall. Financial conflicts may also arise when an investigator becomes involved in a commercial venture that may impinge on other aspects of his or her own research.

Financial compensation for participating as an investigator in a clinical trial should be commensurate with work performed. In no event should referral ("spotter") fees be paid to investigators or other clinicians. Any assistance received for a project should be paid into a specially designated fund established for the conduct of clinical research which is subject to auspice and audit according to established institutional guidelines. Research consent forms should disclose the existence of any significant financial interest held by individuals involved in conducting the clinical trial. Obviously, in all cases, relevant government and institutional guidelines should be observed.

This document does not purport to provide a comprehensive guide for the conduct of research or of the business of ethics committees: for this, readers should refer to the relevant extant publications.^{99 100}

However, it is recognised that in such publications the relationships between individual researchers and other practitioners involved in the conduct of research and industry are often either not well covered or do not contain sufficient detail to provide guidance to researchers working in particular settings. Accordingly, the following notes are intended to enhance existing practices and provide a practical guide to practitioners.

Key points

- Dualities involving researchers with a direct interest in the research should be managed on a case-by-case basis with specific strategies where necessary to protect the integrity of the research process.
- Financial compensation for participating as an investigator in a clinical trial should be commensurate with work performed.
- Assistance received should be paid into a specially designated fund which is subject to auspice and audit according to institutional guidelines.

6.2 Some examples of the ways in which relations with industry may affect researchers

The fact that investigators are paid for their services or have an interest in the outcome can lead to dualities or conflicts of interest in research.¹⁰¹ Special issues arise in relation to investigator initiated research, epidemiological research, research undertaken by academics, industry employees and clinicians, including private practitioners. Questions that may need to be considered relate to the design of studies, the consent process, controls and analyses of the data, and decisions about publication. There may be direct and indirect conflicts arising from payments for services rendered both as clinicians and as researchers involved in clinical research; what is “fair payment for services rendered” may be ambiguous. There may be many non-financial motivations involved, including the possibility of increasing status, achieving fame or advancing a career. In many cases these may be more important than financial considerations.

Here are some examples of settings in which relations with industry may affect the conduct or the outcomes of research:

- A researcher has a direct financial interest in the outcome of a trial in which she is engaged, in the form of a patent, shares, share options or bonuses;
- A researcher stands to gain in non-financial ways from the success of a trial sponsored by industry by enhanced public status or career prospects;
- A clinician/researcher recruits his own patients for an industry-funded study in which he is involved;
- A researcher is paid for conducting a study by a pharmaceutical company;
- A researcher is employed directly by a pharmaceutical company; and,
- A researcher has to make a decision about whether to publish unfavourable or negative results, as a result of which her career may be damaged and financial benefits may be lost, including the possibility of undertaking further work with the industrial partner involved.

6.3 Responsibilities of investigators (See also 4.8)

The above dilemmas are treated in detail elsewhere but summarised here. Individual investigators have particular responsibilities. They must consider:

- Whether the questions the proposed study sets out to answer are sufficiently important to justify the involvement of patients in the study. Alternatively, is it a

promotion to familiarise doctors with a drug or device to encourage a particular brand usage, a post- marketing surveillance study, or a commercial undertaking to permit drug registration in the absence of any substantive scientific content?

- Whether the discomfort and inconvenience, or maybe risks, to which patients are to be exposed are reasonable, taking into account the nature of the project, the patient population to be studied, and the likely benefits;
- Whether the design of the study is appropriate, including whether the use of any placebos as comparators is justified when there is treatment available which has been clearly shown to be effective. This is of particular importance when the test drug is related to a currently available medication;
- Whether patients will be able to consent freely to participation, or whether consent issues are satisfactorily addressed in other ways;
- Whether relevant social or cultural issues are adequately taken into account;
- Whether the information to be provided to patients includes an adequate description of the nature of the project and any potential risks or discomfort associated with it;
- Whether potential participants are likely to be subject to any form of coercion;
- Resource issues, including the cost of the study to the institution (investigations, bed usage and staff time) and expected demands imposed on researchers; and,
- Proposed methods for monitoring the conduct of the trial and obligations imposed on researchers to ensure that the trial remains in accordance with various guidelines published by the NHMRC, the Therapeutic Goods Administration, the World Medical Association and other relevant bodies.

Where a duality of interest exists the steps outlined above should be followed, namely that:

- dualities of interest, whether financial or non-financial, are declared;
- these are considered by the relevant community, in this case usually a research ethics committee;
- an assessment is made concerning whether the dualities constitute a potential or actual conflict;
- if it appears that a conflict of interest is present or likely, practical strategies are devised to separate the pursuit of the conflicting interests, either by withdrawal from or curtailing of a particular activity or delegation of functions or roles to an individual, a group of individuals or a committee; and,
- the decisions and practical outcomes are communicated to the constituency affected, including fellow researchers and research participants.

6.4 Notification to appropriate Human Research Ethics Committees

All research projects involving human subjects must be assessed by a Human Research Ethics Committee which is constituted according to national recommendations such as those contained in the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*.

Since payments to investigators, departments and institutions have ethical implications, the ethics committee must be made aware of financial arrangements for clinical trials, including proposed payments to researchers and research participants and the provision of other resources required to carry out the study.

Payments to research participants should not be so large as to constitute an inducement to participate in the project.

6.5 Investigators with a variety of industry interests

As indicated above, investigators may have a wide range of associations with industry, extending from receipt of payment for the conduct of research planned and coordinated by a pharmaceutical company to the initiation of the process of commercialisation of their own scientific discoveries at their own expense. While the details may vary widely the principles in each case are similar: full declarations should be made and appropriate arrangements must be devised to avoid conflicts of interests.

Some researchers consider that such requirements add to costs and hinder their work. However, they are unavoidable if the results of the research are to be accepted as reliable and impartial. It is the responsibility of public bodies, including government and professional societies, to provide adequate support to individual researchers to carry out work that will provide benefits to the community.

6.6 Clinical trials, including commissioned research projects¹⁰²

Clinical researchers may have financial or non-financial interests in the conduct or outcome of clinical trials supported by industry. Opportunities to profit from research financially or academically may affect - or appear to affect - researchers' judgements relating to the primary obligation to protect patients' interests.

Clinical researchers may benefit from their research financially, through investment in, or ownership of, companies sponsoring clinical trials, as a result of which they may have beneficial interests in the outcomes of these trials, or through payment for work performed in enrolling and managing patients in studies. They may also benefit from their research through non-financial means, such as career advancement based on reporting of new scientific information and academic recognition through association with successful research.

These dualities may not themselves result in harm but may raise concern because of their potential to do so. In dealing with potential or actual conflicts, significant financial interests in human subject research should be disclosed to regulators as required by statute or regulation, to research funders or sponsors, to the editors of any publication to which a covered individual submits a manuscript concerning the research, and in any substantive public communication of the research results, whether oral or written.

Clinical researchers may influence study design (including selection of study drug doses and comparison with placebo or active comparator), patient selection, data collection and analysis, adverse event reporting, or the presentation and publication of research findings.

There is an obligation on both the researcher and the ethics committee to assure an adequate study design to accomplish the study objectives. Where dualities arise – as in the examples mentioned above – special arrangements may need to be created to separate the decision making functions that could be at odds. These will often include the appointment of independent researchers to approach and interact with participants, arm's length processes to collect, store and analyse data and to monitor safety, and the development of clear policies regarding publication or dissemination of results. The complexity of these arrangements will depend on the nature of the duality and the structure of the research project itself.

6.7 Payment to investigators, departments or institutions

The benefits gained by a clinician from the conduct of an industry sponsored clinical trial should be subject to review and approval by an appropriately constituted ethics committee. Adequate compensation should be provided for personal expenses arising from the trial, including reimbursement of practice expenses where applicable. Further, the amount of compensation must reasonably relate to income or time lost and should be administered under a formal contractual arrangement which is open to scrutiny. All remuneration should be paid into a fund used to finance the execution of the study. Other uses of these monies must adhere to institutional arrangements.

Financial incentives for the recruitment of patients, whether in the form of payments on a per capita basis or of other arrangements directly raise the possibility of a conflict between the clinical responsibilities of a physician and his or her financial gain. For this reason, such arrangements should be specifically approved by a responsible ethics committee and care should be taken that subjects are included in the trial only according to the approved protocol and inclusion is not influenced by the payment system.

Research projects conducted by private investigators without institutional affiliations may pose additional problems. This is because on the one hand, surveillance and monitoring of the conduct of such projects is more difficult and on the other, that the investigators do not have access to the protection of such institutions. Where possible, research projects conducted by private practitioners should include investigators with institutional affiliation and be assessed by an ethics committee associated with that institution which is also responsible for monitoring and oversight of the research. In addition, funds associated with the project should be distributed in accordance with the contractual arrangements approved by the ethics committee and conform to the normal requirements of the institution. Where a formal institutional attachment is not possible an alternative arrangement should be made which also involves ethics committee review and oversight and clearly defined and transparent processes for the management of funds. The nature of the compensation to be paid to the investigators should be declared in the explanatory statement provided to potential volunteers.

Grants of money or equipment by pharmaceutical companies to hospitals, health care centres and universities specifically for the purposes of research are generally acceptable but should always be made to the institution and not to individuals, and should be appropriately acknowledged in research and other publications. If the donation is linked to, or contingent upon, a clinical trial or specific research project, a formal contractual arrangement which is open to scrutiny should be in place.

Key points

- Any research project conducted by private practitioners should include an investigator with an institutional affiliation and be assessed by an ethics committee associated with that institution or some other arrangement that ensures ethics committee review and oversight and clearly defined and transparent processes for the management of funds
- Payment arrangements should be approved by a responsible ethics committee.
- Research grants from industry should be made to the institution and not to individuals and should be appropriately acknowledged in research and other publications.

6.8 Publication of results (See also 5.8)

Before a sponsored study commences, the sponsor and principal investigator(s) must agree upon access to any data from the study and how these are to be used, including publication. Data publication in a refereed journal is expected. This should be clearly stated in the protocol and other relevant documents and in submissions to ethics committees.

It is desirable that responsibility for decisions concerning publication of results should include investigators without commercial conflicts of interest. Decisions should be made without undue influence from the sponsoring company. With multi-centre trials, it is desirable that analysis of the results and preparation of results for publication are undertaken by a committee of the investigators independent of the sponsoring company. It is important that negative as well as positive results are published.^{103 104} Financial and other support must be acknowledged in publications, as should associations with sponsoring companies and other dualities of interests.

While these conditions are desirable they are often difficult to achieve in practice. In sponsored studies principal investigators may face dualities of interests as a result of being employees of the sponsoring company or having direct or indirect, pecuniary or non-pecuniary interests linked to the trial outcomes. In multi-centre trials it is often only the sponsoring company that has access to consolidated data. Although undesirable, members of data management boards may also face dualities of interests as a result of their relationships with sponsoring companies. It is often difficult for authors to have papers reporting negative results accepted for publication. Because of the wide varieties of dualities represented disclosures at the time of publication may be insufficient to ensure a disinterested presentation of data.

Both researchers and ethics committees should seek ways of addressing these complex issues with a view to providing public access to the most comprehensive and reliable data sets possible. The principles relating to disclosure and management of dualities of interests articulated above should be instituted at the level of both ethics committee review and publication. If a study is likely to have clinical relevance a commitment to publish results should be a condition of both agreement to participate by researchers and approval by ethics committees. Such publication would normally take the form of articles submitted to peer reviewed journals. However, it is increasingly possible for data to be made available for public scrutiny through web publication or related resources. In particular this may be an effective way of publishing negative results.

Key points

- Responsibility for decisions concerning publication of results should include investigators without commercial conflicts of interest, and decisions should be made without undue influence from the sponsoring company.
- Negative as well as positive results should be published.
- It should be a condition of both agreements to participate by researchers and approval by ethics committees that there is a commitment to make publicly available all results, especially those potentially relevant to clinical practice.

6.9 Responsibilities of medical and other clinical practitioners as members of ethics committees

Individuals may be called upon to become members of ethics, research or drug committees and should make their particular expertise available when asked to do so. Committees are often asked to consider applications which have been developed jointly by investigators and industrial sponsors as local projects or parts of multi-centre trials. Following the accepted processes of such committees, individuals who are personally involved in these projects should absent themselves from discussions within committees of which they are members. Where a committee is to discuss a project involving an industrial partner with which an individual has a present or previous relationship that could raise the possibility of a conflict of interest, this should be openly declared; in these cases, it is the responsibility of either the committee itself or another body identified by the COI Committee to decide whether any additional steps need to be taken.

Ethics committees have a responsibility to ensure that trials are conducted in accordance with national standards, as set out in various statements, including the NHMRC Statement on Human Experimentation. The main principle to be followed is that the likely benefits of the proposed experimentation are reasonable in terms of any risks or potential discomfort to participants, and that consent for participation is freely given. The questions that should be addressed by ethics committees naturally overlap with those mentioned above for medical practitioners. They include:¹⁰⁵

- What is the regulatory status of the drugs to be used in the study?
- Is the design of the study appropriate to its aims and objectives? Is the study likely to provide an answer to the questions being asked? Are doses and durations of therapy consistent with those used in previous applications of the drug?
- Does the protocol include a clear statement of the number of participants to be enrolled in the study, the proposed method of recruitment and selection of participants?
- Do pre-clinical and clinical data indicate that the risks associated with the proposed use of the drug or devices are acceptable? What procedures are proposed for monitoring safety? What are the criteria according to which the trial is to be stopped in the event of new data regarding safety or efficacy becoming available?
- How is consent to be obtained? Have special provisions been made for the protection of vulnerable groups or individuals? Will participants be adequately informed about the implications for existing treatments that they might be receiving?
- Are there resource issues that might affect the conduct of the trial or its outcomes? Do researchers face potential conflicts of interest? Are relevant dualities of interest to be disclosed to potential participants?

Chapter Seven

Issues affecting medical students and postgraduate trainees

7.1 *Introduction*

Many of the issues raised previously and recommendations made apply to students at both the medical student and postgraduate levels of their training as well as to their teachers. For example, issues concerning travel and receipt of gifts, and responsibilities of researchers and professional and other organisations apply equally to students and to other members of the health professions. There are, however, some additional issues that arise in the educational setting to which attention should be drawn.^{106 107}

There is evidence that pharmaceutical promotion to medical students and postgraduate trainees is widespread and that, at least in the latter case, it is effective in influencing behaviour. Students may be particularly vulnerable to approaches by industry representatives because they are not aware of the issues involved, they have not developed the critical faculties necessary for evaluating them and, having limited resources, find small gifts and other perquisites attractive.¹⁰⁸

It should be one of the objectives of curricula in the health sciences to assist students to develop attitudes, habits and practices in relation to industry that are based on clearly articulated values and are open to reflection and review. It is also important to establish a broad culture which values ethical reflection and cultivates sensitivity to community concerns regarding this subject.

Key points

- The issues arising in relation to individual practitioners and researchers apply equally to students, trainees and teachers.
- Occasional additional issues arise in relation to the training setting itself.

7.2 *The need to develop a culture that fosters critical attitudes and prepares for a professional working life as a clinician or researcher*

The training setting provides an environment within which issues can be raised regarding ethical values and standards of behaviour. Students should be encouraged to develop an ability to scrutinise professional behaviour and industry practices and to assess critically the information they receive from all sources. Training programs, including medical student and postgraduate curricula, should include discussions about the role of industry in relation to the health professions, about the nature and management of dualities and conflicts of interest, and about how to evaluate and interpret material presented from industry.

Attention should be given to the cultural environment within which training takes place. Educational institutions, professional organisations and individual practitioners involved in training should seek to set appropriate examples through their own practices. This may require modification of long-accepted practices such as a reliance on pharmaceutical sponsorship of grand rounds and other activities.¹⁰⁹ It may be helpful for educational

institutions to consult their Conflict of Interests Committees to assist with the development of practices and policies that are appropriate in view of their educational responsibilities.

Hospitals sometimes encourage the use of certain pharmaceuticals or devices or restrict the use of others after negotiating with manufacturers or distributors in relation to cost. These actions may be interpreted, especially by students and trainees, to mean that the products supported have greater efficacy or safety than alternatives available in the community. Practitioners involved in training and institutions should ensure that such arrangements are not misinterpreted by students.

Key points

- Training programs should include discussions about the role of industry, dualities and conflicts of interest, and the evaluation and interpretation of industry material.
- The role of institutional policies and the practices of individual clinicians, teachers and mentors in shaping the behaviour of students and trainees should be recognised in the development of curricula.

7.3 Interactions with pharmaceutical representatives

Students should be wary of interactions with pharmaceutical representatives and should consider carefully how they wish to conduct such interactions throughout their future working lives.¹¹⁰

The use of gifts of no educational or informational value to influence students or trainee practitioners should be discouraged. Students should not accept such gifts. Hospitals should seek to discontinue the practice of pharmaceutical company-funded lectures and lunches.¹¹¹

Key point

- Pharmaceutical representatives should not offer, and students should not accept, promotional materials or gifts.

7.4 Gifts, travel and attendance at meetings

In general it is better to refuse gifts of any kind. This includes support for student organisations and publications. Occasional exceptions may be justified, such as support by industry in some cases for conferences or travel or student exchange schemes. The student society or university or hospital Conflict of Interests Committee should be consulted when there is uncertainty. Reimbursement should be through relevant organisations, and should not be made directly to the individuals involved. The principles described above apply also to students.

7.5 Need for specific policies regarding students

Policies need to be devised by the Conflict of Interests Committee regarding the management of issues relevant to students and trainees and their teachers. These may differ from setting to setting. For example, universities and medical schools may need to give consideration to sponsorship of meetings and grand rounds whereas individual practitioners involved in training may need to review their personal approaches to the use of promotional materials.

Appendix 1

Tools

The following four generic “tools” are designed for health professionals working individually as clinicians, as members of clinical teams, as teachers and researchers, and as committee members, employees of and advisers to organisations such as professional colleges and societies, hospitals, universities, community and for profit organisations.³ Their purpose is to assist them to:

- recognise when there could be a real or perceived duality or conflict involving interests of the profession and those of for profit organisations;
- distinguish between a duality and a conflict of interest;
- manage possible and established conflicts of interest; and,
- confirm that they are comfortable about establishing, continuing or changing the terms of a relationship with a for profit organisation.

These tools may be adapted to suit more specifically the needs of individuals and groups of practitioners within particular organisations and institutions.

1. Tool 1: Identification of dualities

Key question

“Might there be duality involving professional interests and those of a for profit organisation?”

Definitions

- An “interest” is a commitment, goal or value arising out of a social relationship or practice.
- A “duality of interest” arises when two or more interests coexist. They may or may not be in conflict, depending on specific circumstances.
- A “conflict of interest” arises when two coexisting interests are in conflict with each other.

Specific questions

- Are there any potentially conflicting interests in this particular association with this for profit organisation?
- Might some professional colleagues consider that there could be conflicting interests in this association?
- Might some lay persons (e.g. family, friends, students, patients, community members) consider that there could be conflicting interests in this association?

³ “For profit” organisations include pharmaceutical, herbal, complementary and alternative medicine, biotechnology, medical device and appliance organisations, pathology and imaging service providers, hospitals and providers of services to ambulatory patients, consumer and other community organisations, and to organisations providing research and teaching.

- Might the relevant professional college or society consider that there could be conflicting interests in this association?
- Might the relevant employer or funder consider that there could be conflicting interests in this association?
- If the answer to any of the above is yes, has the matter been discussed with:
 - those who might perceive the existence of a duality of interest, especially professional colleagues in colleges and societies?
 - the college, professional society or institution's Conflict of Interests Committee?

Tool 2: Identification of conflicts of interest

Key question

Is this duality a conflict of interest?

Definition

- A duality may become a “conflict of interest” when a particular relationship or practice gives rise to two or more contradictory interests.

Key questions

- Are personal interests (pecuniary or non-pecuniary) in conflict with those of the community, including patients and research subjects?
- Might it be perceived that personal interests (pecuniary or non-pecuniary) are in conflict with those of the community, including patients and research subjects?
- Are the interests (pecuniary or non-pecuniary) of the relevant professional society or institution in conflict with those of the community, including patients and research subjects?
- Might it be perceived that the interests (pecuniary or non-pecuniary) of the society or institution are in conflict with those of the community, including patients and research subjects?
- If the answer to any of the above is yes, has the matter been discussed with:
 - those who might perceive the existence of a conflict of interest, especially professional colleagues in colleges, societies and institutions?
 - the college, society or institution's Conflict of Interests Committee?

Tool 3: How should this conflict of interest be managed?

Key questions

- Is there any reason that this conflict of interest should not be disclosed?

If the answer to this question is “yes”, it is highly recommended that the matter be discussed further with professional colleagues or a Conflict of Interests Committee before deciding not to disclose the matter of conflict.

- Has the matter of conflict been disclosed to relevant persons and institutions?

If not, why not? If not, it is highly recommended that the matter be discussed further with professional colleagues or a Conflict of Interests Committee before deciding not to disclose the matter of conflict.

- In the view of the individual involved, professional colleagues or a Conflict of Interests Committee, is disclosure alone an *adequate* means of dealing with this conflict of interest?
- If the answer is “no”, have the individuals involved, professional colleagues or a Conflict of Interests committee considered additional strategies to resolve the conflict of interest such as:
 - taking measures to withdraw altogether from one or more of the components which led to the conflict or from the situation in which the conflict occurs;
 - limiting involvement to those activities in which the individuals, professional colleagues or the Conflict of Interests Committee are sure that conflict no longer exists.

Tool 4: Additional questions to be considered before initiation, continuation or change of a relationship with a for profit organisation

- Are the individuals involved familiar and comfortable with the organisation’s corporate history and business practices, both here and abroad?
- Are they sure that the linkages or sponsorship will not result in any actual or perceived loss of professional independence, either during the association, or in the future?
- Is the proffered association or sponsorship genuinely and clearly linked to clinical care, research, further education or ongoing professional development?
- How would patients and their families and carers, students, professional associations, colleagues, employers, funders, friends, neighbours and the broader community regard any such association or sponsorship?
- Are the reasons for accepting this association or sponsorship compelling?
- Are the individuals involved prepared to be scrutinised by colleagues and by the public as to the propriety of this association or sponsorship?
- Would they be comfortable about this association or sponsorship being publicised on the front page of the newspaper, in films or in radio or television programs?

Appendix 2

Disclosures of members of the working party

Paul Komesaroff is a physician and researcher at Monash University, Director of the Monash Centre for the Study of Ethics in Medicine and Society and Ethics Convener of the Royal Australasian College of Physicians. He has in the past conducted collaborative research involving a number of pharmaceutical companies.

Shane Carney is a nephrologist and also a director of the National Prescribing Service Limited. He has conducted collaborative research involving a number of pharmaceutical companies and was a member of two advisory boards (Roche Products, Bristol-Myers Squibb).

Justin La Brooy is a physician and Clinical Director of Internal Medicine at the Royal Adelaide Hospital. He is an elected member of the Adult Medicine Divisional Committee of the Royal Australasian College of Physicians. He has conducted collaborative research involving a number of pharmaceutical companies in the areas of Infectious Diseases.

Martin Tattersall is a physician and researcher at the University of Sydney and Royal Prince Alfred Hospital. He has chaired the Australian Drug Evaluation Committee since 1997. He has had no pecuniary or non-pecuniary interest in relation to the pharmaceutical industry for more than 8 years. He enters patients on clinical trials but has not been a principal investigator on industry sponsored trials for several years.

Peter Greenberg is a general physician at the Royal Melbourne Hospital and Broadmeadows Health Service and principal fellow in the University of Melbourne Department of Medicine. He subscribes to 'Healthy Skepticism'. He has had no pecuniary or non-pecuniary interests in relation to any pharmaceutical or health technology companies for more than 20 years.

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