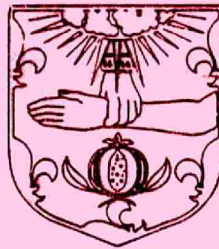


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CONFIDENTIAL

ROYAL COLLEGE OF PHYSICIANS

REPORT ON THE RELATIONSHIP BETWEEN
PHYSICIANS AND THE PHARMACEUTICAL INDUSTRY



A report drawn up by the Working Party of the
Royal College of Physicians.

Council : March 1986

REPORT OF A COLLEGE COMMITTEE

ON THE RELATIONSHIP

BETWEEN PHYSICIANS AND THE PHARMACEUTICAL INDUSTRY

INTRODUCTION

There needs to be a close and constructive relationship between the medical profession, which prescribes drugs for patients, and the pharmaceutical industry, which produces and markets them. Such a relationship brings benefit to patients, the pharmaceutical industry and our nation. It furthers the well-informed and safe use of the drugs which are available and it encourages the co-operative research essential in the development of new drugs. It contributes to our national economy because our research-based pharmaceutical industry has an enviable record of success in its export trade.

New drugs can be properly developed only if doctors evaluate them in patients. The pharmaceutical industry depends on independent and impartial clinical assessment of their drugs by physicians. This brings chemists and scientists in drug companies into a relationship with doctors which is necessary and constructive. It must, however, be conducted on strictly professional lines and neither party should abuse its position for financial or other gain or mislead the other on factual evidence about the drugs under trial.

Once a drug is developed and marketed a new relationship comes into existence between drug companies and doctors: a relationship in which companies in a competitive industry are trying to persuade the medical profession to prescribe their products while at the same time seeking the views of the profession about their efficacy and safety.

This document has been produced by a Working Party and approved by the College as a guide to physicians. It is not a critique of the pharmaceutical industry nor an examination of recent, well-publicised cases of apparent misdemeanour on the part of doctors although its origin lies in anxiety over those cases. It is intended to help doctors when they have to decide how best to handle their complex relations with the pharmaceutical industry.

There has been increasing concern in recent years about the relationship between doctors and the pharmaceutical industry in two respects:-

1) Prescribing. Doctors spend large sums of public money with fewer restrictions than in almost any other area of public expenditure. In return for the trust placed in him the doctor is expected to prescribe for his patients on the basis of the known efficacy and safety of drugs and it is essential that there should be no suspicion that his professional judgement may have been impaired by the receipt of gifts, hospitality, payment or subsidy from pharmaceutical companies.

Consultant physicians have an additional responsibility in as much as they are opinion leaders in drug usage and influence the prescribing patterns of their junior staff and of general practitioners in their area.

2) Clinical Research and Clinical Trials. There has been concern that some of the interactions between companies and physicians who are clinical investigators could compromise the autonomy and independence of the doctors reflecting on the integrity of the profession.

That these concerns in both fields are widely shared is apparent from comments made in three published documents:

i. The General Medical Council's booklet on "Professional Conduct and Discipline: Fitness to Practise" (1985) states: 'doctors should avoid accepting any pecuniary or material inducement that might compromise, or be regarded by others as likely to compromise, the independent exercise of their professional judgement in prescribing. The seeking or acceptance by doctors of unreasonable sums of money or gifts from commercial firms which manufacture or market drugs or diagnostic or therapeutic agents or appliances may be regarded as improper.'

ii. The Department of Health and Social Security has recently re-issued a notice on the acceptance of funding, gifts and hospitality which states that 'it is a basic principle in all parts of the public service that staff should not only be scrupulously impartial and honest but beyond the reach of suspicion.' The notice goes on to state that 'whenever an officer wishes to attend an educational conference or other occasion that is to be financed wholly or partially from promotional or commercial sources he should seek approval from the employing authority...'

iii. The Code of Practice for the Pharmaceutical Industry (1984) published by the Association of the British Pharmaceutical Industry (ABPI) states (section 19) that 'no gift or financial inducement shall be offered or given to members of the medical profession' but excepts inexpensive gifts, which in this context are presumably pens, diaries, books, rulers or similar articles related to a doctor's work.

The Code also states (section 20) that 'entertainment or hospitality offered....should always be secondary to the main purpose of the meeting,...not extend beyond members of the profession, be appropriate and not out of proportion to the occasion,...not exceed that level which the recipients might normally adopt when paying for themselves.'

Comments in television and radio programmes, in The Times, The Guardian, The Economist, a number of medical journals and by the Consumers' Association demonstrate that the media and the public expect and demand that the conduct of doctors, both as prescribers and investigators of drugs, should be above criticism.

ESTABLISHMENT OF THE WORKING PARTY

In the light of this concern, and because of the responsibilities that physicians have for the care and treatment of patients, the President called a meeting of Fellows on February 15th 1984. It was agreed that a College Working Party should be established to examine the relationship between physicians and the pharmaceutical industry. The emphasis of the enquiry was to be on the behaviour of physicians and not on the relationships between commercial organisations and clients.

MEMBERSHIP OF THE WORKING PARTY

Sir Raymond Hoffenberg President and Chairman
Dr OL Wade Honorary Secretary
Dr Barbara M Ansell
Sir Douglas Black
Dr AM Breckenridge
Dr TL Chambers
AJ Collier Esq
Dr MJ Denham
Miss Patricia Lamburn
Dr SP Lock
Dr DR London
Dr MF Muers
Dr PC Reynell
The Rt Hon Sir Kenneth Robinson
Dr PP Turner
Dr DW Wall
Dr DA Pyke
Registrar

In attendance

GMG Tibbs Esq
Mrs Myra Dawson
Mrs Sarah Green

College Secretary
Working Party Secretaries

PROCEDURE

The Working Party met twelve times. It received both documentary and oral evidence (see Appendix I).

EVIDENCE RECEIVED RELATED TO DRUG PRESCRIBING

The Working Party found that there was widespread acceptance that a pharmaceutical company has a duty to inform doctors of its products and collect information of clinical experience but the provision of social functions for doctors or other inducements to use its products was not considered to be part of that duty. The Working Party was reassured by the general standard of the relationship between physicians and the pharmaceutical industry but were aware of frequent examples of minor infringements of the accepted codes and a few examples of gross abuse.

Sponsored Meetings

There has been considerable and welcome development of Postgraduate Centres and of graduate medical education in the last 20 years. Possibly because the Department of Health was slow in giving adequate support to these activities, many years ago drug companies began to sponsor educational meetings. This help was welcomed but in some Postgraduate Centres almost every meeting now held is financially dependent upon funding by a pharmaceutical company. The Working Party was informed that the National Association of Clinical Tutors was concerned that at these meetings there was not always appropriate separation of promotional and educational activities.

Hospitality

The Working Party was given evidence that many doctors receive hospitality on a scale beyond that recommended in the ABPI Code. It was informed that doctors occasionally demand hospitality before agreeing to receive a drug company representative, and that this demand has even on occasions included hospitality for the doctor's wife. We heard of instances in which a company wished to show a promotional and/or informational film but doctors have made it clear they would not attend unless the film was shown and a meal organised at a restaurant of their choice.

If such a film is to be shown to resident medical staff at a hospital it is often understood that there should be accompanying hospitality from the Companies which may vary from in-house food and wine to a more formal dinner at a restaurant.

Gifts and Inducements

The offer of small gifts such as diaries, memo pads or pens by drug firm representatives to doctors is commonplace and acceptable but occasionally hints or demands for more substantial gifts may be made. We heard evidence of doctors being offered gifts or cash payments for every patient started on a product and of a recent approach to a number of physicians in which they were offered the sum of £500 for each five patients treated with a new non-steroidal anti-inflammatory drug. We are concerned that such inducements might influence the prescribing patterns of doctors.

Visits Abroad

The Working Party was informed that pharmaceutical companies receive many letters from doctors soliciting funds to attend meetings abroad. The majority of such requests are refused. Sometimes requests are accompanied by statements which indicate that the doctor is a frequent prescriber of the company's products and one doctor even stated that unless his request

was granted he would stop prescribing the company's products.

A television programme (Panorama) showed some doctors saying that they went to conferences only if they were held in locations of interest and hospitality was likely to be generous. Justification for holding meetings abroad is sometimes based on their ease of international accessibility and lower costs, but the Working Party was told of a meeting of physicians who all lived in one NHS Region which was organised by a pharmaceutical firm to take place on a Mediterranean island, and of other meetings abroad in which the professional and scientific content was minor in comparison with the social content and hospitality.

EVIDENCE ON CLINICAL RESEARCH AND CLINICAL TRIALS

The Working Party was given much evidence concerning the conduct of research projects and clinical trials. For the most part these studies are carried out with great sense of responsibility by members of the medical profession and the officers of the pharmaceutical companies. In such work the companies are usually seeking co-operation with physicians of high scientific and clinical repute; there is considerable mutual respect.

However, concern was expressed about some multi-centre trials and some trials carried out in hospital and general practice which had little scientific value and were of the nature of promotional exercises.

Large sums of money are now being paid to clinical investigators to conduct drug trials, and Research Companies are proliferating. Such companies arrange clinical trials and recruit healthy subjects or patients to take part in them. They act as links between the pharmaceutical companies and members of the medical profession and are often set up in

association with hospital clinic units or university departments. Other companies are purely commercial enterprises, independent of hospital or university associations. In some instances physicians are directors of or have a significant financial interest in the success of the company. Some trials are carried out making use of Health Service or University facilities, without proper recompense to the Authorities. Physicians may receive payment which is not made through the appropriate employing authority, whose facilities are being used.

The use of healthy volunteers for the testing of pharmaceutical products is increasing. A separate Working Party of the Royal College of Physicians is examining the special problem of "Research in Healthy Volunteers". Its report should be read in conjunction with this.

Publishing

Concern was expressed by some research workers that their right to publish data was sometimes restricted unduly in the commercial interest of the companies with whom they had collaborated.

Dissatisfaction was also expressed at the way some companies arranged for the proceedings of symposia to be published as supplements to the normal circulation run of a journal: the papers in these supplements are not always subject to the peer review process of the journal and the reprints are used by the company for promotional purposes. Such papers also contribute to undesirable duplication of published work.

CONCLUSION AND RECOMMENDATIONS DRAWN FROM THE EVIDENCE

General Principles

The Working Party believes that a close relationship between doctors and the pharmaceutical industry is important for the treatment of patients and for the future development and assessment of new drugs. Because this relationship is so important both to medicine and to the pharmaceutical industry, the Working Party recommends that Fellows and Members of the College ensure that their behaviour in relation to the pharmaceutical industry is always seen to be scrupulously impartial and honest.

The overriding principle is that any benefit in cash or kind, any gift, any hospitality or any subsidy received from a pharmaceutical company must leave the doctor's independence of judgement manifestly unimpaired.

When it comes to the margin between what is acceptable and what is unacceptable, judgement may sometimes be difficult: a useful criterion of acceptability may be "would you be willing to have these arrangements generally known?"

RECOMMENDATIONS

MEETINGS

(1) At Postgraduate Centres

- (a) The establishment of postgraduate centres, the development of graduate education and the increasing joint participation of doctors in scientific and educational meetings is much to be commended. It is convenient for many of these meetings to take place at lunch time or in the evening and it is reasonable that light refreshment should be available but not necessarily at the expense of pharmaceutical companies.

(b) For the present we commend to all physicians the Code of

Practice of the National Association of Clinical Tutors (see

Appendix II). The Code insists that the programmes and the

choice of speakers are in the hands of clinical tutors and

are independent of any sponsor. It insists that any display

of promotional material by a pharmaceutical company is limited

and kept apart from the educational and scientific part of the

meeting. It allows a pharmaceutical company which sponsors a

meeting to provide modest refreshment in the form of a working

lunch or a buffet supper. It is not acceptable that the cost

of entertaining non-medical guests should fall on a sponsor.

The expenses and fees paid to lecturers must be moderate. The

Code recommends that no film be shown without a consultant

whose specialty is featured in that film being present and

allowed to comment.

(2) For Resident Medical Staff in Hospitals

(a) The Working Party is concerned about meetings that take place

between pharmaceutical representatives and junior hospital

doctors because these junior doctors have considerable

influence on prescribing patterns in hospitals and may not yet

have the experience necessary to assess new products critically.

These meetings often take place on an ad hoc basis in which

representatives come to a hospital hoping to find a doctor

who is free to be interviewed.

We recommend that such ad hoc meetings should be discouraged

and that meetings should take place only by appointment,

preferably with the agreement of the supervising consultant.

We would prefer to see pre-arranged presentations by a

representative to joint meetings of junior and senior doctors where open and critical discussion can take place. Pre-registration house doctors should be approached only with the permission of a supervising consultant.

(b) Other meetings of scientific or educational merit for junior medical staff should be arranged in accordance with the Code of Practice of the National Association of Clinical Tutors and should take place within a hospital or University setting. If promotional material is displayed an independent consultant should be present. If such meetings are held outside a University or hospital they should conform with the above recommendations.

(3) Meetings and Conferences organised by or with the help of Pharmaceutical Companies

(a) These vary from conferences of high scientific value to meetings which are patently promotional exercises. The distinction rests primarily on the quality and independence of the scientific programme. Physicians should participate in and attend only meetings of educational or scientific value, the content of which has been selected independently of the sponsor.

(b) International meetings may be held at locations which, although exotic, are convenient for access of doctors from a number of countries, but the attractiveness of the venue is not of itself a good reason for attendance. The criteria of educational or scientific value and independent selection of contributions should be paramount.

- (c) A physician may accept fees or travelling or other expenses for attending a meeting but the primary invitation should come from the organising body or delegate of an organisation, eg a university department.

Pharmaceutical support for scientific and educational meetings is invaluable, but sponsorship of speakers and attenders should be decided independently and payment should not be arranged directly between a pharmaceutical company and a physician.

Companies should be encouraged to make their donations for these purposes to the organising committees and proper acknowledgement of their support should be made. If a company offers travel funds in the form of scholarships, its name may be indicated but applications for such support should be submitted to the organisers and the selection made independently by them and not the company.

- (d) Payment of travelling or other expenses by the organisers for the spouse of a physician attending a meeting is not normally acceptable.

HOSPITALITY, GIFTS, PAYMENTS AND INVESTMENTS

(1) Hospitality

- (a) A physician should not accept inordinate or excessive hospitality from any pharmaceutical firm. The borderline of acceptability is not easy to define. The provision of modest refreshment at a conference would be construed as reasonable; a lavish private dinner party at a restaurant would not. A pharmaceutical firm should not be expected to extend hospitality

to the spouse of a physician.

- (b) The Working Party believes that medical students, pre-registration house officers and all trainees should be made aware during their training of the dangers of compromising their professional judgement by accepting or demanding inordinate hospitality or other favours from pharmaceutical companies.

(2) Gifts and Payments

- (a) It is unacceptable for a physician to receive any gift or other inducement from a pharmaceutical company beyond those specified in the Code of Practice for the Pharmaceutical Industry (ABPI 1983) which are "inexpensive and relevant to the practice of medicine". He should not receive payments from a pharmaceutical company for seeing their representative, for sending letters to journals or for reporting adverse reactions to drugs, this last being part of normal clinical practice.

- (b) Reasonable payment to a physician for giving an expert opinion to a company is acceptable if the physician gives time and trouble to dealing with it. If such work is carried out in normal working hours for which the physician is already being paid, no additional payment should be accepted.

(3) Consultancy Fees

- (a) A physician may act as consultant to a pharmaceutical company. The arrangements, which should be agreed in advance, should be

those of any business contract and may include fees and reimbursement of travel and other expenses. If he is a full-time employee of a Health Authority or a University he must obtain permission from his employer to enter such a contract and always declare his interest in the Company. It is inappropriate for him to receive additional payments unless the work for the company is clearly done in his own time. It is his duty to ensure that he always declares his interest in the company. When this is not the case, fees must be paid into a special departmental account and the monies may be used to support research projects or to fund attendance of staff at scientific or educational meetings. Employing authorities should be informed about such transactions and the accounts supervised by their financial officers to obviate any suspicion that the account is used as a means of diverting payments from pharmaceutical companies to support inappropriate personal travel or other expenses.

RESEARCH PROJECTS AND CLINICAL TERMS

(1) Contracts, Payments and the Responsibility of Physicians

(a) Physicians, pharmaceutical companies and ultimately our patients have much to benefit from the close co-operation of physicians with the officers of pharmaceutical companies in research projects and clinical trials of drugs. In providing opinions and services to companies the principles of confidentiality, honesty and decorum must prevail as in other professional activities. Legally binding contracts are essential and should be negotiated through professional colleagues in the pharmaceutical companies. The physician responsible for the project or trial is responsible for

advising his employer, for ensuring that proper accounting procedures are adopted with independent audit and for fulfilling all legal requirements. The Working Party recommends that the financial arrangements should be made through the finance office of a Health Authority or a University.

(b) The monies may be used to finance the execution of the study, which may require salaries of research workers, technicians, nurses or secretaries, the purchase of equipment and expendables, contributions to hospital or university overheads and funding of other research projects. In the view of the Working Party it is not acceptable for a physician to receive personal payment for carrying out a trial. Such payments may be made to Departmental accounts as detailed under section 3(a) on page 13. Payments must be reasonable in terms of the time and effort given to the trial, openly declared, and subject to the condition mentioned in 2(b) on page 16.

(c) It is the responsibility of the physician to ensure that:

1. The studies are of scientific merit and are competently planned.

2. The studies have the approval of an independent research ethical committee to whom all details of the financial arrangements are reported.

3. There is prior agreement with the company that the results may be submitted to journals of the physician's choice and that the company will not influence the publication of the

results of the trial. When the results of multi-centre trials are to be published, all physicians participating in the trial should see and agree the final draft of any paper.

4. Appropriate arrangements are made by the company to indemnify subjects or patients in the event of untoward harm arising because of the trial. (Negligence is, of course, a legal matter).

(2) Research Companies

(a) The Working Party recommends that Research Companies should come under the aegis of a University or Health Authority. There should be full and open declaration of financial arrangements and their work should be reviewed by properly constituted and independent research ethical committees.

(b) All arrangements with Research Companies must be considered with particular care by Ethics Committees in view of their intrinsic commercial nature. It is important that physicians involved in this form of research should not have a significant financial interest in the company.

Some research companies have recently advertised their capability of supplying patients suffering from specific diseases, eg of the liver or kidney. This practice should be monitored most carefully by the Ethics Committees and the welfare of patients must be safeguarded as recommended in the "Guidelines to Ethics Committees" published by the Royal College of Physicians in 1984.

(3) Declaration of interest

The Working Party believes a physician has a duty to declare his interest in a pharmaceutical company to ensure that opinions or decisions are seen to be free of bias. This is particularly important if:

1. He is a member of a committee, national, regional or local, considering matters of pharmaceutical concern, eg purchase of drugs, decisions on drug safety etc.
2. He publishes data which is the result of work with a company.

(4) Publishing

The Working Party commends the paper from the British Journal of Clinical Pharmacology, which is appended as Appendix III. The Working Party approves of the views expressed by the Editorial Board of the British Journal of Clinical Pharmacology concerning the publishing of papers presented at sponsored meetings. It is the view of the Working Party that offprints of such papers should clearly indicate that the papers were presented at a sponsored meeting and were not routinely published papers. It is desirable that the pagination of such papers is distinct from the normal journal pagination.

In accordance with recommendation 3a on page 13 such submissions should only be published if the meetings were of educational or scientific value and the content was selected independently of the sponsors.

CONCLUSION

The Working Party believes the recommendations made in this report substantially represent the present practice of most physicians and of those in training as physicians. However, in the light of the evidence it has received, it believes the publication of these recommendations will be welcomed.

ACKNOWLEDGEMENTS

We are grateful to the Council for Postgraduate Medical Education and the British Journal of Clinical Pharmacology for granting us permission to publish their guidelines.

APPENDIX I

ORAL EVIDENCE WAS GIVEN TO THE WORKING PARTY BY THE FOLLOWING

Dr VR Bloom	- Editor, Journal of the Royal Society of Medicine
Dr A Bowyer	- Association of Clinical Tutors
*Dr DM Burley	- Association of Medical Advisors to the Pharmaceutical Industry
Mrs Ruth Bycroft	- Chairman, National Association of Postgraduate Educational Centres Administrators
*Dr J Clifford	- Association of Medical Advisors to the Pharmaceutical Industry
Mr Philip Cox QC	- Chairman, ABPI Code of Practice Committee
Dr CT Dollery	- Department of Clinical Pharmacology Royal Postgraduate Medical School
Dr JG Domenet	- Ciba Geigy
Mr JJ Dower	- Deltakos (UK) Ltd.
Rev Prof GR Dunstan	- Department of Theology, University of Exeter
*Dr O Gillie	- Medical correspondent of the Sunday Times
Dr EL Harris	- Deputy Chief Medical Officer, DHSS
*Dr A Herxheimer	- Department of Pharmacology, Charing Cross Hospital Medical School
Dr BH Mascie Taylpr	- St. James's University Hospital, Leeds
*Dr O Morton	- Association of Medical Advisors to the Pharmaceutical Industry
*Dr MD Rawlins	- Department of Clinical Pharmacology University of Newcastle
Dr PR Read	- Hoechst, UK, Ltd.
Dr ES Snell	- Association of the British Pharmaceutical Industry (ABPI)
Dr A Thillainayagam	- Manchester Royal Infirmary
Dr P Turner	- Department of Clinical Pharmacology St. Bartholomew's Hospital Medical School
Sir John N Walton	- General Medical Council

* Also supplied documentary evidence.

APPENDIX I - continued

DOCUMENTARY EVIDENCE WAS RECEIVED BY THE WORKING PARTY FROM

Dr S Brandon - Department of Psychiatry, University of Leicester

Dr GM Besser - Chairman of Ethical Committee, St. Bartholomew's Hospital

Dr BW Cromie - Hounslow

Dr B McConkey - Dudley Road Hospital, Birmingham

Dr RN Smith - Glaxo Group Research Ltd.

The Working Party also received a copy of 'A guide to ethical principles in the relationship between physicians and the Pharmaceutical Industry' prepared by a sub-committee of the Royal Australasian College of Physicians, 30 April 1984.

APPENDIX II

THE RELATIONSHIP BETWEEN POSTGRADUATE MEDICAL CENTRES AND PHARMACEUTICAL HOUSES

Representatives of the Association of the British Pharmaceutical Industry, the National Association of Clinical Tutors and the Advisory Committee of Deans of the Council for Postgraduate Medical Education in England and Wales have agreed that:

1. Meetings sponsored by a pharmaceutical house may be allowed in a postgraduate medical centre subject to the decision of the clinical tutor.
2. Arrangements for all sponsored meetings should always be made through the clinical tutor. Staff from the sponsoring pharmaceutical house should be invited to attend.
3. Some vetting of lecture material and films should always be undertaken.
4. An independent opinion by a doctor sufficiently experienced in the topic should always be available at such meetings.
5. Publicity by the pharmaceutical house is allowed but should be separate from the educational content of the meeting.
6. Sponsorship by the pharmaceutical house should be limited to a grant paid to the Postgraduate Dean or to the provision of light refreshments and the printing of programmes. Meetings sponsored in other ways cannot be approved under Section 63, but may be recognised for the postgraduate training allowance on application by the Postgraduate Dean to the Department of Health and Social Security.

Council for Postgraduate Medical Education in England and Wales
7 Marylebone Road
London NW1 5HH

Revised May 1978

Reaffirmed 1985

APPENDIX III

Statement by
British Journal of Clinical Pharmacology

Supplements

The British Journal of Clinical Pharmacology is willing to consider publishing Supplements at the request of a sponsoring organisation. The papers included will normally have been prepared for oral presentation at a symposium, but manuscripts submitted for publication should adhere to the format of original papers published within the Journal itself. However, review papers covering the background of an area of pharmacology or therapeutics and serving as an introduction to original papers can be included where appropriate in a Supplement. Sponsors and authors are asked to give some thought to the potential problem of duplicate publication in preparing a manuscript on data that has already been published or is being prepared for publication elsewhere. Although the Editors realise the advantages of collecting together up-to-date information on a new drug, they are committed to minimising duplicate or repetitive publication. Problems which are anticipated in this area should be discussed with the Editorial Secretary.

The Editorial Board insists upon retaining editorial control of Supplements, with the right to reject any paper considered to be of an inadequate scientific standard. The sponsors are therefore asked to discuss with the Editorial Secretary nomination of a member of the Editorial Board to act as one of the editors of the Supplement (most Supplements have two or three editors, but at least one should represent the Journal). This can be most easily achieved by ensuring that an appropriate member of the Board participates in the symposium, and problems would therefore be avoided if an approach to the Editorial Secretary is made at the time of planning the symposium rather than at a later stage.