Not for publication

84/07

Private & Confidential

Evidence to the Royal College of Physicians Working Party on "Ethics of the Relationship between Physicians and the Pharmaceutical Industry"

M.D.Rawlins, BSc, MD, FRCP
Professor of Clinical Pharmacology
Honorary Consultant Clinical Pharmacologist

Wolfson Unit of Clinical Pharmacology,
The University,
Newcastle upon Tyne

1. Introduction

When prescribing drugs, doctors spend large sums of public money (approximately £1400 million during 1983-84) with fewer restrictions than in almost any other area of public expenditure. In return for the trust placed upon the medical profession patients, the general public, parliament and the government can reasonably expect doctors to balance risk, benefit and cost when prescribing drugs.

Most prescribed medicines are the products of the pharmaceutical industry whose prime responsibility is to make profits for its shareholders by research, development, production and marketing of its discoveries. Individual companies compete for their share of the market, predominantly on the basis of claims of safety and efficacy, by vigorous promotion of their products to the medical profession. Only few studies have been published showing the relationship between advertising effort and prescription sales, but the industry clearly believes that such an association exists, and Schwartzman (1976) has calculated highly significant correlations between promotional expenditure and sales both between companies and between products.

In assessing the value of various sources of prescribing information used by general practitioners, UK studies (Sainsbury Report, 1966; Eaton & Parish, 1976) have shown that there is a sharp distinction between sources of knowledge about the existence of a drug, and about its usefulness. In the case of the former, general practitioners rely predominantly on the pharmaceutical industry for information, whilst for the latter they depend on articles in journals and the opinions of local consultants. Physicians therefore have a special responsibility in relation to drug promotion: first, they and their junior staff are prescribers of drugs and

thus consume public funds; second, and probably of greater importance, they are "opinion-leaders" since in many areas of therapeutics they are the editors and referees of learned journals, they are the authors of journal articles, they lecture at meetings organised at postgraduate centres and elsewhere, and they provide examples of practical therapeutics for general practitioners to observe when patients are referred to hospital.

2. Direct Promotion

As with general practitioners, the main promotional thrust of the industry towards physicians and their junior staff is made by its sales force of representatives. Hospital reps will try to ascertain whether or not the physician or his firm use the particular product and, if not, reps will try to obtain a committment to try it out. The rep may offer to arrange a lunch-time film, together with refreshments, by the firm.

The physician may also be invited to attend, at the company's expense, a company-sponsored symposium in London or overseas. Such symposia have, in the last few years, become a common feature of the "launch" of a new product. They are usually chaired by prominent members of the medical profession, and although mainly promotional they include one or two non-promotional lectures for cosmetic reasons. The notorious Panorama programme featuring Carlo Erba's meeting in Venice to launch indoprofen (Flosint) was only one of many overseas "launch" meetings that pharmaceutical companies have organised in the past decade: Carlo Erba was just the one who was caught.

The proceedings of company symposia may be published either as a volume in its own right, or as a supplement to a learned journal. These are valuable

documents for the company because they can be used to demonstrate, particularly to general practitioners, the "academic credibility" of the drug. Some of these publications have had little scientific value, but their publishers have made considerable profits: where the publisher has been a learned Society, its members have benefited considerably.

The Working Party should also be aware that some sections of the pharmaceutical industry wish to see direct promotion of prescription products to the general public. In the UK, there are already precedents for this and the Association of the British Pharmaceutical Industry's Code of Conduct does indeed sanction direct contact with the non-medical press - where "the importance of such information and the existence of legitimate public interest in acquiring it may exceptionally justify holding a press conference or the issue of a press release". In the recent past, physicians have promoted products to the media during their launch (Medawar, 1984) .

3. Postgraduate education

Physicians play a major role in postgraduate medical education. Articles in journals written by physicians, and views expressed by them at postgraduate meetings, are important in providing general practitioners with knowledge about the indications and usefulness for a particular drug. Members and fellows of the Royal College of Physicians play an important part in such activities whether as general physicians or as specialists in various branches of internal medicine.

The work of Eaton & Parish (1976) provides information about attendance of general practitioners at medical meetings. According to the results of a questionnaire, the greatest attendance appeared to be at drug company meetings,

with attendance at local postgraduate centre meetings coming second. Physicians, particularly local consultants, are important and influencial speakers at both types of meetings.

Physicians are often organisers of, or attenders at, national or international meetings. The organisers of many useful scientific meetings may receive valuable financial sponsorship from a group of drug companies in return for no more than an acknowledgement in the programme. However, some organisers have allowed entire scientific sessions to be taken over by a single drug or company. Davey (1984), for example, has described how the 13th International Congress of Chemotherapy held in Vienna last year contained 22 out of 72 Symposia devoted mainly to single drugs. Doctors may also seek personal financial support from pharmaceutical companies to attend international meetings or congresses. Conversations with colleagues suggest that this is common, but individuals working within the industry have told me that they find these requests embarrassing most especially when they are made by distinguished people.

4. Research

There is considerable research contact and collaboration between physicians and the pharmaceutical industry. Physicians may undertake consultancy work for companies either on an ad hoc , or a contractual, basis. They may perform contractual research for a company with the prime purpose of generating funds either for their departmental, or their personal, use. They may participate in joint research projects with individual companies in areas of mutual scientific interest, and largely financed by the company concerned. They may also approach companies for financial support for their own personal research.

There must be few academic departments which have not obtained financial support from drug companies, and clinical pharmacologists by the nature of their discipline are probably able to attract funds more readily than most other physicians. Some departments of clinical pharmacology have established private companies to undertake contractual work with the industry; in some instances their profits revert to the institution, whilst in others profits go predominantly to the members of staff of the Department who own the company.

5. Discussion

Relationships between physicians and the pharmaceutical industry are thus complex and varied. It is obviously for the industry to promote its products to physicians particularly when a drug is launched because the company is the main source of information about its quality, safety and efficacy. Clinical studies with both new and established drugs invariably require collaboration between physicians and the industry and successful drug development in the UK requires this co-operation to flourish. Funds generated by collaborative research are, moreover, likely to become increasingly important to sustain academic research if the government's expenditure plans for higher education and the research councils remain unaltered.

On the other hand, physicians play a major role in shaping the prescribing of their colleagues in hospital and in general practice. For this reason, they are subjected to considerable pressures by pharmaceutical companies with the intention of obtaining approval and endorsement for particular products and for their corporate image. The ways in which this process is executed has been previously discussed in this evidence. However, although overt promotion is easily recognised, what appears to be "non-promotional" support for meetings and research

may carry as subtle promotional interest. Moreover, the weight of evidence from my own experience, from regional and national prescribind statistics, and from the continued use of various promotional techniques by the industry, all testifies to the fact that none of us is impervious to the pressures that the industry places on us.

I hope therefore that the Working Party will provide physicians with guidance on their ethical relationships with the pharmaceutical industry (Rawlins, 1984). I believe that this guidance should include three general features: first that physicians should be aware of the pressures that are placed upon them; second that physicians should avoid placing themselves under an obligation to a particular company to promote its products or its image; third that physicians should act, and appear to act, impartially when discussing and prescribing the products of individual companies. I also believe that the Working Party should offer specific guidance:

1) Under no circumstances should physicians promote a drug directly to the general public through interviews on radio, television or to the press.

2) Physicians should not accept any form of hospitality that accompanies drug promotion.

3) Physicians should not seek financial support from pharmaceutical companies for their expenses to attend scientific meetings.

4) When physicians publish work supported by a pharmaceutical company, they acknowledge this in the text.

5) All payments made by a pharmaceutical company to support research projects carried out in volunteers or patients should be included in the submission made to the local ethics committee before the project is started.

6) All funds received by a physician from a pharmaceutical company, irrespective of whether they are for departmental or personal use, should be declared to the local district health authority.

7) Physicians employed in full-time clinical or academic NHS practice should not undertake research for personal financial gain. Physicians who also hold part-time NHS consultant contracts should seek the approval of their local district health authority before undertaking research for personal financial gain.

8) Physicians should exercise considerable care before accepting invitations from drug companies to attend sponsored meetings. In particular, they should consider whether their participation is "cosmetic", whether the programme appears to be promotional, and whether its main attraction to them is relaxational rather than scientific. They should also seek the approval of their local district health authority for "study leave".

9) Before entering into a sponsorship arrangement with a pharmaceutical company for the support of an educational or scientific meeting physicians should ensure that both the content of the programme, and the conduct of the meeting, is free from a promotional bias. Recognition of the company's support should be limited to an acknowledgement in the programme

10) When a physician enters into a financial commitment with a company to undertake a clinical trial, only exceptional circumstances should prevent him from

fulfilling his/her obligations.

In addition to observing these guidelines, physicians-in-training should also be advised that:-

1) They should not introduce new drugs into their firm's practice without first obtaining the agreement of their consultant.

2) They should attend company-sponsored meetings only after seeking the advice of their consultant, and with the approval of their local district health authority.

3) They should meet representatives of pharmaceutical companies only with the agreement of their consultant. Furthermore, it would enhance their training if consultants were to be present at some of these meetings in order to increase trainees' critical awareness of the claims being made.

References

Davey, P. (1984) Comparative clinical trials of antimicrobial drugs. Journal of Antimicrobial Chemotherapy. 13;204-8.

Eaton, G. & Parish, P. (1976) Sources of information used by general practitioners. Journal of the Royal College of General Practitioners, 26:(Suppl 1), 58-64.

Medawa, C. (1984) The wrong kind of medicine? London: Consumer's Association & Hodder & Stoughton.

Rawlins, M.D. (1984) Doctors and the drug makers. Lancet, ii:276-278.

Sainsbury Report (1967) Report of the Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service 1965-67. London: HMSO

Schwartzman, D. (1976) Innovation in the Pharmaceutical Industry. The Johns Hopkins University Press, Baltimore and London.