The academic clinical pharmacologist and the Royal College of Physicians Report on the relationship between physicians and the pharmaceutical industry

The Royal College of Physicians set up a Working Party in 1984 to consider relations between physicians and the pharmaceutical industry because of anxiety over 'well publicised cases of apparent misdemeanour'. Its Report sets out to 'help doctors when they have to decide how best to handle their complex relations' with the industry. It says that physicians should ensure that their behaviour should always be seen to be 'scrupulously impartial and honest', and to this end, it suggests as a useful criterion of acceptability of benefits of any kind from industry, that the recipient consider the question, 'Would you be willing to have these arrangements generally known?'

In the case of research the Association of the British Pharmaceutical Industry (ABPI) and the British Medical Association have objected publicly to declaration of investigator's financial interests to Ethics Committees. Such interested parties are unwise to object unless they can produce support for their view from manifestly disinterested sources. It is unlikely that such support will be forthcoming. I do not believe that investigators' financial interests in research on human subjects can be an entirely private matter.

An academic clinical pharmacologist who wishes to practice in accordance with both the letter and the spirit of the College Report would certainly wish to consider specially the following items (I take them up in the order of the Report and offer some comments).

1. Meetings at Postgraduate Centres

Clinical pharmacologists will often be contributing to, or members of, organising committees in these centres. Meetings are commonly held either midday or evening and associated with a meal. This is reasonable. Participants are in the middle or at the end of a working day and a meeting is more relaxed and convivial, and so more intellectually profitable, if the ambience is agreeable. I have spoken at meetings in these centres and I have seen that, in programmes covering many weeks, each meeting is advertised as 'lunch/dinner by courtesy of company X'. This is not by chance because here and there has been a notice

indicating that a sponsor for the meal has yet to be found. The College 'regrets' the 'need' for such frequent sponsorship and advises that the Department of Health should encourage Health Authorities to contribute support to these meetings. The possibility that doctors might pay for their own food is not mentioned because, I suppose, it simply does not arise nowadays.

Moderation in all matters is counselled and the Code of Practice of the National Association of Clinical Tutors is commended and is reprinted as an appendix to the Report.

2. Resident Medical Staff in Hospitals

The Report expresses concern at the way in which company representatives penetrate hospitals. Clinical pharmacologists will commonly be members of hospital Drugs and Therapeutics Committees and so will have an opportunity to attempt to curb wandering representatives seeking to buttonhole junior doctors who 'have considerable influence on prescribing patterns in hospital and may not yet have the experience necessary for the critical assessment of new products'. No doubt, as in my experience, any guidelines to control representatives will be ignored. That Consultants have a duty to supervise prescribing of junior doctors and to educate them in the choice and use of medicines, especially of new medicines, and that the views of Consultants may, or should, command greater respect than those of company representatives, is not mentioned. For a moment it has crossed my mind that it is because this duty of Consultants is often 'more honour'd in the breach', but I have put it behind me as a subversive and unprofessional thought, though I have been told by Consultants, in moments of frankness, that they learn what is new from their house officers.

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

Clinical pharmacologists are often involved in these, and I have frequently been approached by physician colleagues asking me to suggest the names of companies who might be sympathetic to approaches for support. The Report advises

sensibly on the balance between scientific and recreational content, on exotic locations, on 'laundering' of money through, for example, academic organisers, and the unacceptability ('normally') of payment of travel or other expenses for physicians' spouses.

The recommendation that physicians should 'participate in and attend only meetings of educational or scientific value, the content of which has been selected independently of the sponsor' (my emphasis) seems to me impossible of realization. But the College considers these conditions as 'paramount'. Some pharmaceutical companies organise meetings of high scientific quality and their scientists play an often important role in planning the programme. This advice illustrates the difficulty, even the impracticability, of all-inclusive prohibitions in a field where standards vary so widely.

4. Hospitality

This should not be 'inordinate or excessive', but the 'borderline of acceptability is not easy to define'. Medical students and doctors should be made aware of the hazards of hospitality during their training. My experience, which may be exceptional, though I doubt it, is that the ordinary student has his tongue hanging out for hospitality and readily admits this in private, though he is quite prepared to bite the industrial hand that feeds him. But some older doctors will equally accept a visit to, e.g. Glyndebourne Opera, alone or in groups, with gratitude and even hope for the following year. In fact it is almost, even quite, impossible to provide lucid guidance on this topic as so much depends on the judgement of the recipient, and I see little or no possibility of control, except of the most flagrant, extravagant jamborees. But the Working Party does its best and may at least persuade physicians to think a little more about what they accept.

The Code of Practice for the Pharmaceutical Industry, published by its Association (and quoted here) advises that our profession should not be offered hospitality exceeding the 'level which recipients might normally adopt when paying for themselves'. I wonder if there has ever been a meeting sponsored by industry where the industrial participants were accommodated at the usual 5-star hotel and the clinical pharmacologists at a 3 or 4-star hotel? The Department of Health is quoted as saying that its 'officers' (Does this include doctors?) should obtain approval from their employing authority before attending an industry-promoted 'conference or other occasion'. This kind of advice induces feelings of unreality, but it is easy to see how

important it is to, e.g. purchasing officers (drugs, equipment) who can dispense great patronage—and so also indirectly could a clinical pharmacologist on a District Health Authority Drug and Therapeutics Committee or on a national drug regulatory committee.

5. Payments

Payments for expert opinions should only be charged for if the 'time and trouble' in dealing with the matter is 'outside normal working hours'. This seems a little naive where clinical pharmacologists who work closely with industry (the Report approves of close relationships) are concerned. Obviously they should not neglect their ordinary duties for such work.

6. Consultancies

Consultancies should be undertaken with 'permission from [the] employer' and fees should, again, only be accepted for work done outside normal working hours (see comment on 5 above).

7. Research Projects and Clinical Trials

Those that are done for industry should always be subject to formal arrangements. The employer of the physician or clinical pharmacologist should know of these and there should be independent audit by finance officers of the Health Authority or University. Sweetness and light, i.e. 'confidentiality, honesty and decorum' must prevail. 'It is undesirable for a physician to have any personal financial interest in studies carried out on patients under his care'. As far as I am aware it is commonplace for physicians and clinical pharmacologists to have just such interest, ranging from a straightforward fee (of which the patient knows nothing) to various less direct arrangements that bring personal profit. I do not know how stern the Working Party felt about this but I note that it had before it a guide to ethical principles by the Royal Australasian College of Physicians which in 1984 asserted this admirably purist principle. I wonder if this matter will be formally sorted out, or be informally and quietly ignored (here and in Australia). This matter could be an ethico-political time-bomb unobtrusively waiting to explode sometime in the future.

The report advises 'appropriate' arrangements to be made by the company to indemnify healthy subjects or patients in the event of harm arising out of a trial. This important matter should always, in my view, be before research ethics committees. Progress in this area is already considerable and likely to be further developed in

other places, e.g. The ABPI, and the Department of Health.

8. *Research companies*

Research companies that offer to conduct, under contract, studies on healthy or patient volunteers receive passing attention and a reference to the companion College Report on *Research on Healthy Volunteers*. In particular it is mentioned that companies selling clinical pharmacological studies to the pharmaceutical industry have advertised their capability of supplying patients suffering from liver or kidney disease, for (apparently non-therapeutic) pharmacokinetic studies. I do not know how patients are recruited for such studies, nor indeed even if they are actually being done. But if they are, the ethical, including financial, implications for the physicians who care for these patients, and for the patients themselves, must be a matter for concern, as indeed is the whole recent development of 'marketing' of human beings for drug testing. But, I suppose, if I had stable renal insufficiency and found I could make enough money to provide me with a lovely holiday by undertaking a non-therapeutic pharmacokinetic study or two, I might be annoyed if I was told that an Ethics Committee had said 'No'. On the other hand I do not wish to be 'marketed' by my doctor, and I should wish to know if he got a fee for recruiting me. I do not know what is actually happening in this area, but I suppose that any demand for such studies in subjects who do not need the drug in question must be for the purpose of including them in licencing applications to the regulatory authority. This area needs very close watching in my opinion.

9. *Declaration of interests*

Declarations of interests should be made by clinicians concerning their industrial relations,

and this is particularly important in publications (the New England Journal of Medicine now requires it) and where there is obvious possibility of bias, e.g. purchasing of drugs by institutions and service on official regulatory committees (where it is already required by the authorities).

10. *Publication*

Publication must be independent and not subject to veto by a commercial sponsor.

Conclusion

The Royal College of Physicians states that it believes that its recommendations 'substantially represent the present practice of physicians'. The somewhat hair-raising examples of unacceptable practice given in the Report are the exceptions, but they are sufficient to warrant its production. Clinical pharmacologists may welcome it as likely to help form professional standards, to raise them and to curb excesses. Of course the Royal College of Physicians has no sanctions, and could not easily have. But those who are in a position to exercise sanctions (The General Medical Council, and the Department of Health) will doubtless take note of the Report. It is in everybody's interest that standards be high and be seen to be so.

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