Fraud and malpractice in clinical research

Sir—In your article 'Fraud and malpractice in the context of clinical research', (January 1993, pages 45–6), the authors omit to address several very important issues.

They suggest that the adoption of *Guidelines on good clinical research practice* by the pharmaceutical industry will detect and prevent fraud.

Sadly, this is not so. These guidelines will help the company personnel to detect error. The authors suggest that an analysis of these errors will lead to the detection of fraud and yet all investigators do and will make mistakes in the completion of case record forms and study documentation. There may also be a legitimate disagreement between investigators, monitors and quality and assurance departments. The latter are usually not clinically trained in disease classifications and adverse events.

Some of these problems could be alleviated by using input from a principal investigator in any study. Great care must be taken to avoid false accusations or, even worse, persecution by well meaning clinical research associates before the suspicions are passed to the Director of the Association of the British Pharmaceutical Industry (ABPI).

The authors also suggest that inconsistencies be reported to an independent person. The Medical Director of the same company can hardly be described as 'an independent person'.

Finally, whereas all clinicians are governed by the General Medical Council, sadly not all pharmaceutical companies and few contract houses are bound by ABPI rules.

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The 'do not resuscitate' decision

Sir—We respond to the recent 'For discussion' item in the College *Commentary* (January 1993, pages 12–13; also revised and reprinted in this issue of the Journal, pages 000) on the subject of 'do not resuscitate' (DNR) decisions and the formation of defined policy for making a DNR order. We have, by means of audit, been piloting such a policy over recent months. The impetus for this was the 1991 report from the Chief Medical Officer [1]. Like others before us [2,3] we found poor documentation of any decision around the subject. We reviewed decision making practice in our hospital prior to initiating a trial policy by carrying out a cross sectional survey of all 351 hospital inpatients aged between 16 and 96 years. A decision not to resuscitate had been made in 61 (17%) cases. Reasons for the decision were given in 39 cases (64%) and whether this decision should affect other treatment in only four (6%). There was considerable discrepancy between the medical and nursing notes: 22 (36%) patients 'not for resuscitation' in the medical notes had no such entry in the nursing notes. Similarly six patients had DNR entries solely in the nursing notes. Only three of the 16 patients with untreatable metastatic carcinoma were excluded from cardiopulmonary resuscitation by their attending doctor. Two of five patients with chronic respiratory failure were excluded, and so were 47% of those with cerebrovascular accidents of any severity.

We are now reviewing the results of our policy, which incorporates regular review by senior staff, and hope to modify and improve it to take account of discussion with family members and paramedical staff. We now consider a regular six monthly review more appropriate as this takes into account the turnover of junior staff. This gives them the opportunity to become acquainted with the guidelines thus ensuring continued adherence to policy.

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2 Stewart K, Abel K, Rai GS. Resuscitation decisions in a general hospital. *Br Med J* 1990;**300**:785.
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Therapeutic conservatism

Sir—Griffin and Chew (*Journal* January 1993, pages 54–5) conclude that their data prove that as a result of the therapeutic conservatism of British doctors, '. . . patients are being denied the advantages of newer medicines'. A previous similar statement by Dr Griffin [1] attracted considerable attention in the lay press, but this is the first time to my knowledge that it has appeared in a forum which allows reply, and I welcome the opportunity. The conclusion quoted above is not in any way justified by the data presented in their article.

Griffin and Chew consider the rates of the prescribing of new products in different countries, although such a comparison is almost meaningless since new products vary from country to country. Between September 1988 and March 1991, the period to which the article refers, the British National Formulary [2] shows 245 new products (including dressings and nutrients). The majority (173) were merely new formulations of existing products. Of the 72 new drugs, 47 were 'me-too' drugs, from the same therapeutic class and of little added clinical value over existing products. Twenty-five were new drugs with possible therapeutic advantages, although this might be argued in the case of drugs such as dexfenfluramine or zopi-