progestogens desogestrel and gestodene.¹ Rawlins claims that the committee has to take on the responsibilities of peer reviewers with regard to unpublished information.² In this it presumes to act as both judge and jury, a single role that the United States Food and Drug Administration rightly refuses to assume. Presented with similar problems, the administration embarks on detailed public hearings, with the eventual publication of a comprehensive report.³ The necessity for such consultation is evident in the dissent from John Guillebaud, with his great experience of oral contraceptive prescribing⁴; Clifford Kay, who directed the Royal College of General Practitioners' classic investigation into the safety of oral contraceptives⁵; and W O Spitzer, whose transnational study was used by the Committee on Safety of Medicines in reaching its decision.⁶

In justifying the committee's decision Rawlins dismisses the methodological problems in the recent studies of venous thromboembolism in women using the pill yet attempts to undermine the importance to be attached to the accumulating data on stroke and myocardial infarction.² He also denigrates the importance of changes in lipoprotein concentrations induced by oral contraceptives, on the basis of a review that hardly discusses this issue. The risks of stroke and myocardial infarction are a critical consideration. Women of childbearing age are 15 times more likely to die of arterial disease than of venous thromboembolic disease, and the third generation pills were introduced specifically to reduce the risks of arterial disease in women using oral contraceptives. This is acknowledged in the fact that the European Committee for Proprietary Medicinal Products is to defer a decision on the safety of the third generation pills.

Unfortunately, the precipitate action of the Committee on Safety of Medicines may have seriously damaged our chances of learning just what effect the new pills have on arterial disease. More importantly still, it may also have irrevocably undermined any further research and development on oral contraceptives by the pharmaceutical industry. What justification can there be for such work if it is to be rendered irrelevant overnight by a single rush to judgment?

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Was Committee on Safety of Medicines' advice arrived at lawfully?

EDITOR,—Michael Rawlins seeks to defend the Committee on Safety of Medicines' recent advice on third generation oral contraceptives.¹ Prescribers should be aware that the committee's published advice may not have been arrived at lawfully because of questions regarding process and whether the advice was disproportionate and beyond the committee's authority.

Consideration of the issue seems to have been hasty and not based on all relevant data. Spitzer *et al*'s analysis was made available on 9 October and Jick *et al*'s manuscript on 11 October, and

members of the committee were given 30 minutes to consider the data on 13 October.² Rawlins's refutation of "undue haste" is unconvincing. Furthermore, Rawlins suggests that there are three relevant studies. That is incorrect. Farmer *et al* published a study recently,³ and have subsequently conducted further relevant analyses. The committee does not seem to have considered these data.

The committee's advice may not be proportionate. The statement in the "Dear Doctor" letter that third generation oral contraceptives should "only be used by women who are intolerant of other combined oral contraceptives"⁴ does not seem to be supported by the totality of data available to the committee.

The statutory framework within which the committee exists provides only for its giving advice to the licensing authority. As the committee disseminated advice unconnected to regulatory action it is arguable that it was acting beyond its authority.

Rawlins has set an unenviable precedent since the committee's advice was not accompanied by licensing action affecting the licensed products referred to in the "Dear Doctor" letter. The licensing authority has a statutory duty to take licensing action on issues of drug safety. Thus in the continuing absence of regulatory action one must conclude that the authority considers that there is no concern over safety. To use Rawlins's phrase, the position is "frankly absurd." If there is a credible concern over safety the licensing authority should take appropriate licensing action. If the concern is not credible then the committee's advice should be withdrawn. Rawlins was generous enough to "apologise unreservedly" about the manner in which the advice was disseminated. In the continuing absence of licensing action showing confidence in the committee's advice it seems that further apologies are to be expected.

Recent events suggest that regulatory consideration of issues concerning drug safety in Britain falls short of acceptable standards. An independent inquiry should examine the failures of safeguards in the regulatory system. Improved quality assurance procedures are needed, perhaps including guidelines on good pharmacovigilance. British patients and doctors should not again be subjected to scares over drug safety that arise from processes that seem unlikely fully to have met relevant scientific and legal standards.

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Placebo effects

Psychological, sociological, and general practice research may elucidate effects

EDITOR,—While I agree with E Ernst and K L Resch that the benefit of an intervention is based on "the optimisation of both the specific treatment effect and the true placebo effect," I question their conclusion that the best way to research the complexity of the true placebo effect is to include an untreated control group in placebo controlled trials.¹

The controlled trial is responsible for the concept of the placebo effect, but there is no evidence that it is the best research method to elucidate the

concept. We might instead look to psychological research, which shows people's need to make sense of their illness, gain some control over it, and build hope and self esteem²; to sociological research, which describes how people canvass opinion from many sources before making decisions about treatment options³; and to general practice research into the therapeutic relationship⁴ and the importance of sharing lay and medical understanding in the consultation.⁵ This sort of research, most of which uses qualitative methods, allows us to take a broader view of the factors that optimise a given intervention. It suggests that interpersonal relations and communication are of prime importance in health care.

Once we have this wide perspective, which goes well beyond that of biomedical medicine, it is possible and necessary to design pragmatic trials to learn how to maximise these central therapeutic skills that make up the placebo effect. Complementary medicine, because it challenges the scientific paradigm and insists on treating each patient as an individual, undoubtedly has much to teach us in this. However, a research programme that is limited to placebo controlled trials is unlikely to be fruitful.

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Concept of placebo should be discarded

EDITOR,—E Ernst and K L Resch state that the true placebo effect can be measured in trials that compare an untreated group with a placebo group.¹ They assume that non-specific effects other than the true placebo effect produce the same response in the two arms of a trial. This assumption may not, however, be true. Some effects, such as increased skill of an investigator and white coat hypertension, which the authors call "other time effects," could well be different in the two groups. Furthermore, unless the outcome was survival it would be difficult to measure the effect in the untreated group without interference with the patients.

Thus it may not be justified to speak of a true placebo effect.² One could speak of placebo maximising and placebo minimising groups rather than placebo groups and untreated groups.³ It might, however, be preferable to discard the placebo concept altogether since defining it in a consistent way that distinguishes it from so called specific treatment effects seems impossible.² One should therefore focus on the choice of outcome measure and the magnitude of the effect rather than on interventions that are difficult to define.² As an example, when compared with usual obstetric care, the presence of a support person during labour has dramatic effects on the use of analgesics, anaesthesia, episiotomy, and caesarean section and the incidence of severe postpartum depression.⁴ Thus, what one chooses to call such an intervention is unimportant.

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Placebos used not to be used in studies

EDITOR,—I qualified in medicine before the second world war, when clinical trials were not the common events that they later became in hospital practice. In the prewar and early postwar years we used to ask patients to give us signed permission to add or substitute new drugs in their treatment without informing them; there was no placebo.¹

In the early days of corticosterone treatment for rheumatic disorders in 1949 and 1950 expectations were so high that, in trials of substances reported to have been effective before cortisone became available, dramatic clinical reactions were often seen after the first injections of what later proved to be inactive agents. These reactions, however, rapidly disappeared after the next two or three injections. In one such trial films taken of a patient after the first injection were almost as dramatic as the original film that Hench *et al* showed in New York in 1949 of patients receiving large doses of cortisone (seventh international congress on rheumatic diseases). In a later controlled trial of cortisone versus aspirin carried out by the Empire Rheumatism Council, however, no such dramatic results were seen.² The Empire Rheumatism Council carried out a multicentre controlled trial of gold in 77 patients with rheumatoid arthritis, who received 50 mg sodium aurothiomalate weekly by intramuscular injection to a total of 1 g over five months.³ There was a significant improvement by all criteria except radiological criteria in these patients from month 3 to month 18 (one year after completion of the course), but in 82 control patients, who received 0.5 µg of the same substance weekly to a total of 0.01 mg, the improvement was not significant. A homoeopathic influence was suspected by some.

The most satisfactory assessment of the clinical benefits of a new treatment probably occurs when the patient is unaware that a trial is in progress and no placebo is necessary. Because such trials are as much to assess unwanted as to assess desired effects, however, patients today have to be fully aware of all possibilities in agreeing to such trials and placebo control is necessary.

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Deciding which selective serotonin reuptake inhibitor to prescribe

EDITOR,—Recent articles have debated the relative costs of selective serotonin reuptake inhibitors for depression in relation to their tolerability and efficacy.^{1,2} I M Anderson and B M Tomenson raise the point that cost-benefit analyses should include real life prescribing situations rather than the atypical situations found in short clinical trials.¹

Intense media publicity and debate have been

given to fluoxetine, with many sensational stories and claims being made. Particular prominence has been given to stories of suicide, aggression, and personality changes in patients taking the drug, despite the paucity of supporting evidence.³ This has led, understandably, to great concern in many patients taking the drug. I have begun to spend a large proportion of consultations with patients for whom I have prescribed fluoxetine discussing these news items and repeating the true facts about the drug.

In a retrospective audit of my practice over the past 18 months I found that six of 11 patients prescribed fluoxetine had raised concerns related to the media coverage. Two of the six stopped taking the drug, and three of the others admitted to reduced compliance, directly because of the adverse publicity. In comparison, only one patient out of eight prescribed one of the other selective serotonin reuptake inhibitors mentioned the media coverage, and compliance remained unchanged.

Several differences between selective serotonin reuptake inhibitors could influence the choice of drug on clinical grounds.⁴ In the absence of specific indications, however, I am now more likely to prescribe an inhibitor other than fluoxetine. This permits more productive use of consultation time and means that an unfortunate cause of poor compliance does not arise. While fluoxetine may be the cheapest selective serotonin reuptake inhibitor in terms of direct costs,⁵ the added costs of additional consultation time and longer duration of illness because of non-compliance may well nullify this advantage.

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Treating mentally disordered prisoners

Mental Health Act Commission should visit prisons

EDITOR,—“The numbers of untreated psychotic men in prison will grow,” state H Needham-Bennett and I Cumming.¹ In the late 1950s the doors of local mental hospitals were unlocked and Broadmoor Hospital became so overcrowded that it was difficult to run a therapeutic regime. The private hospitals, starting with St Andrew's in Northampton, then expanded and absorbed many patients who needed some security. The private hospitals were followed by the regional secure units, which in their turn absorbed many patients who were difficult to place.

Today Broadmoor Hospital is full and at times can accept only emergency cases, private hospitals have a waiting list, and regional secure units are struggling (in some weeks Fromeside Clinic receives one or two requests for admissions from other parts of Britain, usually London). So, as in the past, prison health care centres fill up with psychotic patients. These patients cannot be treated because it is unlawful to treat them, nor can they be moved to hospitals as there are often no empty beds with appropriate security. While this may not be the scenario in some parts of England,

it evidently is in the prison described by the authors.

If the situation worsens, as the article implies it will, is the next step to allow the Mental Health Act to function in prison hospitals? And, if so, will this be just for short term emergency treatment or for longer term treatment? The implications are profound, and some people would fear that re-designed and reserved areas of prisons could become revolving door asylums with patients with chronic psychosis and personality disorders manipulating their way into prison by the time honoured method of throwing a brick through a police station's window.

Furthermore, if the Mental Health Act is to be used in prisons the Mental Health Act Commission would need to be involved. While allowing for the circumstances, it would insist on at least reasonable physical standards for those prisoners being treated under the Mental Health Act.

It is time for the Mental Health Act Commission to have a remit to visit the local prison when it inspects a hospital. After all, it is of little value writing satisfactory reports on a hospital when a number of its psychotic patients are being detained untreated in the local prison's health care centre. Should the commission start to visit prison health care centres it might identify a lack of intensive care units and medium stay beds as an important factor contributing to the steadily worsening situation.

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Solution to treating prisoners in hospital is financial

EDITOR,—The situation that N Needham-Bennett and I Cumming describe in a prison health care centre¹ is all too familiar,² despite successive initiatives to improve provision for mentally disordered prisoners.^{3,4} We take issue, however, with the authors' proposal that the Mental Health Act 1983 should be revised to allow compulsory psychiatric treatment in prisons.

In March 1992 the Department of Health and the Home Office invited proposals from the four Thames regional health authorities to provide a better service for mentally disordered male prisoners remanded into custody. Our successful proposal combined a medical and nursing prison based assessment service and a 14 bedded locked ward exclusively for the inpatient care of mentally ill men who would otherwise have been remanded into custody. In its first year the service saw 150 referrals and admitted 62 patients, who had been charged with offences ranging from murder to shoplifting. A full description of the service is in preparation, as is a report of an independent audit of the impact of the service on the remand population at Wormwood Scrubs prison. More than half of those seen were referred within two weeks of their remand into custody. More than two thirds of those referred were assessed within five days of referral. Of those for whom admission was recommended, one fifth were admitted within five days and more than half within two weeks of assessment.

The independent evaluation has confirmed the success of our service. We are currently funded entirely through regional health budgets, without any contribution from the Home Office. A major determinant of our costs has been the delay in concluding cases dealt with at crown courts: the mean length of admission for cases dealt with at magistrates' courts is 42 days and at crown court 95 days. We are therefore constrained in the clinical management of patients by external judicial processes over which we have no control and which