ideology and the values of their culture surely shows a false dichotomy. Indeed, what is an ethical code if not a reflection, a formal representation, of the values of a particular society? We do not practise medicine in a cultural vacuum; what is this absolute ethical code to which Rose refers? As the paper points out, the profession's attitudes to homosexuality, like all other issues, mirror those of society at large. The author clearly has her own ideological stance on issues of sexuality; perhaps the paper shows more of her position than that of the participants.

While the abstract exhorts us to treat HIV infection as purely a medical condition, the discussion describes the personal as well as the medical aspects of HIV infection and AIDS. Although these two seemingly opposing positions are represented in the paper, it is surely the latter that is the more complete account.

I believe that the paper deals with an important issue—that of prejudice and discrimination in our profession. It was published in a week in which homosexuality was very much in the news. This is not a reason, however, to publish a paper with such evident flaws; Rose's arguments would have been more appropriately presented in the personal view column.

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1 Rose L. Homophobia among doctors. *BMJ* 1994;308:586-7. (26 February.)

Guidelines for management of hypertension

Metabolic effects of drug treatment exaggerated

EDITOR,—Recently, the World Health Organisation and International Society of Hypertension published guidelines on the management of mild hypertension. Peter H Winocour is concerned that these guidelines place too little emphasis on the impact of metabolic control on the management of essential hypertension.¹ He fears that treatment with diuretics and β blockers as the first among equal agents of choice in the guidelines could lead to an 11-fold increase in the incidence of diabetes mellitus.

Two long term studies have described an increased incidence of diabetes mellitus in treated hypertensive patients.^{2,3} Both studies, however, compared hypertensive patients with an untreated healthy normotensive group. The results of both studies come as no surprise since the association between glucose intolerance and hypertension in untreated hypertensive patients has been well known for more than 70 years. Therefore, a higher incidence of diabetes mellitus would be expected in hypertensive patients compared with normotensive subjects. Hence, these data do not provide any evidence for a diabetogenic effect of diuretics and β blockers in essential hypertension.^{2,3}

On the contrary, in large cross sectional studies, as well as in prospective longitudinal studies such as the Framingham study and the San Antonio heart study, no differences were found in the prevalence or incidence of glucose intolerance and diabetes mellitus between hypertensive patients taking β blockers and diuretics and hypertensive patients without treatment or taking other antihypertensive drugs.

In the treatment of mild hypertension study—the biggest long term trial comparing different antihypertensive agents—no differences were found between the β blocker and diuretic groups and placebo or other antihypertensive agents with regard to fasting blood glucose concentration.⁴ In addition, when glucose intolerance or diabetes is already present prevention of potassium loss

during low dose diuretic treatment and use of β_1 selective β blockers prevents deterioration of glucose tolerance.⁵

Hence, published evidence does not show any clinically relevant effects of β_1 selective β blockers or low dose diuretics on glucose metabolism that would restrict their use as the first line antihypertensive drugs in either diabetic or non-diabetic hypertensive patients.

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- 1 Winocour PH. Management of essential hypertension. *BMJ* 1994;308:470. (12 February.)
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Sticking to guidelines can be expensive

EDITOR,—Gene Feder points out what has been clear for some time—that there are important differences between published guidelines for the treatment of hypertension.^{1,2} Feder also refers to the development of a "guidelines industry."

I have no objection to the creation of guidelines for minimal acceptable levels of medical care: indeed, I chaired the working party that prepared the British Hypertension Society's first report.³ The reasons for the diversity of guidelines are fairly obvious: evidence is inadequate and different people working in different health care systems do not always concur on all value judgments. Comprehensive documentation of a large literature with which most experts are depressingly familiar will not help them to agree on questions that they have been debating for years. Such a strategy will certainly favour the growth of a guidelines industry.

I have a more pressing concern, however, when expert guidelines are used to inform government decisions. Each national expert group producing advice works independently of developments in other fields of medicine. The impact of recommendations for funding these other fields is therefore ignored. Nevertheless, quite small differences in, for instance, the threshold pressure for drug treatment can have a massive effect on the eligible population and consequent expenditure. It is perhaps no coincidence that guidelines published in the United States, which has the highest expenditure on health care, also make the most radical recommendations for drug treatment while British recommendations are the most conservative. Even so, in Britain and many other countries only a minority of hypertensive patients are detected and only a minority of these are effectively treated. Effective optimal care therefore implies the prospect of a major increase in expenditure.

Under the circumstances only three outcomes seem possible. These are that guidelines continue to be ignored in practice; that expenditure in other areas not covered by guidelines is further reduced; and that the overall budget is increased. The last would undoubtedly be the best outcome in the best of all possible worlds but also seems the most unlikely. It would be foolish to stand in the way of clinical effectiveness, but I wonder whether those who launch the guidelines industry appreciate its full implications.

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Insurance against injury in clinical trials

Urgent action needed but . . .

EDITOR,—I support the views expressed by Anne Ferguson¹ and wish to enlarge on them. The East Berkshire Research Ethics Committee sought legal advice on the question of seeking indemnity, not only for the health authority which appoints us but also for the trust, when a locally generated study is to take place. This advice concurred with our view that an indemnity in the format agreed between the Department of Health and the Association of the British Pharmaceutical Industry should be provided for a locally generated study in the same way as it would be provided for a study sponsored by the manufacturer of a pharmaceutical product. This was thought to be particularly important when a drug was being studied for a purpose other than that for which it had been originally licensed. Experience shows that manufacturers are reluctant to offer indemnity under such circumstances even though they would stand to benefit financially if the work resulted in expanded use of their product.

The primary purpose of any research ethics committee must be to encourage ethically acceptable clinical research. I emphasise this not only as the chairman of a committee but also as a frequent participant in studies. It must come as a bitter disappointment to an applicant and an ethics committee when approval has to be withheld simply because no form of indemnity is offered, especially when the intended study is found to be not only sound but also potentially beneficial.

Unlike Anne Ferguson I do not envisage academics, clinical investigators, or for that matter NHS trusts being able to afford the insurance cover required in the absence of manufacturers' indemnity. It would be interesting to hear from other ethics committees, researchers, and health bodies how they have addressed these problems and whether they agree with my committee's view that urgent action by the Department of Health is required to ensure that valuable clinical research projects are not lost because of failure to resolve these issues.

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1 Ferguson A. Clinical research in trust hospitals. *BMJ* 1994;308: 412. (5 February.)

. . . still no guidelines from Department of Health

EDITOR,—Early in 1993 the Department of Health, the Association of the British Pharmaceutical Industry, and a firm of solicitors representing the South West Regional Health Authority produced, after much discussion, an agreed form of indemnity for clinical studies. The department indicated that it would be issuing a guidance note for the benefit of health authorities, the note to be used in conjunction with the form of indemnity. Despite numerous letters from the association to the department, and many more telephone calls, the guidance note has still not been issued. Drafts which have been seen indicate that the document is entirely non-controversial. The difficulty with its non-appearance is that some health authorities are taking the view that the form of indemnity issued to them by companies is unofficial—that is, that it