Perhaps, as del Pozo points out, we should be inspired to ethically evaluate and debate paid blood donation, if only as part of an attempt to prevent shortages of blood occurring.

Up until the present, ethical discussion has generally been lacking on many issues confronting blood banking and transfusion medicine. This is no less important at a time when the majority of the world is promoting and holding up the non-remunerated donor as the only safe blood donor (7). The article by del Pozo will serve as a point of departure for the many ethical debates that are yet to come, and should come, in this and related areas in transfusion medicine.

References
(2) Domen E R. Paid versus volunteer blood donation: a historical review [submitted for publication].
(7) Consensus statement on how to achieve a safe and adequate blood supply by recruitment and retention of voluntary, non-remunerated blood donors. Transfusion today 1994; 18: 1–2.

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Drug trial ethics

SIR
I would be grateful for the views of your readers about the ethics of open-continuation studies after the double-blind, placebo-controlled phase of a drug trial. The ethical committee at my hospital take the view that continuation studies are never justified because they give little scientific information and any humanitarian benefit is outweighed by the danger of giving a drug with unknown efficacy.

I have always taken the view that ethical decisions are rarely absolute but depend on balancing relative values. Even taking a life may be justified if by so doing one saves more lives (when, for example, a terrorist is about to blow up an aircraft). I would suggest that the same principle applies to continuation studies. If the treatment under study is for a self-limited condition like eczema, where there are recognised and effective remedies available, it would seem incontrovertible that a continuation study before analysis of the outcome of the double-blind phase was of doubtful value. If, however, the disease is progressive, ultimately lethal, treatments are more likely to be effective in the early phase, and there are no known effective remedies available, I would suggest that giving all participants of the double-blind phase a chance to try the ‘active’ medication was essential, and to deny them this opportunity was itself unethical.

Clearly another factor to weigh in the balance is the risk of side-effects, a drug with serious side-effects requiring more evidence of efficacy than one without.

The issue has arisen over a proposal to allow subjects with Alzheimer’s disease who have completed a 12-week double-blind phase to go on ondanestron in a dose far below that given for nausea and for which the risk of side-effects must be very small.

One agrees that this phase is essentially for humanitarian reasons although it would allow one to examine the important issue of whether the drug slows the progression of the disease, in which case those on the double-blind active wing would always remain ahead of those starting later, or whether it only causes a functional improvement, the later starters catching up with the others.

The statistical power of a study is increased by delaying the analysis until data collection is complete but the time this takes makes it likely that the first participants in the study would have deteriorated too far to benefit when the final results were through.

My patients and their relatives are alarmed at the prospect that they may be prevented from trying this treatment through an ethical decision which to my biased mind is decidedly unethical.

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In defence of ageism

SIR
Dr Shaw’s article (1) contains flawed arguments and contradictions. One of his principal contentions is that as age is objective it should be used a criterion for rationing as to do so negates the necessity for making subjective value judgements. Dr Shaw writes: ‘age is an objective factor in rationing decisions’, implying that it is right that it should be. He further writes: ‘Health care should be preferentially allocated to younger patients’. However, later in his article Dr Shaw writes, referring to the Bradford Coronary Care Unit Model which he says should be copied, ‘the care is targeted on younger patients but none are denied treatment where need arises and benefit is substantial.’ This seems to me to show that Dr Shaw does not believe in ageism. If he did, he would not advocate the treatment of any elderly patients once they had reached the cut-off age that had been decided on. Surely the whole point of an ageist policy was that after a certain age had been reached the patient would not receive treatment whatever the benefit. (Note that Dr Shaw refers to treatment, as opposed to care, as he makes the point that treatment is given if the ensuing ‘benefit would be substantial’. This is an important point because Dr Shaw cannot claim that all he is suggesting is that patients of all ages should be given care, which is different from saying all patients should be given treatment.)

Dr Shaw makes other assertions that should not be accepted on face value. He assumes that the elderly would willingly give up their lives in favour of the young. He gives the example of the grandmother who would want the lifebelt to be thrown to her granddaughter before herself.
Drug trial ethics.

J M Kellett

*J Med Ethics* 1994 20: 270
doi: 10.1136/jme.20.4.270

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