Letters

Human Experimentation

In their thoughtful editorial of 25 April (p. 315) on the February Academy Forum "Experiments and research with humans: Values in conflict," Gaylin and Gorovitz emphasize the need for scientists and their critics to "not merely state their positions, [but] come to understand each other's point of view."

The dialogue begun in the Forum will be extended by a new working group brought together by the Institute of Medicine and the Forum. This group will encompass a diversity of disciplines and viewpoints that characterize scientists, their critics, and their supporters. They will expand the discussions of the Forum in an interdisciplinary manner to the point of recommending specific studies and other activities that will aid all of the concerned segments of society in reaching acceptable and appropriate decisions on the use of human subjects in research.

We hope that other organizations, such as the new section on science and technology developed by the American Bar Association, will include all related professions in their consideration of this multidimensional problem.

The following statements may be helpful in directing further inquiry:

1) The concern about the way in which human experimentation is conducted is greater than many investigators realize.

2) It is not enough to calculate risk-benefit ratios. Many ethical, moral, and political considerations are involved which cannot be addressed solely by improved calculation of cost-benefit ratios.

3) The increasing demands for greater proof of efficacy of therapeutic measures implies increasing need for experimentation involving man.

4) Although informed consent is a critical requirement for the ethical conduct of research, the larger share of protection for the rights of the subject devolves upon the processes for peer review, procedures that still may be less than adequate.

5) The subject of the appropriate conduct of research on humans is one that itself requires more critical research.

The broad interest and concern reflected by many reactions such as those expressed by Gaylin and Gorovitz is, in our view, most important in furthering the goal of an understanding of the role of humans in research and the effective recognition of the human values involved.

DONALD S. FREDRICKSON
Institute of Medicine, National Academy of Sciences, 2101 Constitution Avenue, NW, Washington, D.C. 20418

FREDERICK C. ROBBINS
School of Medicine, Case Western Reserve University, Cleveland, Ohio 44106

ROBERT R. WHITE
Academy Forum, National Academy of Sciences

The letters from Jonsen (11 Apr., p. 98) and Lovinger (11 Apr., p. 100) regarding the use of children, prisoners, and others as medical research subjects deserve thoughtful consideration. The often nonexplicit premise in the debates in this area is that "research" or "experimentation" can be clearly and unequivocally defined, so that the issues lie in determining the ethical boundaries of experimentation in humans. However, such definitions are often anything but clear or unequivocal. Sometimes there is little reasonable argument, such as when a new drug or an entirely new surgical procedure is used, but the gray area is rather wide. For example, the use of surgical procedures such as dorsal column electrode implantation or aortocoronary bypass, where the long-term safety and therapeutic value are not completely known, is regarded as experimental in some places and as standard (nonexperimental or proven) in other institutions. The controls, reporting, and consent procedures could conceivably differ as a result of the definition used. There is as yet no established mechanism by which specialty societies could elaborate such definitions for adoption across the country. These are not simply issues of semantics, and most likely a large number of patients is involved. Perhaps open discussion of such problems may be helpful in placing the ethical issues in proper context.

E. EIDELBERG
Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, Phoenix, Arizona 85013