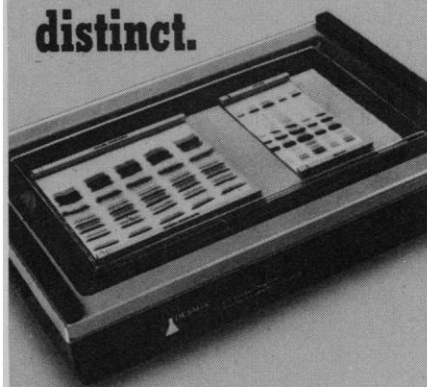


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## LETTERS

### The Ethics of Experimentation

The ethics of biomedical research have been a matter of concern to the public and to the profession for some time. Jewish Chronic Disease Hospital, Willowbrook State Hospital, Vacaville, and Tuskegee are familiar names in the litany of "horror stories" which the press has publicized since the early 1950's. Federal regulations governing research, which mandated peer review, have existed since 1967. Revisions of these regulations proposed in 1974 elicited considerable comment in professional literature and in the research community. In 1974, Congress established a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission has a 2-year mandate to review a range of problems and to recommend policy to the Secretary of the Department of Health, Education, and Welfare and to Congress.

Yet, despite wide publicity and frequent discussion, the nature of the problem remains ill-defined. A forum convened by the National Academy of Sciences (NAS) in Washington, D.C., on 18-19 February included a pantheon of distinguished researchers. They were summoned to discuss "Experimentation using human subjects: Values in conflict." Experimentation they did discuss; value conflict they barely noticed. The sessions manifested, among those presenting papers, an apparent lack of perception about the ethical issues.

The dominant note was the benefit brought by human experimentation to modern medical care. Indeed, while this thesis could scarcely be doubted, the abundant benefits add up to only half an argument in favor of experimental medicine. They constitute only the major premise. Another premise is needed to draw any conclusion. That premise must read, "but these benefits are sufficient ethical justification for doing x, y, and z, where x, y, and z stand for such activities as the use of children, prisoners, and the poor as research subjects." The planners of the conference clearly intended the second premise to be addressed, for they scheduled sessions on children, the poor, and the institutionalized. But again and again, even in these sessions, the circular argument emerged: "We would not have made the progress we have without these subjects; therefore, it is ethical to use these subjects."

I believe that it is possible to carefully frame the premises necessary to justify ethically certain research. Unfortunately, that was not done and those who have given most thought to doing it were either missing from, or given only minor roles in, the Academy forum.

Admittedly, doubts were occasionally expressed and sharp dissent was several times entered. But, as one commentator—a philosopher—remarked, the panelists almost to a man seemed to miss the public perception of the problem: research appears to involve a threat to the integrity and dignity of significant populations. Repeatedly, that concern was voiced by persons speaking from the audience. But on the stage, the participants either ignored, denied, or excused, with affirmations of peer review and informed consent, the "public perception of the problem."

Three reflections are stimulated by this event. First, it is imperative to point out the necessity and the utility of biomedical research. But every eulogy must be tempered with a confession, either of abuses (which may not be frequent, but when they occur, are flagrant) or of serious problems about selection of subjects, assessment of risks, and adequacy of consent. These matters still need to be studied, pondered, and improved by careful and innovative techniques. Awareness that a great portion of research is done among vulnerable and captive populations urges us to consider a fairer distribution of both the burdens and the benefits of modern medicine.

Second, the total absence of ethicists on the platform of the forum was remarkable. Certain professional theologians and philosophers of considerable ability have devoted attention to these problems. They are not scientists nor physicians, but they understand what an ethical issue is. They are generally able to define these issues in terms suitable for public debate. Also, those who practice the academic trade of ethics seldom advocate particular moral views. They may be deeply committed to certain positions, but their professional skills are directed principally to the analysis of moral arguments of all colors. They expose presuppositions and explore the logic of debate in order to render the issues more obvious for public discussion. One suspects that the absence of ethicists from the platform and their relegation to the audience was dictated by the fear that they would "take sides." Ironically, their

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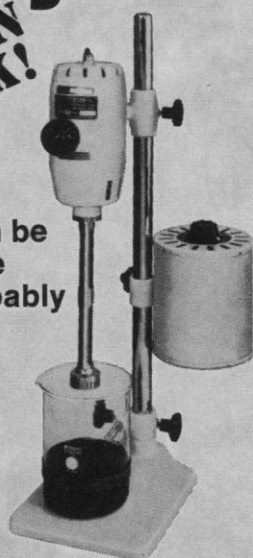
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presence may have prevented just that from happening.

Finally, the forum did make evident how necessary it is to educate the profession and the public on these issues. The National Commission for the Protection of Human Subjects has been given certain definite tasks by Congress. Its work will consist of making many recommendations about legislation, regulation, structures or review, reporting, and surveillance. But these practical tasks must not overwhelm its basic responsibility: "To determine the ethical principles underlying research." This responsibility would be poorly discharged if the commission issued a list of moral precepts. It must also find ways to instruct the profession and the public in the serious moral choices posed to our society by experimental medicine.

These reflections are prompted by my own triple role. As member of a medical faculty, I participate in the biomedical research community. There one sees vividly the values of research and the integrity of researchers. As a teacher of bioethics, I am engaged in the attempt to render moral problems more intelligible and suitable for reasonable public discussion. As a member of the National Commission for the Protection of Human Subjects, I recognize the unique educational opportunities of such a body. Its policy recommendations will be meaningful only if the research community and the public comprehend the issues.

Peculiarly enough, the proper task of the forum was enunciated at its end rather than at its beginning. In his closing remarks, NAS president Philip Handler stated that, although some might consider it trivial to discuss experimentation when worldwide problems of starvation, poverty, and pollution press upon us, "It is never trivial to seek to determine what is human and appropriate to human dignity." A sustained and refined concentration on "what is human and appropriate to human dignity" would have made the forum an exercise in ethics rather than an exposure of partisan enthusiasm.

ALBERT R. JONSEN

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The Secretary of the Department of Health, Education, and Welfare has requested statements regarding the use of prisoners as experimental subjects. The Medical Committee for Human

Rights holds that prisoners cannot be considered "normal volunteers" in experiments.

The fundamental requirement of "free and informed consent" is inevitably compromised within the prison's closed and coercive system. Such "consent" by a prisoner is not truly "free" or adequately "informed," nor is it "consent" in the sense of an agreement freely entered into by equals under conditions of trust. It is not "informed" because sources of information are lacking in prisons. These considerations cannot properly be set aside simply because his status as a member of a captive population has made the prisoner a convenient and inexpensive experimental subject.

The major considerations motivating prisoners to "volunteer" are material inducements which promise to make their incarceration more tolerable and the hope or promise that participation will bring an earlier release. An unequivocal elimination of such factors would sharply reduce this reservoir of human subjects.

Prisoners cannot be considered "normal" subjects because their response to experimental activities may be distorted by the fact that they are not in a "normal" environment; also, covert drug abuse is rampant in prisons; finally, prisoners may consciously or unconsciously distort experimental results if this will, in their view, aid in their release or ameliorate the conditions of their confinement.

Efforts to protect subjects of experimentation by the establishment of committees with representation by fellow prisoners is no solution: such prisoner representatives are more or less subject to the same constraints as their fellows and cannot, therefore, serve them as free agents.

In view of the foregoing considerations, concern for the human rights of the subject and for the scientific validity of experimental results compels us to oppose in toto the use of prisoners as experimental subjects and to insist that the Nuremberg Code prohibiting such use be stringently applied. Other countries have demonstrated that they are able to carry out necessary research involving human subjects without resort to the prison population; we can and must do likewise.

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