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MEDICAL EXPERIMENTATION ON HUMAN SUBJECTS

INTRODUCTION

Edward M. Kennedy*

Today, as this special issue of the Case Western Reserve Law Review is preparing to go to press, scientists may stand on the threshold of being able to recreate man. They will soon have the power to modify and control his behavior—indeed they can already do so in certain controlled, clinical settings.

In the last decade, we have witnessed an unparalleled expansion of our technological capabilities. The technology of biomedical research is the technology of man. Today, we have more biomedical research scientists at work on more kinds of projects than at any time in our history. Their success in these endeavors has taken us beyond the frontiers of man's understanding. Moreover, the gap between the development of the technology of man and our capacity to understand the nature and implications of that technology widens every day.

In the last decade, we have seen a surgeon hold a human heart in his hands and transplant it into another person's body; we have seen scores of surgeons renew life for thousands of people by the transplantation of kidneys; we have seen scientists unravel the mysteries of the genetic code, learning how to alter the very structure of the building blocks of life; we have seen scientists begin to unlock the mysteries of the brain and begin to understand the physical basis of feelings—of sorrow and joy, of pain and pleasure, of anger and understanding; we have seen a breakthrough in the treatment of Hodgkin's disease, a dreaded cancer of the lymph nodes; we have seen a vaccine developed to eliminate measles. We have all been

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touched by, and have all profited by, the fruits of biomedical research.

In the next decades scientists will place even more powerful tools in our hands. The appropriate use of these tools will require that we, as a society, be ready to answer many questions:

Under what conditions, if any, would genetic manipulation of our population be allowed?

Under what conditions, if any, would neurosurgical or pharmacologic modifications of behavior be allowed?

What constitutes death?

Who will have access to lifesaving equipment if it is in short supply—like kidney dialysis machines, or artificial hearts?

When, if ever, may a society expose some of its members to harm in order to seek benefits for the rest of its people?

Between February and July of 1973 the Senate Health Subcommittee held extensive hearings on the state of experimentation with human subjects in this country. The subcommittee heard: of the widespread use of experimental drugs as part of the routine practice of medicine, without informed consent; of the freedom of an individual surgeon to try experimental techniques without proper peer review and in the absence of sufficient experimental controls; of the development of medical devices by individual practitioners, in isolation from colleagues, which resulted in grievous harm to patients.

Subsequent to the hearings the committee reported, and the Senate passed, two important pieces of legislation: The Medical Devices Amendments\(^1\) and the Protection of Human Subjects Act.\(^2\) The former would give the Food and Drug Administration long needed authority to regulate the development and marketing of medical devices. The latter has since become law and establishes a National Council, composed of members from a wide variety of disciplines, who are charged with identifying the basic ethical principles underlying the conduct of research involving human subjects, and will implement policies to be sure that research is carried out in accord with those principles.\(^3\) Most importantly, the Council should become a permanent focus for consideration and debate about

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complex ethical problems as they arise or are crystallized by technological advances.

I want to commend the editors of the *Case Western Reserve Law Review* for undertaking this special issue. This nation has had, and must continue to have, a biomedical research program second to none. It must also have a policy for the protection of human subjects of biomedical research which is second to none. This issue can contribute toward the development of such a policy.