Medical Experimentation on Human Subjects--Introduction

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INTRODUCTION

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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 re-
search.

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 pharma-
cologic 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 Subcom-
mittee 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 individ-
ual 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 iso-
lation 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 sub-
jects, 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

\(^{1}\) S. 2368, 93d Cong., 1st Sess. (1973); 120 CONG. REC. S1035 (daily

\(^{2}\) H.R. 7724, 93d Cong., 1st Sess. (1973); 119 CONG. REC. S16333

\(^{3}\) National Research Service Award Act of 1974, Pub. L. No. 93-348,
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.