As one British physican serving with a government organization here explained it, even the use of inmates of a penitentiary in medical tests raises serious questions about whether the subject actually "volunteered" or was pressured to get involved because of the promise of reward.

He said that the absence of absolute quality of consent among prisoners undermines their scientific value for experimentation.

Possibly more important, however, was his opinion that medical research in Great Britain has not been retarded by the stiff standards in selecting subjects for tests.

Discipline—Herein lies the nub of the greatest controversy about medical experimentation. Who decides if a test on humans is necessary, if consent is "informed" and if all other procedures are valid.

By and large the medical profession both here and abroad have jealously guarded its right to decide what's good for the public. But other voices are creeping in.

In New York, a state senator is proposing a law to oversee human experimentation; in other areas laymen (ministers, social workers) are being placed on medical research review committees to take part in review of projects.

Critics of the medical profession claim its internal discipline is not strong enough to afford the public real protection against the incompetent or overzealous researcher. They cite, for example, one of the few instances in which physicians have been "censured" for research foul-ups—a New York case in which two doctors were given a year's "probation" by the state licensing agency for administering live cancer cells to patients without consent.

As one critic charges, "These doctors never even lost a day of practice . . . is that disciplining them?"

He and others foresee a race in which the profession moves to tighten internal controls before the lawmakers take over.

Senator NELSON. That is a rollcall. I will have to leave. If there are any questions from either the minority or the majority or any of the members, if they want to submit them to Dr. Ley to respond for the record—yes, Mr. Duffy.

Mr. DUFFY. Doctor, there has been some considerable publicity about a study that FDA has released recently. If you would care, perhaps you might submit a statement in regard to that.

Dr. LEY. I would not wish to submit a statement as Commissioner, because that is a very preliminary study. My staff will not finish comment on it until September. At that time, we probably will have a statement.

Mr. DUFFY. All right, thank you.

Senator NELSON. That will conclude the hearing for today.

(Subsequent information follows:)

WAYNE STATE UNIVERSITY,
Detroit, Mich., October 28, 1969.

HON. GAYLORD NELSON,
U.S. Senate,
Old Senate Office Building, Washington, D.C.

DEAR SENATOR NELSON: It has come to my attention, through Geoffrey Cowan of the Center for Law and Social Policy in Washington, that your Committee is about to publish recent hearings with Dr. Ley and other data about new drug testing. I would like to urge you to include our critical review of proposed FDA regulations for peer group review of clinical investigation of new drugs in human beings. These recommendations to FDA from the Council of Health Organizations were prepared by myself and Dr. Henry K. Beecher. They include a proposal to strengthen the entire area of new drug evaluation with special reference to protection of human subjects and scientific adequacy of testing.

The Council of Health Organizations which has undertaken to advise in this matter is composed of three organizations, the Medical Committee for Human Rights, Physicians Forum and Physicians for Social Responsibility, comprising approximately 10,000 doctors, nurses and other health professionals. I will ask our Washington counsel to forward our full statement to you for consideration.