

The impact of the Nelson Committee is excellent in the health institutions which I have visited recently.

Sincerely,

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COMMENTS OF THE COUNCIL OF HEALTH ORGANIZATIONS ON PROPOSAL FOR PEER GROUP COMMITTEE REVIEW OF CLINICAL INVESTIGATIONS OF NEW DRUGS ON HUMAN BEINGS

On August 22, 1969, the Food and Drug Administration published a Notice of Proposed Rule Making concerning Peer Group Committee Review of Clinical Investigations of New Drugs on Human Beings. 34 Fed. Reg. 13552-53. The notice stated that interested persons had 30 days to submit written comments on the proposal. By letter of September 17, 1969, the Council of Health Organizations ("The Council") requested an extension of time for the filing of its comments. A 30-day extension was granted.

The Council is a coalition of medical organizations, including the Medical Committee for Human Rights, The Physicians Forum, and Physicians for Social Responsibility. The Council represents the interests of more than 10,000 health personnel on issues of national health policy. The Council and its constituent organizations are concerned with the social aspects of health care and the responsibility of the health professions in the society.

Since many of our members are actively engaged in new drug testing, the Council has a special interest in the FDA's methods of insuring the safe and effective development of new drugs. We are familiar with the tragic consequences of unsafe or inappropriate new drug tests. We know that testing must be more effectively regulated, not only in order to produce good scientific data, but also to protect the safety and welfare of the human test subjects. The drug industry appears to share this view. The drug manufacturers and new drug investigators who had filed comments on the FDA's proposal by the time these comments were prepared, do not question the basic thrust of the proposal—more effective review of new drug tests on human subjects.

The Council considers the FDA's proposal grossly inadequate. While it appears to recognize the problem, the proposal is hopelessly fragmentary and vague. Unhappily it does not represent a meaningful step toward effective regulation. On behalf of thousands of members of the health professions who have a professional interest in adequate drug testing, the Council urges the FDA to reconsider its proposal and to seize this opportunity to take effective action.

In these comments the Council will analyze the problem of new drug testing on human subjects, set out the inadequacies of the FDA proposal, and suggest some methods for establishing meaningful review committees.

In the preparation of its position, Dr. Henry K. Beecher served as a consultant to the Council. A statement released by Dr. Beecher on October 6 regarding the FDA proposal is appended thereto.

I. THE PROBLEM

The ethical and practical problems inherent in new drug testing on human subjects pose a dilemma which requires great sensitivity to resolve. America prides itself on new developments in medical science and people have come to expect new scientific advances each year. Doctors and patients across the country anxiously await the development of new drugs—yet for all those who await the benefits of new drug testing, who is willing to share the risks? The FDA must daily deal with the tension between the government's obligation to safeguard the rights and safety of test populations and its obligation to assure that the safety and efficacy of new drugs has been demonstrated by human experimentation before new drugs are made available to the general public. As members of the health professions, the members of the Council of Health Organizations appreciate the difficulty of finding suitable and acquiescent patients, of fully informing them of the nature of the test and how it may affect them, and of providing adequate medical supervision once a test is underway.

The welfare and safety of the test population for new drugs has never been adequately protected. Every few years some freshly revealed drug testing abuse shocks the conscience of the nation. The studies conducted on prison inmates by Dr. Austin Stough have been the focus of recent attention. Five years ago the public was aroused by the case of 22 elderly, seriously ill patients at the Jewish