Existing standards, controls and enforcement measures contribute importantly to the protection of the public, but they would be inadequate to assure reliability without the incentives and dedication of responsible pharmaceutical companies. Moreover, generic identity of principal drug ingredients is a futile goal, for it does not guarantee uniform therapeutic effect of finished products in all patients.

The quality-minded producer who identifies his products and promotes them under unique names or under his company name has an interest in furthering his reputation and his services to a point that goes far beyond any norms that could reasonably be established and enforced as a general system of governmental regulations, even under complete domination of the industry.

The overall reputation and performance of a company serve as reliable indexes to the quality of its products.

No measures should be instituted that might abridge the physician's prerogative and responsibility to determine the proper therapy and prescribe the type and quality of medication which in his opinion will best serve the needs of his patients.

Senator NELSON. Who is your next witness?

Mr. CUTLER. Our next witness, Senator, is Dr. Leonard Scheele. But before he begins, let me just add in response to a question asked earlier—there is at least one of the references in this book which specifically recites that the drug in question, which happened to be prednisone, did meet U.S.P. standards, and yet was found to be therapeutically deficient. And that is from the Journal of Pharmaceutical Sciences, volume 52, No. 5, June 1963.

Senator NELSON. Mr. Cutler, I am sure you will be pleased to know that is one of the drugs named by Dr. Miller as one of the 15 examples. So you have not yet added to my list. Prednisone is also one.

Mr. GORDON. Mr. Cutler, was that a clinically controlled study?

Mr. CUTLER. It is a study done by Dr. Eino Nelson, and a number of other doctors experienced in this subject.

Mr. GORDON. They are pharmacists, not medical doctors.

Mr. CUTLER. Dr. Campagna, one of the four, is a physician.

Mr. GORDON. Do you know if it is a double blind study?

Mr. CUTLER. I cannot tell you, but I will be glad to hand you the study.

Mr. GORDON. I have a letter on this subject by Dr. Harold Aaron that I would like to submit for the record at this point.

(The letter referred to follows:)

JUNE 12, 1967.

DR. J. A. CAMPBELL,
Department of National Health and Welfare,
Food and Drug Directorate,
Tunney's Pasture,
Ottawa, Ontario, Canada.

DEAR DR. CAMPBELL: Many thanks for your comments on our preliminary draft of "Tests of Prednisone Tablets." Dr. Gerhard Levy made the same comments. If we turn to the articles cited by you and Dr. Levy we find the following: The article by Dr. Campagna cites one case in which a patient with paroxysmal peritonitis did not respond clinically to one brand of prednisone. The dissolution time of tablets of this brand of prednisone was slower than that of the clinically effective tablets. However, there were no *in vitro* determinations of prednisone or its metabolites or conjugates in the blood, urine or other body fluids. Such determinations are generally required to confirm "physiologic availability" and absorption of the drug. Clinical response as a test of adequate dissolution rate and absorption is usually unreliable because of spontaneous changes or remissions in clinical behavior. Such tests can be reliable only when they are double-blind and the number of subjects is large. This is likewise true in the case cited in the second reference, in which a patient with "arthritic pain" failed to respond to one brand of prednisone. In a telephone conversation with