

ments of safety and effectiveness. This could be accomplished by authorizing FDA, where there may be a lack of therapeutic equivalency, to establish by regulation, requirements to insure production of drugs of uniform effectiveness; a firm would then be required to follow the procedures in the regulation when manufacturing the drug unless it had presented adequate evidence that an alternative procedure would produce a comparable product and had FDA's approval for use of the alternate method.

In conclusion, Senator Nelson, we must recognize that many difficulties still exist in the drug area; however, we do not believe these problems are insurmountable. We will continue to foster meaningful cooperation among the industry, the scientific community, and the Federal Government to the optimum extent. We will also continue to emphasize the need for education, not only for the medical profession but for the general population as well. When necessary, we will impose the full force of our regulatory authority to achieve our objectives.

The approval process for drugs, the review of drug efficacy, the regulation of manufacturing quality controls, and the regulation of prescription drug advertising will be improved and strengthened. Our endeavors in these areas, we believe, will be of significant value in assuring the public of a drug supply of impeccable quality and purity.

I can also assure you, Senator Nelson, that every effort will be made to solve the complex and varied questions this committee has broached. We must maintain perfection—and no less—as our goal in this vital, life-sustaining field of science.

I will be happy to answer any additional questions you may have.

Senator NELSON. I must leave shortly but first I want to say that the committee appreciates very much your coming here today to present your testimony. It is most helpful to the record that we are accumulating here. As you know, we hope that at some subsequent date you will be available to come back to explore some other aspects of the drug field with us.

Dr. GODDARD. Be glad to make myself available at your request.

Senator NELSON. As a member of the Department of Health, Education, and Welfare task force on prescription drugs, are you familiar with Joseph Barrows' proposal? Joseph Barrows is the president of the Drug & Allied Products Guild, a trade association which represents small manufacturers of generics. He proposed that the Government utilize academic facilities for the preparation of, "complete master formulas," providing detailed instructions and procedures for making and testing all official drugs. Do you have any comment you would like to make on that?

Dr. GODDARD. The university community will have an opportunity, I believe, to comment, make their suggestions as we improve our good manufacturing practices. I do not know any high degree of expertise, and this is a reflection of my own ignorance, frankly, that exists in the university community with respect to the technical aspects of the production of drugs. I just do not know of this existing. There is some expertise of this type in the food area, oddly enough. We have it at the MIT Institute of Food Technology. There is nothing comparable for the training of drug industry personnel, and this is a need that has been recognized both by us and members of the drug industry.

I would be somewhat reluctant to turn that job over to the uni-