COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

TUESDAY, MAY 9, 1972

U.S. SENATE, SUBCOMMITTEE ON MONOPOLY OF THE SELECT COMMITTEE ON SMALL BUSINESS, Washington, D.C.

The subcommittee met, pursuant to recess, at 10:05 a.m., in room 318, Old Senate Office Building, Senator Gaylord Nelson (chairman of the subcommittee) presiding. Present: Senator Nelson.

Also present: Benjamin Gordon, staff economist; and Elaine C. Dye, clerical assistant.

Senator Nelson. The Subcommittee on Monopoly of the Select Committee on Small Business is today resuming its hearings on the efficiency, economy, and rationality of the Federal agencies and departments in the procurement and use of drugs as well as reimbursement under various programs of the Government.

Our witness today is Dr. Charles C. Edwards, Commissioner of the Food and Drug Administration, who has been invited to discuss:

1. The steps taken to insure that the recommendations of the panels of the National Academy of Sciences-National Research Council have been effectively implemented;

2. The use of New Drug Applications and abbreviated New Drug

- Applications prior to marketing both new and "me-too" drugs;
 3. How the FDA notifies other Government organizations as well as private physicians about the effectiveness and adverse reactions of new drugs;
- 4. What the FDA is doing to provide information in order to influence the prescribing habits of physicians from both cost and effectiveness viewpoints;

5. FDA's combination policy; and

6. Advertising policy especially with respect to informing the physician about the role of particular drugs in the physician's

We are very pleased to have you here this morning, Dr. Edwards. Your statement will be printed in full in the record and you may present it however you desire.1

¹ See Appendix I, p. 8753.