

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

TUESDAY, AUGUST 12, 1969

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

The subcommittee met, pursuant to recess, at 9:30 a.m., in room 1202, New Senate Office Building, Hon. Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson and Dole.

Also present: Benjamin Gordon, staff economist; Elaine C. Dye, clerical assistant; and James P. Duffy III, minority counsel.

Senator NELSON. The hearing of the Monopoly Subcommittee of the Small Business Committee will come to order.

Our witness this morning is Dr. Herbert L. Ley, Commissioner of Food and Drugs.

We welcome you here this morning, Mr. Commissioner. Although the Food and Drug Administration is charged with the responsibility of assuring that the drugs permitted to be marketed are both safe and efficacious, its decisions are based on the evidence supplied by the drug company that seeks to market the drug. As we all know, the FDA does not test drugs.

The dangers involved in the dependence on drug firms to perform, finance, direct, and arrange for the testing of drugs in which they have a commercial interest is obvious. Drug firms are anxious, of course, to get new drugs on the market and to increase their sales. There is thus an inevitable tendency, no matter how conscientious the firm, to emphasize the positive features and deemphasize the negative. Many of the people they engage to do their testing are equally anxious to secure additional contracts for drug testing. FDA has found that the accuracy and objectivity of some of these drug testers leave much to be desired.

Considerable testimony on this subject, which can be found in parts 7 and 10 of our hearings, has already been heard by the subcommittee.

Today, Dr. Herbert Ley, Commissioner of the Food and Drug Administration, will discuss the role of his agency in evaluation and testing of the drugs before they become available to the public.

Dr. Ley, we are glad to have you here today, along with your counsel and Dr. Jennings. You may proceed to present your statement as you wish. I believe I will, unless some difficulty arises, permit you to go through your whole statement so that we get it into the record, because I am informed by my legislative assistant that there is likely to be a rollcall or two this morning, so there may be an interruption.

Please proceed, Dr. Ley.