

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

FRIDAY, NOVEMBER 19, 1976

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

The subcommittee met, pursuant to recess, at 10 a.m., in room 318, Russell Senate Office Building, Hon. Gaylord Nelson, chairman, presiding.

Present: Senator Nelson.

Also present: Benjamin Gordon, staff economist; and Karen Young, research assistant.

Senator NELSON. The subcommittee will please come to order.

Today's hearing by the Monopoly Subcommittee of the Senate Small Business Committee constitutes the fifth and perhaps the last day in this series of hearings on the antiobesity drugs.

Our witnesses today are:

J. Richard Crout, M.D., Director, Bureau of Drugs, Food and Drug Administration, and his associates; Frederick A. Rody, Acting Deputy Administrator, Drug Enforcement Administration, U.S. Department of Justice; and Mr. Isaac McGraw, president of the pharmaceutical division of the Pennwalt Corp.

In 1972, FDA's Advisory Committee on antiobesity drugs after considerable study, submitted the following conclusions and recommendations to the Food and Drug Administration:

One, adult obese subjects on diet plus drug tend to lose more weight than those on diet alone.

Two, the amount of weight loss associated with the use of an "anorectic" drug varies from trial to trial.

The possible origins of the increased weight loss due to the various drug effects are not established.

The increased weight loss appears to be related to variables other than the drug prescribed, such as the physician-investigator, the population treated, and the diet prescribed.

Studies do not permit conclusions as to the relative importance of the drug and nondrug factors on weight loss.

Three, the magnitude of increased weight loss of drug treated patients over placebo treated patients was only a fraction of a pound a week. The rate of weight loss was greatest in the first weeks of therapy