

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

THURSDAY, FEBRUARY 27, 1969

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

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

Present: Senator Nelson.

Also present: Chester H. Smith, staff director and general counsel; Benjamin Gordon, staff economist; Jay Cutler, acting minority counsel, and Elaine C. Dye, clerical assistant.

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

Dr. Ley, the committee appreciates your taking time to come here this morning and present your testimony. You may proceed to present it in any fashion you desire. And if at any time you wish to elaborate on anything in your prepared text, feel free to do so. We may have some questions from time to time.

Go ahead, Dr. Ley.

STATEMENT OF DR. HERBERT L. LEY, JR., COMMISSIONER OF FOOD AND DRUGS, CONSUMER PROTECTION AND ENVIRONMENTAL HEALTH SERVICE, PUBLIC HEALTH SERVICE; ACCOMPANIED BY DR. B. HARVEY MINCHEW, ACTING DIRECTOR, BUREAU OF MEDICINE, FDA; AND WILLIAM W. GOODRICH, GENERAL COUNSEL, OFFICE OF GENERAL COUNSEL, HEW

Dr. LEY. Mr. Chairman, I appreciate the opportunity of appearing before your committee today to discuss the current status of the antibiotic, chloramphenicol.

Approximately 1 year ago, we came before you to discuss FDA's actions and intentions in regulating the interstate distribution of this drug. Today, I would like to report on the steps we have taken and the results of these actions.

Shortly after the hearing in February of 1968, we notified the Parke, Davis Co. which markets the antibiotic under the trade name Chloromycetin, that substantial revision in the labeling would be necessary. The new labeling was completed and approved in April 1968.

Senator NELSON. In preparing the new label, who does the original preparation?

Dr. LEY. The original preparation in this particular case was done