

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

TUESDAY, FEBRUARY 6, 1968

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

The subcommittee met, pursuant to call, at 10:15 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; James H. Grossman, minority counsel; Susan H. Hewman, research assistant; and William B. Cherkasky, legislative director, staff of Senator Nelson.

Senator NELSON. We will now open the hearings of the Monopoly Subcommittee.

During the course of the Monopoly Subcommittee hearings on prescription drugs, the committee's attention has been called to a number of cases in which the administration of certain drugs has resulted in serious side effects.

A short time ago an industry witness, in relating to the committee the effectiveness of the company's broad spectrum antibiotic, Chloromycetin, concurred in the statement that the drug had been the cause of serious blood dyscrasias, some of which have resulted in death.

The "Physicians' Desk Reference" says that chloramphenicol "should not be used when other less potentially dangerous agents will be effective, or in the treatment of trivial infections, such as colds, influenza, or viral infections of the throat, or as a prophylactic agent," and so forth.

Yet, the manufacturer of Chloromycetin reported total domestic sales of \$45,000,000 in 1966, and a total sales of \$70 million worldwide.

There is a growing mountain of evidence that Chloromycetin is being widely overprescribed.

Dr. William Best, who has studied 408 cases of adverse reactions to the drug, has surfaced information on the indications for which doctors generally prescribe chloramphenicol.

In 30 percent of the cases cited, he found that the drug had been administered for "relatively trivial indications for which the drug should never have been used." He says that many complications occurred in patients who "should not have received chloramphenicol."

Recently FDA Assistant Commissioner Theodore O. Cron acknowledged that physicians in large numbers continue to ignore label warnings about misuse of the drug.