

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

WEDNESDAY, JANUARY 31, 1979

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The committee met, pursuant to notice, at 10 a.m., in room 6226, Dirksen Senate Office Building, Hon. Gaylord Nelson, chairman, presiding.

Present: Senators Nelson, Morgan Baucus, Weicker, Hatch, and Hayakawa.

Also present: Gerald D. Sturges, professional staff member; Stanley A. Twardy, Jr., minority counsel; and Judith K. Hillegonds, staff assistant.

Senator NELSON. The Senate Committee on Small Business will be in order.

The Senate Small Business Committee today resumes its hearings on competitive problems in the drug industry, and during the next several days we shall be hearing testimony specifically on the safety, efficacy and usefulness of propoxyphene, an analgesic widely sold under the trade name Darvon.

Testimony by medical experts in 1970 before this committee held that Darvon, on which Americans spent \$140 million in 1977, is less effective than aspirin.

Since that time, no independent, well-designed studies have offered any evidence to the contrary.

Major Federal agency actions taken since the hearings 8 years ago that affect Darvon and preparations containing propoxyphene include:

1. The Drug Enforcement Administration ordered that dextro-propoxyphene be included in schedule IV of the Comprehensive Drug Abuse Prevention and Control Act of 1970, effective March 14, 1977.

The principal effect of schedule IV classification is to limit a patient to one propoxyphene prescription and no more than five refills in any 6-month period.

2. The Food and Drug Administration amended the labeling for propoxyphene-containing preparations, effective August 7, 1978, "to include a warning against their use in pregnancy and a warning about their additive depressant effect when used with certain other products that are central nervous system depressants."