

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

MONDAY, FEBRUARY 5, 1978

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

The committee met, pursuant to call, at 10:05 a.m., in room 5110, Dirksen Senate Office Building, Hon. Gaylord Nelson, chairman, presiding.

Present: Senators Nelson, Baucus, Levin, Weicker, Hatch, Hayakawa, and Boschwitz.

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

Senator NELSON. Our first witness this morning will be Donald Kennedy, Commissioner of Food and Drugs accompanied by J. Richard Crout, Director, Bureau of Drugs and Richard Cooper, Chief Counsel, Food and Drug Administration.

Commissioner, we have your statement. You may proceed to present it as you desire.

STATEMENT OF HON. DONALD KENNEDY, PH. D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY RICHARD COOPER, CHIEF COUNSEL, FDA; AND J. RICHARD CROUT, DIRECTOR, BUREAU OF DRUGS, FDA

Commissioner KENNEDY. Thank you very much, Mr. Chairman. I am glad to have the opportunity to discuss our activity with respect to propoxyphene.

Although previous actions by both FDA and the Drug Enforcement Administration have had an important impact on the labeling and use of these drugs, the abuse and misuse of propoxyphene is nonetheless a genuine problem.

Senator NELSON. May I ask a question at this point? I have a copy marked "draft" and then you have another one. Are they significantly changed in any respect? I have marked up the copy marked "draft."

Commissioner KENNEDY. I would say that the changes are not extensive, Mr. Chairman, although I do not regard them as insignificant either. I think you will be able to follow just fine on your draft copy except for one or two places, but I would rather be held to the final version if that is all right.