

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

WEDNESDAY, JULY 9, 1975

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

The subcommittee met, pursuant to notice, at 10:15 a.m. in room 318, Russell Senate Office Building, Senator Gaylord Nelson (chairman of the full committee) presiding.

Present: Senator Nelson.

Also present: Benjamin Gordon, staff economist, and Kay Klatt, research assistant.

The CHAIRMAN. Today the Monopoly Subcommittee of the Senate Small Business Committee resumes its hearings on the safety, efficacy, and use of oral blood-sugar-lowering drugs, which are taken by diabetics.

Well-controlled studies showed that users of these drugs are $2\frac{1}{2}$ to 3 times more apt to die from heart problems than those who depend solely on diet or diet and insulin. According to expert testimony, these drugs also have limited uses, and Dr. John Davidson, the director of the largest university-based diabetes clinic in this country, estimated that more than 99 percent of the people using these drugs should not be using them.

In early 1974 the FDA moved to change the labeling of the blood sugar lowering drugs to reflect the latest scientific evidence about their dangers and lack of efficacy, but the agency's efforts were blocked by a court order. Nevertheless, recent additional studies confirming the dangers of these drugs have made a change in the labeling imperative, and the Commissioner of the Food and Drug Administration is here today to discuss the new labeling of the oral blood-sugar-lowering agents as well as the recent human and animal studies that confirm the need for prescribing physicians to be informed in the clearest terms possible of the latest knowledge in the field.

The new labeling—as well as other aspects of these drugs—will be discussed tomorrow by a number of medical experts.

Dr. Schmidt, you may present your testimony however you desire. The statement will be printed in full in the record.¹

¹ See prepared statement, page 13697.