

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13705

in the control animals. The FDA recently received the final report on this study, which has not yet been published in the literature.

At Dr. Wissler's request, FDA is supporting a further review of the pathologic findings by several independent pathologists.

6. Dr. D. F. Wu, et al., reported on the effects of tolbutamide on heart function in dogs with chemically induced diabetes at the meeting of the American Federation for Clinical Research on May 3, 1975 (abstract in Clinical Research 22:215A, 1975). The investigators found that, after one year of treatment with tolbutamide, left ventricular function was reduced and cardiac morphology altered compared to the control groups.

The animal studies do not necessarily bear directly on the excess cardiovascular mortality seen in tolbutamide-treated patients in the UGDP study, but they do suggest several mechanisms by which this might have occurred.

PROPOSED LABELING FOR ORAL HYPOGLYCEMIC DRUGS

Mr. Chairman, as you know, it has been the position of the FDA since 1970 that the findings of the UGDP study should be reflected in a warning in the labeling for oral hypoglycemic drugs and, in turn, in the use by