

13456 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

this study. What is needed is a new prospective study or studies to resolve the issues raised regarding oral hypoglycemics, coupled with immediate, balanced labeling reflecting the controversy.

The Committee on the Care of the Diabetic intends to pursue, through the National Institutes of Health, access to the raw data of the UGDP Study and further to continue its opposition to the proposed amendment of Regulation 1.3, as expressed in comments which we filed relative to this regulation.

I would like to call your attention to the fact that one of the most fruitful aspects of this matter which has continued these many years was the meeting held with FDA officials in October 1973. At that meeting I felt that real progress was made in achieving labeling acceptable to all parties engaged in this controversy. I am enclosing a draft of this labeling prepared by the Committee on the Care of the Diabetic and request that all parties meet once again at the FDA to further discuss this matter,

We offer our full cooperation in continuing the dialogue between the FDA and the Committee on the Care of the Diabetic which will result in new fairly balanced labeling which reflects the current scientific status which we feel, and have felt, is urgently needed.

Very truly yours,

Neil L. Chayet

NLC:GF