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SUMMARY OF THE COMBINED MEETING OF REPRESENTATIVES
FROM THE UGDP - FDA, June 16, 1969

The introductions were performed by Dr. Ortiz and following this, Dr. Max Miller presented a historical review of the UGDP. Dr. Klimt then presented a summary of the statistical structure of the study and then very briefly presented our conclusions as noted in the guide lines previously prepared. Dr. Klimt also summarized the conclusions of Drs. Cornfield and Brown. A variety of questions were raised by the FDA group. The great majority of these had to do with the question of whether the excess deaths in the tolbutamide group were significant. This despite already expressed reservations by the UGDP group regarding this point. Our major emphasis was on the lack of any evidence of efficacy in the tolbutamide treated group.

Among the questions were the following: 1. What was the difference in deaths overall and cardiovascular by clinic? 2. Why were the dropouts maintained in original groups? In partial response, it was mentioned that the mortalityis located in the good adherence group segment of the tolbutamide group. 3. What is the likelihood that there was physician bias in follow-up of patients? 4. What was the fate of the 51 patients who had glucose tolerance sums below 500? 5. Is it possible that the deaths are not significant since there has been only one tolbutamide death in the past six months? 6. Would it be possible to reveiw the deaths more intensively particularly with reference to other drugs or other modifying influences? 7. What placebo will be used in place of tolbutamide?

When asked what action the FDA might take, Dr. Ortiz summarized the possibilities. These included, (1) no action, (2) a modification of the circular or labels accompanying the drug, (3) a withdrawal of tolbutamide from the market. Dr. Ortiz could not provide any specific information as to which of these alternatives would be followed but he thought that perhaps the second was most likely. Members of the Coordinating Center offered to provide any further data that might be requested.

Finally, Dr. Ortiz thought that it would be unlikely that any action would be taken toward other marketed self-aneurias.

Respectfully submitted,

Theodore B. Schwartz, M.D.