



DIVISION OF CLINICAL INVESTIGATION

600 Wyndhurst Avenue
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October 21, 1977

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Stadium Gate 27
Minneapolis, Minnesota 55455

Dear Henry:

I have just obtained a copy of the analysis report of the UGDP audit by the FDA. Since a good deal of the discussion centers on their re-evaluation of the ECG's, you may wish to respond to that part. As a channel for doing so, may I suggest that you send me your comments at your earliest convenience. You do have copies of the pertinent ECG's.

The FDA has released the ECG's under the Freedom of Information Act to Mr. Chayet who I am told is about to have them separately evaluated by his own expert or experts. In the strict sense of the word, the ECG section is not part of the audit of the UGDP but an attempt at individual re-evaluation undertaken for reasons I need not explain. Thus, whatever the differences in interpretation, it can shed no light on the adequacy or lack thereof of data gathering in the UGDP.

You will be interested to note that in spite of the addition of nine cases, the deaths of whom we did not know about at the time of publication of the first UGDP reports (we published this later), the difference in cardiovascular mortality for the placebo/tolbutamide contrast stays identical and the one for placebo/phenformin was increased by two deaths, lowering the P-value which was published as .04.

Looking forward to hearing from you, I remain

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Cordially yours,

Christian R. Klimt, M.D., Dr. P.H.
Professor and Director