UNIVERSITY OF MINNESOTA
TWIN CITIES

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School of Public Health
Stadium Gate 27
Minneapolis, Minnesota 55455

December 1, 1978

Mr. Nathan Horwitz
Special News Editor
Medical Tribune
641 Lexington Avenue
New York, N.Y. 10022

Sent?? ([illegible] I was advised not to reply. See cc.)

Dear Mr. Horwitz:

I don't know whether your letter of November 15th was a routine letter or specifically addressed to this center. This center, of course, has no knowledge whatsoever of any of the UGDP clinical cases. Our technicians simply received and coded electrocardiograms in a standard fashion, blinded to any information about their origin. This is proper trial design in making any standardized group comparisons. In regard to any differences found in the clinical versus central coding of ECG's, it is my understanding that Dr. Ronald Prineas, who directs our ECG Center, has provided a current coding of cases selected for the FDA audit and that the agreements were within the realm of expected variations in classification of any clinical item.

One of the important points perhaps missed by some discussants of UGDP is that when diagnostic criteria are applied systematically across the board to experimental and control groups, then the comparisons can tolerate a certain amount of random variation for the many advantages of standardized and bias-free comparison. Of course, such variation is not allowable in the clinical handling and diagnosis of a given case. It is to be expected in the central, blinded classification of trial and other epidemiological data. The object is to eliminate systematic error or bias, and to keep random error to a minimum. The ECG coding from this center was not used for clinical purposes in the UGDP.

Sincerely,

Henry Blackburn, M.D.

HB:cre

cc: R. Prineas
C. Klimt