

UNIVERSITY OF MARYLAND  
SCHOOL OF MEDICINE  
DEPARTMENT OF SOCIAL AND PREVENTIVE MEDICINE

DIVISION OF CLINICAL INVESTIGATION  
600 Wyndhurst Avenue  
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Henry W. Blackburn, M.D.  
Laboratory of Physiological Hygiene  
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Stadium Gate 27  
Minneapolis, Minnesota 55455

*last folder for his weekly meeting*  
*Dr. R.P. - see me please*

Dear Henry:

I regret to have to inform you that I have learned that the FDA has made available, among other things during the UGDP audit, copies of the baseline ECG's of the 129 dead patients and 21 living patients for which they obtained this material. They have released these to Mr. Chayet, the lawyer for the Committee on the Care of the Diabetic, leading the suit now pending before the Appellate Court in Washington, D.C. You have a set of copies of these ECG's, and I presume you have already personally reviewed them. Thus, you would be prepared for any statements which may emanate in this regard from the FDA and from whomever the Committee on the Care of the Diabetic has retained to interpret them. As you know from the copy of my letter to Dr. Crout, I have protested in advance against their use for reinterpretation, which does not fall in the category properly associated with an audit. Moreover, I am afraid that some persons either mistakenly or maliciously may try to judge, from their interpretation, baseline comparability by treatment group. This would clearly seem to the scientifically initiated as totally inappropriate, but it is precisely this use which was brought to my attention.

With best regards.

Cordially yours,

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

CRK:pcb