

March 27, 1972

Donald Gallant, M.D.  
Professor of Psychiatry & Neurology  
Tulane University School of Medicine  
New Orleans, La. 70112

Dear Don,

I read your impressive ECDEU report with interest-- particularly the data on ORF 8063 and the neurophysiologic studies. But one issue stood out, that of the EKG effects of thioridazine. You report extensive and persistent EKG effects of thioridazine and mesoridazine. In our studies in St. Louis, Turan and I were also impressed with the EKG effects of thioridazine, in ~~our~~ studies of chlordiazepoxide and thioridazine.

This data becomes even more important when we review the clinical data for thioridazine, for this compound is no better than other antipsychotic drugs, and occasionally has been rated as worse.

Why, then, is the drug not withdrawn; or, as with iproniazid, limited to the few cases of confirmed therapeutic failure with other agents? Perhaps the ECDEU group could discuss this question in Spring Grove in June, and if other investigators agree, bring the data to the attention of the FDA.

Or, do you feel that the EKG changes are so trivial as not to affect the cardiovascular functions in these patients?

I look forward to seeing you in June.

Sincerely yours,

Max Fink, M.D.

cc: Jerome Levine, M.D.  
PRB-NIMH