

September 3, 1968

Dr. William Guy  
ECDEU Coordinator for Data Analyses  
The George Washington University  
Biometric Laboratory  
Washington, D.C. 20036

Dear Bill,

I want to thank you for the data analyses of our two studies, butaperazine and ketimipramine. These have been most helpful and I believe that these results, as I have presented them to the staff will assure their greater cooperation in future projects.

Enclosed are data outputs from our present laboratory data forms. You will note that there are three types of output - a reading of the optical scan report; a summary by patient giving a portrayal in time of each of the laboratory reports; and a summary for each laboratory test of all the reports in that study.

The data form used in these analyses did not have room for the drug, dose or route and these have had to be added by keypunching. Also, the forms developed in Missouri have many items which do not come from the clinical laboratory. As a result, we have created a new form which corrects many of these apparent deficits. Copies are enclosed.

If such a form could be used, and especially if various centers could be encouraged to carry out laboratory analyses in patients not receiving novel psychoactive drugs but either placebo, no drug or accepted FDA approved compounds, then we can develop a set of laboratory standards both for individual laboratories and for the ECDEU program as a whole. Such standards would be most useful in answering the questions of the FDA and of industry with regard to the significance of "abnormal" laboratory findings.

Dr. Guy

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I should like to make a report of the old laboratory form, the data outputs, and the new form available to members of ECDEU. Before doing so, I would like to discuss this with you, Dr. Salzman and/or Dr. Levine - whichever you recommend.

Again, my thanks for your helpful analyses.

Sincerely yours,

Max Fink, M.D.  
Professor of Psychiatry

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