

July 3, 1969

Mr. Marcus G. Grodberg, Director  
Research and Development  
Davies Rose Hoyt  
633 Highland Avenue  
Needham, Massachusetts 02194

Dear Mr. Grodberg:

The principal phase I drug evaluators of the NIMH-ECDEU study program are:

Sidney Merlis	Central Islip State Hospital, N.Y.
Arthur Sugerman	New Jersey Neuropsychiatric Institute
Donald Gallant	Tulane University
George Simpson	Rockland State Hospital

These men are accustomed to evaluating new psychoactive drugs, but do not usually report studies of sedatives.

There are also a number of fine researchers in Europe who are now doing phase-I studies, often at a cost less than U.S. investigators, and with U.S. investigators as monitors or co-analysts. In one study, the data was prepared on NIMH-type forms and analyzed here. There has been some discussion as to whether such trials can be included in an FDA submission. This objection to foreign work is to my mind, not relevant in phase I studies, where drug toxicity and dosage are the principal questions.

If such a European trial interests you, my laboratory may be able to monitor and process the data. One advantage of a European trial is the possibility that some EEG data for classification purposes may be obtained concurrently.

It was kind of you to visit my laboratory. I trust these suggestions may be helpful.

Sincerely yours,

Max Fink, M.D.  
Professor of Psychiatry

MF:kp