December 20, 1966

Dr. Alain Sanseigne
The Squibb Institute for Medical Research
Georges Road
New Brunswick, New Jersey

Dear Alain,

Enclosed is a protocol of our proposed fluphenazine decanoate study in ambulatory psychotic patients at the New York Medical College - Metropolitan Hospital Medical Center. A completed set of FDA forms and my curriculum vitae are also enclosed for your files. This protocol follows our recent discussions closely. Patients receiving other phenothiazines are first to be transferred to oral fluphenazine and then to intramuscular decanoate. Patients not receiving phenothiazines are first to receive oral fluphenazine and then the intramuscular preparation.

As a control group later in the study, a number of patients who are doing well on the intramuscular preparation are to continue receiving injections but with the fluphenazine at 1/100 the dose. By this novel method, I believe we can obtain some understanding of the direct pharmacological effects of fluphenazine.

If this study meets with your approval, we will be able to undertake the first transfers or administrations of oral fluphenazine about mid-January and the intramuscular administrations early in February. We will require continued supplies pf oral fluphenazine, fluphenazine decanoate, and about April, a low strength fluphenazine decanoate.

Initially, 200 cc of fluphenazine decanoate at a concentration of 25 mg/cc would be useful. This could be supplied in small multi-purpose vials or 2 cc ampules, whichever is available. As for the fluphenazine hydrochloride, I note that the usual preparation is as 1, 2.5 and 5 mg tablets. Since we are planning dosages averaging 40 to 60 mg, can 10 mg tablets be supplied? If so, an initial supply of 2000 tablets would be helpful. In addition, a placebo form (1000 tablets) would provide us with maximum flexibility in the management of our patients.

The data to be provided will include short case summaries and the clinical laboratory information. I will request the form used by the NIMH - ECDEU programs. If these are not available when the study is begun, we will create our own form and send it to you for your comments.

In addition to the supplies of medication, which for such a large study will be a significant contribution to the program, I would request your consideration of a grant-in-aide of $8,000 to be made available at the end of the study for data analysis, appropriate case reports and a final evaluation.

I look forward to your comments and to undertaking this study.

My best regards.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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