

May 25, 1965

William C. Janssen, M. D.
Director of Clinical Research
Lakeside Laboratories
1707 E. North Avenue
Milwaukee, Wisconsin 53201

Dear Dr. Janssen:

At the last meeting of the Pharmacological Committee of this Department, our letters were reviewed. It was suggested that an outline of our research program might be of special interest to you and would provide a more definite basis for providing us with the material for an IND application to the FDA for Ditrán.

During the past two years we have focussed some of our interest on the problem of the long term psychotic patients in our State Hospitals. We have admitted a number of these patients to our special research wards and after a number of months living in a new environment, have undertaken their retreatment with phenothiazine medications, intensive psychotherapy, and milieu therapies. During the first year we were able to discharge about 30% of the group. Of those remaining, we noted that there were a number of patients who failed to show any response to high doses of our psychotropic drugs, and very limited response to test doses of a variety of drugs including LSD, Sernyl, and pentothal.

In these patients we undertook a program of cerebral stimulation using Ditrán, either alone or combined with chlorpromazine. The patients developed a confusional state which could be sustained only by repeated administrations. After a few weeks of such repeated treatments, the patients showed a decrease in their psychotic symptoms during their recovery from the toxic state induced by Ditrán. This recovery persisted for many weeks and we were stimulated to expand this study program.

For this reason, we wrote to you in March requesting additional supplies of Ditrán. Since we do not have this drug available, we have made some trials with atropine as a substitute but are disappointed with the results. We believe that our observations are sufficient to warrant a more extensive trial of Ditrán as a therapy in treatment resistant psychotics.

We would like to undertake such a trial and have received authorization from the Pharmacology Committee of this Department to make the necessary applications to the FDA and to your laboratories to provide us with supplies of Ditrán.

Dr. Janssen

-2-

May 25, 1965

In your recent letter, you indicate that you are planning to turn over the data to the FDA and submit an NDA.

Is it necessary for us to wait until that application is processed to receive supplies of Ditran?

Are the Lakeside Laboratories interested in participating in such a clinical trial?

We would be grateful for your consideration of this request and for your assistance in our program.

Sincerely yours,

Max Fink, M. D.
Professor of Psychiatry

MF:kp

cc: Dr. Itil
Dr. Ulett