October 26, 1970

Dr. Harold Meiselas
New York State Narcotic
Addiction Control Commission
1855 Broadway
New York, New York 10023

Dear Harold, RE: Contract C44116

We are actively pursuing the development of a long acting narcotic antagonist for the prophylaxis and treatment of opiate dependence. Our clinical studies with naloxone will be re-instituted with new supplies about November 1; the contract with Food and Drug Research is operational; and we are negotiating another with Alza Corporation.

At the June 4 meeting we became acquainted with another antagonist, M 5050, developed by Reckett and Colman of Hull, England, for veterinary use. This antagonist is another "pure" antagonist, 16-20 times as potent as naloxone in animal trials, both abroad and at the University of Michigan in studies by Villareal.

We have received the cooperation of Reckitt and Colman to undertake human studies. With a permit to import issued by the FBN, I now have 10 grams M 5050.

Before clinical assays may be done, the FDA requires minimal animal toxicology data in 2 species, and such tests have not been done - they are not necessary in veterinary medicine.

We have submitted copies of the available data on M 5050 to the FDA, inquiring as to the minimal testing they would accept for an IND. On the basis of our discussion and my past experience, they will require testing in 2 species for 6 months with complete pathology. Such work is done by various university and commercial laboratories on a contract basis, and usually costs between $20,000 and $40,000, depending on the species studied.

We have written to Dr. Louis Harris of the University of North Carolina for his estimate of the FDA requirements and cooperation in this testing. He is the pharmacologist who developed cyclazocine at Sterling-Winthrop and is the most capable authority in this complex field.

You will recall that in our 1970-71 contract with the Narcotic Addiction Control Commission, we requested additional sums to purchase supplies of naloxone. Fortunately, Endo Laboratories were persuaded to make 6 Kg naloxone available at no cost.

We are writing to:

1) Acquaint the Commission with our progress and thoughts;

2) Request your review of the enclosed data, and ask that an opportunity be provided us to meet with Commission representatives to discuss this program; and,

3) Enable us to request use of the naloxone supply funds for a subcontract for animal pharmacology of M 5050, to shorten the time from animal testing to clinical trial.

Thank you for your interest.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

MF:kt

encs: FDA Submission
Ltr. L. Harris
M 5050 reprints