June 22, 1971

Dr. Lawrence Bergner
Health Services Administration
135 Worth Street
New York, New York 10013

Dear Dr. Bergner:

In continuing our program of study of the role of narcotic antagonists in opiate dependence, we are interested in assessing the clinical use of a new narcotic antagonist, M-5050. In animal trials, it is 8-10x as potent (on a mg basis) as naloxone with a duration that is slightly longer. In contrast to the manufacturing problems of naloxone, we have been assured by the manufacturer that adequate supplies for clinical purposes can be made.

We believe clinical trials with M-5050 should be undertaken. An IND must be filed and pre-clinical toxicity studies adequate to meet our standards prior to such trials. To file an IND we require animal toxicology data. These are not available from either the manufacturer or his U.S. representatives.

We have obtained proposals for the safety evaluation of M-5050 sufficient to meet our needs, including single oral and intravenous studies in rats, intravenous studies in dogs, oral administration for 13 weeks to rats and to monkeys, from various laboratories. The two principal proposals are from the Food and Drug Research Laboratories of Maspeth, L.I., and Woodard Research Corporation of Herndon, Virginia.

To carry out these studies, prepare and file an IND, prepare the necessary protocols, and undertake the initial human trials using the heroin "challenge" model will require funds for:

(1)	Animal toxicology	$31,500
(2)	Consulting costs	7,500
(3)	Nursing and psychiatric support	4,500
		$ 43,500

This study will require 18-24 weeks for the animal toxicology; 6 weeks for the IND; and 10-12 weeks for the initial heroin challenge data.

We trust these data will be sufficient to provide the basis for definitive clinical trials in opiate dependent subjects, and for trials in developing a long-acting formulation.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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