July 19, 1968

Dr. Merle L. Gibson
Acting Director
Division of Neuropharmacological Drugs
Office of New Drugs
Bureau of Medicine
Food and Drug Administration
Washington, D.C. 20204

Dear Merle,

I want to thank you for the cooperation which you have expressed on behalf of the FDA to Endo Laboratories regarding naloxone. In a meeting with one of their vice presidents last week, we were assured that supplies of naloxone would be made available for clinical trial early in August.

I am writing to ask your advice on another matter. In 1956-58 I investigated the effects of intravenous procyclidine in patients receiving convulsive therapy. Recently in response to suggestions from NIMH, I have reestablished a study program in convulsive therapy. It seems advisable to repeat some of the observations made earlier and to build on that experience. With this in mind, I called Burroughs Wellcome and requested a supply of parenteral procyclidine, since such is not listed in the PDR. Dr. William Colvin indicated that the IND for parenteral procyclidine was withdrawn and supplies of parenteral procyclidine were no longer available but could be produced. When I asked that he do so, at our expense, he indicated that this was not possible insofar as the IND had been withdrawn.

What are the steps necessary for me to meet existing FDA regulations and to permit Burroughs Wellcome to supply parenteral procyclidine for experimental use in a project approved by the appropriate authorities of the college, NIMH and the City of New York.

Thank you for your assistance.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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