

9-19-71

Hon. Paul Rogers
U.S. House of Representatives
Washington, D.C.

Dear Mr. Rogers,

You may recall that this laboratory has been in the forefront of research in the use of narcotic antagonists (naloxone and cyclazocine) in the treatment and prophylaxis of opiate abuse; and that we organized the 1970 meeting on this subject at the New York Academy of Medicine. I am writing to you at the suggestion of Professor Daniel Freedman of the University of Chicago, for I shared with him some of my doubts about our present national effort, and he recommended that I share these doubts with you.

I attended the September 8 meeting on new approaches to the treatment of opiate abuse organized by Drs. Jerome Jaffe and Robert Rees of the special office of the President. That meeting was a distinct disappointment, for the agenda was poorly prepared; the chairman was clearly ambivalent about the approaches and his interest in them; and the industry representatives were unwilling to alter their present commitments, expressing the view that there was little more that could be done.

Your committee is reviewing the President's request for the development of a centralized approach to drug abuse. Such an office could have some merit, were the officers available with experience and knowledge to lead the national effort. The preliminary suggestions for the control of abuse in the military; their cavalier dismissal of suggestions for prophylaxis in the armed forces; and their apparent mishandling of the problem of narcotic antagonists makes me less than sanguine that the President's request will serve a useful purpose. It is true that the established agency for research, the National Institute of Mental Health, has lacked leadership, but the approach of a new office, with its own large staff and apparent inexperience cannot serve a useful public purpose.

What of the narcotic antagonists? It is clear that there is a useful role for the narcotic antagonists in treatment, and that naloxone is the drug of choice at present. It is also probable that a combination of cyclazocine and naloxone may have a distinct role in the present crisis in opiate dependence, particularly in

a confined population, as in the military in Viet-Nam, both for treatment and for prophylaxis.

From the meeting, I would conclude that Endo/DuPont are not able to make the efforts necessary to develop a long acting antagonist. While they ascribe their difficulties to the practical issues of raw materials, patents and limited staff, it is clear that they have other issues of greater concern to them, and their efforts in the area of drug abuse control are only the minimum required to assuage public demands.

It is also my opinion that the leadership in the President's office is also ambivalent, for they have not the experience with the combination of naloxone and cyclzocine, as well as having a public committment to methadone.

For these reasons, among others, it may be useful for your Committee to consider the special commission approach-- a commission dedicated to evaluate the possible uses and roles for the narcotic antagonists. Such a commission could:

assure adequate supplies of naloxone for clinical trials, in part by alleviating the artificial quotas for the raw materials, principally thebaine;

coordinate, finance, and evaluate clinical studies of cyclazocine and naloxone, particularly in prophylaxis in the military;

invite contracts for the development of a long acting formulation of naloxone- (our experience with a silastic polymer formulation of naloxone makes us believe this approach to be feasible);

support studies of new antagonists; and,

provide an independent evaluation of methadone and the antagonists in treatment.

Such a commission could include some of the industry representatives, called together at your request by the P.M.A., and some independent university members.

The President's interest in drug abuse is commendable; the approach of developing a new office committed to no definite goal makes it likely that it will be less efficient than a commission approach-- even one designed as an integral part of the existing National Institute of Mental Health structure could be considered.

I shall be in Europe until October 8, but should you or your staff be interested in discussing these views further, I shall be available thereafter.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry