

July 07, 1970

Hearing Clerk
D. H.E.W.
5600 Fisher's Lane
Rockville, Maryland

Re: Methadone Regs, Proposed

Dear Sir:

I am writing in response to the proposed regulations entitled, "Conditions for the Investigational Use of Methadone". Since 1965, this laboratory and Department have been involved in studies of methadone maintenance and other forms of narcotic antagonism (cyclazocine, naloxone). I believe the exclusions listed, namely pregnancy, psychosis, physical disease and age less than 18 are too restrictive, and possibly illogical. I would suggest that these exclusions not be written in the regulations.

The treatment of pregnant women is a logical step in the methadone maintenance programs. After all, who is in more need of help out of the sordid drug addiction cycle than mothers? We do not know whether methadone is safe and surely every effort should be made to investigate this application.

Psychosis may be helped by methadone, which has antipsychotic effects in some reports, and such a study should be encouraged. Again, it seems illogical to restrict this medication, if it is indeed helpful, to healthy addicts only.

The same applies to serious physical disease. We have successfully treated a number of older patients with evidence of cardiovascular disease and methadone may have been life-saving in these subjects. Rather than restrict the studies, I would encourage these trials as particularly helpful.

If one restricts methadone to persons over 18, what treatments are to we offer the younger addict? What is the magic of '18'? While one may agree that it would be unfortunate to start younger persons on a life of addiction to methadone, is the same not true for an older person?

These restrictions are illogical to me, and may represent the artificial and puritanical views of the authors of this regulation, who, I suspect, may have had little experience with treatment of opiate dependent subjects with methadone. If they had, the regulations would reflect an expression of the need for these studies, rather than their exclusion.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry