July 2, 1971

Dr. Jerome H. Jaffe
Special Counsultant
to the President
The White House
Washington, D.C.

Dear Jerry,

The grapevine has you off for Viet-Nam, and I trust your trip will be helpful in clarifying the facts of drug abuse among our servicemen and their dependents.

Roger called earlier this week, and I freely shared our data with him. I also sent him a copy of the program of the meeting on narcotic antagonists to be held in Aberdeen, July 12-13, and a copy of a small project to get studies of M-5050 off the ground.

It is apparent that neither NIMH, BNDD, NAS/NRC, nor industry have provided the leadership to develop the antagonists. I believe the appointment of either a committee or an "office" for this development would be a necessary first step. New York City has established such a committee but included no one with dedication or interest and it is ineffectual.

A. In answer to your questions, the projects that are important are:

(1) Testing cyclazocine prophylaxis in Viet-Nam, using available oral doses of 2-4 mg/day, a rapid induction schedule, combined with naloxone during the first week.

(2) Develop a long acting antagonist.

(a) Contracts for trials with naloxone, using such methods as depot-oil, silastic, plastic film;

(b) Change import quotas for thebaine and import this and other raw materials for naloxone; and, establish an adequate supply of naloxone for clinical research.

(c) Trials for a long acting cyclazocine.

(3) Test and establish the pharmacology, clinical toxicology and clinical trials with M-5050 and EN 1639A. If either compound is useful, introduce it into trials of a long acting formulation.

(4) Clinical trials of cyclazocine or naloxone in direct comparison with methadone or l-alpha-acetylmethadol.

B. The "guesstimate" costs for the projects, on a "crash" basis:

(1) Prophylaxis - for consulting expenses US-VietNam, 4-6 staff members - $10,000; local military costs; supplies to be defined by Sterling-Winthrop based on size of study.

(2) Long acting development (1st year).

Naloxone	$800,000 (4 contracts @ $200,000)
Thebaine and naloxone supplies - ?	
Cyclazocine	$250,000

(3) Pharmacology M-5050 and EN 1639. I do not know the status of 1639A, but for M-5050:

Animal pharmacology	$42,000
Clinical trials	120,000
Supplies	50,000

(4) Clinical Comparison Cyclazocine-Methadone: 6 VA clinics, 600 patients, additional $200,000 organization cost added to present VA allocations of $400,000/unit.

C. Role for myself.

If you establish a commission, I suggest you consider A. Freedman, J. Villareal, D. Jasinski, G. F. Blane or K. W. Bentley (Great Britain), J. Woods and A. Kurland. I would be pleased to be a member or to chair it.

I have been actively soliciting the cooperation from industry for a few years and now know many of the people who could be involved in a long acting drug research program. If a committee were set up and given the support its studies justified, the programs would be successful in a reasonable time. They may require some special regulations regarding financial rights to industry, however, and some cooperation from BNDD.

Should you wish to undertake this program yourself, or have Roger, John or someone else do it, I will make my files available and introduce your appointee to the appropriate persons.

Incidentally, Villareal and Kosterlitz are chairing a symposium on the antagonists in Aberdeen, July 12-13 and you may wish to attend or send someone. I sent Roger a copy of the program in case you had not seen it.

Again, my best wishes for the rapid success of your mission.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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