738B-621

April 13th, 1973

Mr. John R. Cozzolino,
Narcotic Investigator,
Suffolk County Health Dept.,
Hospital Affairs Division,
Route #113,
Riverleigh Ave.,
Riverhead, N.Y.

Dear Mr. Cozzolino,

I am pleased to give you the following summary of our use of Schedule I drugs at the Health Sciences Center.

1. The principal study program is an evaluation of narcotic antagonists and narcotic substitutes in the treatment of opiate dependence. This study is in two parts - an experimental part at the University and a clinical part at the Veterans Administration Hospital in Northport. This study program is supported by a contract from the National Institute of Mental Health, HSM 42-72-115 (Antagonists to Opiates).

In the clinical program at the V.A. Hospital in Northport, we are treating veterans who have been using opiates for two years or longer with cyclazocine, methadone, levomethadyl (l-alpha-acetylmethadol) and naltrexone. As part of this program we also use heroin challenges.

During the next two years we anticipate expanding the range of substances to be tested to include diprenorphine and BC2605, as narcotic antagonists, and such other opiates as may be of interest in order to define their duration of action.

Specifically, patients with a two year history of opiate use are examined and based on their psychological characteristics, recommended for maintenance or deconditioning therapy. If maintenance therapy, we follow the FDA guidelines for the treatment with methadone. Approximately one half of the subjects are maintained on low dose methadone (approx. 50 mg)

and half on high dose (approx. 100 mg). During the next month a portion of the patients who have been on methadone two months or longer will be transferred to levomethadyl at 80 mg three times a week. This, too, will follow FDA regulations.

Some patients are inducted into deconditioning therapy in which they receive cyclazocine up to 4 mg a day (or beginning July, naltrexone to 100 mg a day). At these dosages blockade is measured by challenges with heroin or morphine, usually 25 mg of each.

In the experimental program at the University, we are attempting to find the EEG and other physiologic effects of various substances. Under this contract we are assessing the EEG effects of naltrexone, morphine, diacetylmorphine, etorphine, and extracts of cannabis. A portion of this work is supported by MH 24020 - "EEG in Human Psychopharmacology", a grant from the NIMH.

In this program suitable volunteers are given participating experiments in the EEG laboratory and for periods of up to six hours have physiological recording after administration of one of the scheduled substances.

When substances are delivered, they are usually sent to my office (at Stony Brook). Such supplies as may be necessary at the Veterans Administration Hospital are transshipped to the V.A. and maintained in a safe similar to that which we have at the University. (For methadone and other substances usually available to the V.A., we obtain our supplies from the pharmacy which maintains the basic supplies and records, and delivers to us, in individual bottles, drugs for individual patients for specified days).

2. For a number of years we have been studying the effects of smoking cannabis, hashish, and various derivatives, such as THC-delta-9, THC-delta-8, cannabidiol and cannabinol on physiological measures such as EEG, heart rate, respiratory rate, pupil size, etc. This work was done in New York under NIMH grants, and a contract HSM 42-70-98. This contract included a study of chronic hashish users in Greece, where we have also examined the physiological effects of these substances in acute inhalation experiments. This part of the work in Greece is continuing and we have requested funds to continue the U.S. portion at the University.

In the laboratory work, suitable volunteers inhale these substances in the EEG laboratory and remain under supervision for periods up to eight hours. Physiological recordings are then analyzed.

3. At the present time we are negotiating a contract with the V.A. for the comparison of l-alpha-acetylmethadol and high and low dose methadone in the maintenance of patients. This study, if it is funded, will be done at the V.A. in Northport with outpatient units at still to be designated sites in the County, one of which will be at the Health Sciences Center.

We are not limited in our studies to Schedule I substances, but also assess substances in Schedules II, III, IV, and V. For all these studies, for such substances as heroin, marihuana, THC, etc., supplies are obtained from the NIMH. We have in the past, and plan in the future, to obtain supplies of cannabis from this source and transship these to the University of Athens under our contract HSM 42-70-98. Shipment is to Professor Costas Stefanis, at the University of Athens (74, Vasillissis Sophias Ave., Athens, Greece).

Occasionally we deal with substances which are sent to us by laboratories in Europe or the U.S. In the past, this has been true for hashish, etorphine, and diprenorphine. As our studies continue, we anticipate importing such other substances as may be necessary for our studies, and which may be similar to the ones already studied.

This statement is submitted in support of our application for a license to engage in research with controlled substances. I trust this information is useful.

Thank you for your assistance.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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