

Alcohol, Drug Abuse and Mental Health Administration Rockville MD 20857

August 22, 1991

Mr. Carl E. Olsen P.O. Box 4091 DesMoines, Iowa 50333

Dear Mr. Olsen:

This is in response to your letter of August 4 to Dr. Richard Hawks about the Government's marijuana program. There are two aspects to the program: one is the distribution program to which you refer in your letter and the other is the long-standing program of marijuana research carried out by the National Institute on Drug Abuse and the National Institute of Mental Health.

The use of marijuana as a "medication" to treat a variety of disorders—including the nausea that accompanies cancer or AIDS chemotherapy, increased intraocular pressure from glaucoma, pain, and the muscle spasticity of multiple sclerosis—has been promoted by a number of individuals and groups, both professional and non-professional, over the past 20 years. During this time, the PHS has allowed a very small number of patients (fewer than 15) to use marijuana for these indications.

The program is administered by the Food and Drug Administration (FDA) and is part of what is called the "compassionate" IND (Investigational New Drug) program. The program requires that the patient's physician submit a research protocol to examine the effects of marijuana on the symptoms of his patient. An annual report of results is required. The physician must also obtain a license from the Drug Enforcement Administration (DEA) to dispense Schedule I drugs. The only role of the National Institute on Drug Abuse in this process is the distribution of the actual cigarettes, once appropriate approvals have been obtained from the FDA and the DEA. You may obtain additional information on the compassionate IND program from Ms. Corrine Moody, Pilot Drug Program, Food and Drug Administration, Room 9B-45, 5600 Fishers Lane, Rockville, Maryland 20857.

Recent increased interest in the therapeutic use of marijuana has caused the Public Health Service (PHS) to reexamine its policy on the distribution of marijuana cigarettes. In the past, PHS policy has been to support the study of the therapeutic potential of various active ingredients in marijuana, such as THC, while discouraging the use of the plant material, marijuana. This has allowed the therapeutic potential of cannabinoids to be realized while the campaign against drug abuse continues. Thus, <u>Marinol</u>

(synthetic THC, the principal active ingredient in marijuana) and Nabilone (a synthetic cannabinoid) have been approved by the FDA for the treatment of nausea due to cancer chemotherapy. For a variety of technical reasons having to do with the route of administration of marijuana (smoking) and the complex metabolism and distribution of cannabinoids within the human body, the PHS has decided not to expand the compassionate IND program for use of marijuana. Anyone who is already receiving marijuana cigarettes from the Government will continue to do so. The PHS will continue to encourage physicians to use synthetic THC, which has been proven safe.

Through the National Institute on Drug Abuse and the National Institute of Mental Health, the PHS sponsors an active program of cannabinoid research. Over the last 20 years, many millions of dollars have been spent on hundreds of scientific research projects investigating the properties of marijuana and the cannabinoids. If you would like information on the results of this research, please contact the National Clearinghouse on Alcohol and Drug Abuse Information, 800-729-6686, P.O. Box 2345, Rockville, Maryland 20852.

Sincerely,

Christine R. Hartel
Christine R. Hartel, Ph.D.

Deputy Director Division of Preclinical Research National Institute on Drug Abuse