aids wasting syndrome protocol update

A decision from the NIH peer review committee is expected around September or October.

ALMOST FOUR YEARS HAVE PASSED since MAPS began assisting Dr. Donald Abrams, UC San Francisco, in the attempt to secure permission to conduct a clinical study comparing the medical use of smoked marijuana and dronabinol (Marinol, the oral THC capsule, Roxanne Laboratories, Columbus, OH) in the treatment of people suffering from the AIDS wasting syndrome. For anyone interested in the history of this long and wearisome saga, the entire tale can be found in back issues of the MAPS newsletter posted on our web site at http://www.maps.org. The brief summary is that Dr. Abrams' research proposal had been approved by the FDA and all the appropriate regulatory authorities. However, the study could not go forward because the National Institute on Drug Abuse (NIDA), which has a monopoly on the supply of marijuana that can legally be used in research, refused to provide any. According to NIDA, the protocol was "scientifically deficient." This rationale is transparently political and poor politics at that, since about 75% of U.S. voters support the medical use of marijuana when prescribed by a doctor.

The revised protocol was submitted for review in the NIH grant cycle beginning May 1, 1996.

The only ray of hope offered by Dr. Alan Leshner, the Director of NIDA, was an offer to reconsider NIDA's refusal to provide the required marijuana if and only if: a) the protocol was rewritten in the form of a grant application to the National Institutes of Health (NIH), b) was favorably reviewed by an NIH peer review committee and, c) government funding for the study was provided. This is a rather difficult hurdle to clear since only about 10-15% or less of all grant applications are funded. Nevertheless, in order to keep pressing ahead, MAPS contributed $4,000 and the Drug Policy Foundation contributed $1,000 to support the efforts of the staff of the San Francisco Community Consortium, of which Dr. Abrams is the research director, in the redesign of the experimental protocol.

The revised protocol which is discussed below was submitted for review in the NIH grant cycle beginning May 1, 1996. A decision from the NIH peer review committee is expected around September or October.

As stated in the protocol, "the Community Consortium is an association of HIV health care providers in the San Francisco Bay area and was established in March 1985 to encourage communication and collaboration between AIDS researchers at the University of California San Francisco AIDS Program at San Francisco General Hospital and front-line primary care physicians in practice in the community. Shortly after its inception, the Community Consortium developed into one of the nation's pioneer community-based clinical trials organizations. One of the Community Consortium's primary goals has always been to investigate agents that are in widespread use in the community in a controlled fashion in order to evaluate their safety and possible efficacy."

Specific aims of Dr. Abrams' study

"The primary aim of the investigation is to evaluate the safety and efficacy of smoked marijuana as an appetite stimulant for HIV-associated anorexia and weight loss. Dr. Abrams proposes to do this by conducting two related, sequential studies: a Phase I/II randomized, double-blind placebo-controlled, within-subjects evaluation of smoked marijuana conducted in an inpatient setting at the General Clinical Research Center at San Francisco General Hospital, and a Phase II/III randomized, open-label study of smoked marijuana versus dronabinol conducted as an outpatient study. The NIH grant application is a proposal to conduct only the initial outpatient component of these investigations.

The inpatient study will provide data on the effects of moderate (≈ 4%) THC-content marijuana on appetite and food intake, as well as safety data on immunologic function, HIV viral load, pulmonary function, endocrine function and neuropsychological functioning. Based on results of the inpatient study, Dr. Abrams plans to conduct an outpatient study that will provide comparative data on the effects of smoked marijuana to the licensed oral synthetic preparation, dronabinol. The outpatient study will also provide safety data on immunologic function, HIV viral load, pulmonary function and endocrine function when these agents are used to treat patients with HIV-associated anorexia and weight loss over several months.

As the public policy implications posed by the medical use of marijuana are significant, an inpatient study conducted under well-controlled, experimental conditions and an outpatient study conducted under "real world" conditions in primary care settings are needed to fully evaluate the safety and efficacy of this highly controversial therapy. •"