

MAPS: Missoula Chronic Cannabis Use Research Study

By Ethan Russo, M.D. (erusso@mtneuro.com)

MAPS is pleased to announce that funding has been secured for the Missoula Chronic Cannabis Use Research Study. This research project will examine the overall health status of six of the eight surviving federally-supplied medical marijuana patients. These patients receive their medication in canisters containing 300 cigarettes of regulated and federally-grown medical marijuana on a regular basis, according to their FDA-approved protocols.

Patients receive their medicine from the "Compassionate Use" Program of the National Institute of Drug Abuse (NIDA) under the medical supervision of their Investigational New Drug (IND) study physician. The Compassionate Use Program was closed by NIDA in 1992 to any new patients beyond the first fifteen (seven are now deceased).

Despite the obvious opportunity to generate data on the use of cannabis by these patients, and its possible sequelae, neither NIDA, other branches of the National Institutes of Health, nor the FDA has ever attempted to collect or analyze information from this cohort. The Missoula Chronic Cannabis Use Study provides a unique and important opportunity to amass and analyze the long-term effects of cannabis on patients who have used a known dosage of standardized, heat-sterilized quality-controlled supply of low-grade medical marijuana for 8-22 years. Six of the eight remaining legal patients have agreed to participate in this study. Two prefer to retain anonymity.

Each study patient will undergo the following tests:

- Pulmonary function tests
- Chest X-ray, P-A & lateral
- Neuropsychological tests
- Hormone and immunological serum assays
- Electroencephalography (EEG)
- P300 testing (a computerized EEG test of memory)
- Neurological examination

The study is being conducted in an effort to further scrutinize federal claims that the harmful sequelae of the chronic use of smoked cannabis for therapeutic purposes are far worse than the benefit derived.

The proposed study will be conducted at St. Patrick Hospital and the offices of Montana Neurobehavioral Specialists, Missoula, Montana. Institutional Review Board (IRB) approval for the study has been obtained. The study will be co-conducted by Ethan Russo, MD, and Mary Lynn Mathre, RN. The essence of the study is to evaluate the functional condition of these chronic cannabis patients. All physiological systems will be probed to some degree but concentration will be on pulmonary and neurological functions. Three subjects were fully evaluated from May 3 - May 6, 2001.

MAPS has pledged \$10,000 to this study, as has a private donor, while the Zimmer Family Foundation has pledged \$1050. The results of the study are to be distributed as widely as possible. Data will be presented at the International Cannabinoid Research Society meeting in Madrid, Spain, in June 2001, and at the Second National Clinical Conference on Cannabis Therapeutics to be held in Portland, Oregon, in the spring of 2002.

A full report of the results will be published in the *Journal of Cannabis Therapeutics*. Articles on the study will also be submitted to peer-reviewed journals of wide circulation.

This is designed as a one-time study. Replication is possible at a future time if the need or advisability of such replication is deemed appropriate, and if the patients agree to participate. When completed this study can serve as a baseline for future comparisons.

Key Operating Personnel

Primary Investigators:

Ethan B. Russo, M.D. Dr. Russo is a practicing neurologist, board certified in neurology with special qualification in child neurology. Clinical Associate Professor at the Department of Medicine, University of Washington, and Adjunct Professor of Pharmacy at the University of Montana. He is the editor of *The Journal of Cannabis Therapeutics*.

Mary Lynn Mathre, RN, MSN, CARN, is the Addictions Consultant to the University of Virginia Health Sciences Center. She is the President of the Virginia Nurses Society on Addictions, and the Co-founder of Patients Out of Time.

Co-Investigators:

Juan Sanchez-Ramos, MD, PhD, is a neurologist and faculty member of the University of South Florida School of Medicine in Tampa, Florida.

Paul Bach, Ph.D., is a Montana Neurobehavioral Specialists Neuropsychologist.

Rob Velin, Ph.D., is a Montana Neurobehavioral Specialists Neuropsychologist.

Fund and Logistic Administrator:

Al Byrne, Lcdr., USN, (ret.), Co-founder Patients Out of Time.