

Preliminary Report Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis

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The Missoula Chronic Clinical Cannabis Use Study was proposed to investigate the therapeutic benefits and adverse effects of prolonged use of “medical marijuana” in a cohort of seriously ill patients approved through the Compassionate IND (Investigational New Drug Program) of the Food and Drug Administration (FDA) for legal use of cannabis obtained from the National Institute on Drug Abuse (NIDA), under the supervision of a study physician. The aim was to study the overall health status of 4 of the 7 surviving patients in the program.

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Unfortunately, its first patient, Robert Randall, passed away of complication of AIDS during the course of the study. The program began in 1976 when Randall successfully won a legal case demonstrating the medical necessity of cannabis to treat his progressive glaucoma.

This project provides a unique and important opportunity to scrutinize long-term effects of cannabis on patients who have used a known dosage of a standardized, heat-sterilized quality-controlled supply of low-grade marijuana from 10 to 19 years. Preliminary results demonstrate clinical effectiveness in these patients in treating glaucoma, chronic musculo-skeletal pain, spasm and nausea, and spasticity of multiple sclerosis. All 4 patients are stable with respect to their chronic conditions, and are taking many fewer standard pharmaceuticals than they were previously. Mild changes in pulmonary function were observed in 2 patients, while no significant attributable sequelae were noted in any other physiological system examined in the study, which included: MRI scans of the brain, pulmonary function tests (spirometry), chest X-ray, neuropsychological tests, hormone and immunological assays, electroencephalography (EEG), P300 testing (a computerized EEG test of memory), and neurological history and clinical examination. These results would support the provision of clinical cannabis to a greater number of patients in need. We believe that cannabis can be a safe and effective medicine with various suggested improvements in the existing Compassionate IND program.

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