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First Medicinal Cannabis Studies Approved by Research Center

The Center for Medicinal Cannabis Research (CMCR), a University of California-based center funded by the State of California, announces the approval of its first proposals for the study of cannabis as a treatment for specific medical conditions.

Four proposals out of thirteen submitted from various California research institutions were recommended for funding by the CMCR's independent Scientific Review Board following rigorous scientific review, with full approval pending final review by state and federal regulatory agencies. The studies are:

- Marijuana for the Treatment of HIV-Related Peripheral Neuropathy, Project Director Donald Abrams, M.D. (UCSF)-An inpatient study on the efficacy of smoked marijuana for the alleviation of peripheral nerve pain associated with HIV infection.
- Short-Term Effects of Cannabis Therapy on Spasticity in Multiple Sclerosis, Project Director Jody Corey-Bloom, M.D. (UCSD)-An outpatient study of the efficacy and safety of smoked marijuana versus placebo for the treatment of muscle spasms, loss of function, and related pain in patients with Multiple Sclerosis (M.S.).
- Placebo-controlled, Double-Blind Trial of Medicinal Cannabis in Painful HIV Neuropathy, Project Director Ronald Ellis, M.D., Ph.D., (UCSD)-An outpatient study on the efficacy of smoked marijuana versus placebo for alleviation of peripheral nerve pain associated with HIV infection.
- Impact of Repeated Cannabis Treatments on Driving Abilities, Project Director Thomas Marcotte, Ph.D., (UCSD)-An outpatient study on the effects of repeated administration of medicinal cannabis on driving ability (acute and/or long-term). Patients with
HIV-related neuropathy or spasticity associated with M.S. will be evaluated for impairments using driving simulator assessments.

The Research Advisory Panel of the State of California has reviewed and approved the proposals. They have been submitted to the human subjects review boards of both campuses, and they are also being reviewed by a scientific review group within the Office of Public Health and Science of the Department of Health and Human Services (HHS). They will be forwarded for final review to the Food and Drug Administration (FDA), the National Institute on Drug Abuse (NIDA) and the Drug Enforcement Agency (DEA), to ensure that the proposals are in full compliance with federal regulatory policies. Upon final approval, these studies will use cannabis provided by NIDA in accordance with procedures developed by the Public Health Service.

"We have followed a careful process of protocol review, engaging senior scientists from around the country on our Scientific Review Board to evaluate proposals and recommend funding for those that meet our high scientific standards, within the strict procedures established by Health and Human Services, the DEA and the FDA," said CMCR director Igor Grant, M.D., professor of psychiatry at UCSD.

Besides the Scientific Review Board, the CMCR also has named a National Advisory Council to advise and assist the Center's directorate. The Council held its first meeting in February. Grant noted that the National Institutes of Health, the Institute of Medicine, NIDA, and other experts were consulted, providing names for the Review Board and Advisory Council.

"These approved studies will begin to gather evidence to determine whether or not marijuana is effective as a medical treatment for certain conditions," said Senator John Vasconcellos (D-Santa Clara).

The CMCR was established in August 2000 as a result of SB847 (Vasconcellos), passed by the State Legislature and signed into law by
Gov. Gray Davis in October 1999. California voters approved the use of marijuana as an alternative treatment for specific medical conditions, but in the absence of data regarding appropriate use and potential adverse effects, the medical guidelines for administration of cannabis are ambiguous. The legislation called for a three-year program of high quality medical research on the efficacy and side effects of medicinal cannabis in patient care for diseases and conditions as defined by a report by the National Academy of Sciences, Institute of Medicine, and by the National Institutes of Health expert panel.

The CMCR is a collaboration between UCSD and UCSF, headquartered at UCSD, with Grant serving as director. Co-directors are Donald Abrams, M.D., clinical professor of medicine at UCSF; J. Hampton Atkinson, M.D., professor of psychiatry, and Andrew Mattison, Ph.D., associate clinical professor of psychiatry, and family and preventive medicine, both at UCSD. The CMCR coordinates the submission, review, and funding of proposals from statewide research institutions.

A spring call for proposals was issued in January 2001, with a deadline of March 15, 2001 for submission of proposals. It is anticipated that additional studies will be reviewed and approved to begin their work in the late spring of 2001.