

## medical marijuana research: NIDA Just Says No to Science

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### The struggle to conduct Dr. Abrams' study continues.

#### Background

For the last three years, MAPS has been working with Dr. Donald Abrams, a world-renowned AIDS researcher on the faculty of UC-San Francisco. We have been attempting to obtain governmental permission to conduct a double-blind pilot study comparing the use of smoked marijuana and the oral THC capsule in the treatment of weight loss associated with the AIDS wasting syndrome. Thousands of AIDS patients are using marijuana illegally to treat the wasting syndrome and are reporting beneficial results, making a controlled clinical trial the logical next step. What makes our effort so difficult is that the federal government has not permitted a single study into any of the reported beneficial medical uses of marijuana in over a decade.

After years of effort, critique, review and redesign, Dr. Abrams' study design has been approved by the Food and Drug Administration (FDA), the UC San Francisco Institutional Review Board, the California Research Advisory Panel (which must approve all research in California with Schedule I and 2 drugs), and the Scientific Advisory Committee of the San Francisco Community Consortium (where Dr. Abrams is research director). Dr. Abrams' study has also been endorsed by the Physicians Association for AIDS Care (the nation's oldest and largest association of physicians involved with AIDS research and treatment) and the Federation of American Scientists.

For the last year, the only remaining bureaucratic hurdle has been the need to obtain a legal source of marijuana for Dr. Abrams' study. MAPS initially tried to import marijuana from a legally licensed marijuana research firm in the Netherlands. However, the Drug Enforcement Administration (DEA) refused to grant a Permit to Import, citing Dutch lack of compliance with provisions of the Single Convention, an international drug treaty. Though the Single Convention contains special exemptions for the import/export of marijuana for medical purposes, we have not yet succeeded in reversing DEA obstructionism.

#### NIDA says "No science"

In August 1994, Dr. Abrams requested marijuana from the National Institute on Drug Abuse (NIDA), which has a monopoly on the domestic supply of marijuana for research purposes. On April 19, 1995, after almost nine months of silence, NIDA Director Dr. Alan Leshner wrote to Dr. Abrams to say that his

request for marijuana was rejected. Dr. Leshner claimed that the study's design, scientific merit and rationale were inadequate.

Not surprisingly, Dr. Leshner's critiques of the protocol were without merit. For example, he claimed that the study was too small to generate reliable results. While this seems to be an important issue, Dr. Leshner purposefully overlooked the fact that Dr. Abrams' study was not intended to be a large-scale clinical trial designed to generate reliable results. Dr. Abrams' study was designed to be a small preliminary pilot study, one of the purposes of which is to generate information about how many subjects should be included in the subsequent large-scale clinical trial. The use of a pilot study is well-established in scientific research and is a procedure preferred by the FDA. Dr. Leshner's other critiques, such as the concern that Dr. Abrams did not require that subjects smoke every bit of their daily maximum allowance, directly contradicted FDA policy as established in the clinical trials for the oral THC capsule. As Federal law specifies, FDA, not NIDA, is the government agency with responsibility for the design of clinical trials. NIDA's position that FDA policies are inadequate reflects NIDA's political opposition to medical marijuana research, which NIDA tries to cover with specious scientific arguments.

#### What now

The struggle to conduct Dr. Abrams' study continues. MAPS is exploring the possibility of purchasing marijuana directly from NIDA's supplier, thus privatizing the entire research effort. In addition, we are exploring the option of creating our own legally licensed marijuana-growing company. We are also working to overcome DEA opposition to the importation of marijuana. Though the Clinton Administration lacks the courage to stand up for scientific freedom and the needs of patients, MAPS will not give up.

#### Related research

The MAPS/California NORML marijuana smoke filtration study, designed to evaluate drug delivery devices such as water pipes and vaporizers for possible use in Dr. Abrams' study, will be completed soon. The next MAPS Bulletin will report on the results of the study. •