FOR IMMEDIATE RELEASE
September 29, 2011

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PRESS RELEASE:
NIDA Refuses to Sell Marijuana to Scientists, Blocking FDA-Approved Research for Vets with PTSD

SANTA CRUZ, Calif. – A proposed pilot study of marijuana for 50 veterans with chronic, treatment-resistant posttraumatic stress disorder (PTSD) is at a standstill, following a refusal by the US Department of Health and Human Services (HHS) to sell researchers marijuana for the study.

The study, to be conducted by Dr. Sue Sisley of the University of Arizona-Phoenix and sponsored by nonprofit research and educational organization the Multidisciplinary Association for Psychedelic Studies (MAPS), has clearance from the US Food and Drug Administration (FDA). However, the monopoly held by the National Institute on Drug Abuse (NIDA) on the legal supply of marijuana for research allows it to deny researchers permission to purchase marijuana regardless of FDA clearance.

Hundreds of veterans in medical marijuana states already report using marijuana to control their PTSD symptoms. The growing number of service members returning from Iraq and Afghanistan with combat-related trauma combined with large numbers of treatment-resistant veterans highlights the pressing need for research into additional treatments for PTSD. To date, no studies have examined marijuana for PTSD.

On April 28, the FDA accepted MAPS' study protocol. That same day, MAPS submitted the protocol to be reviewed by NIDA and the Public Health Service, both part of HHS. This additional review is required solely because of NIDA's monopoly. Researchers do not need approval from NIDA or the PHS when initiating studies into the therapeutic uses of more controversial compounds, such as MDMA and LSD.

On September 16, after a delay of four and a half months, HHS informed MAPS that the five NIDA/PHS reviewers had unanimously rejected the study as currently designed. According to MAPS Executive Director Rick Doblin, Ph.D., the reviewers offered contradictory critiques, misunderstood key protocol design elements, requested expensive and tangential additions to the protocol, and made unfounded assumptions about the study design, revealing their focus on basic science research and lack of familiarity with drug development research. The reviewers also treated the submission as if MAPS were requesting a government grant for the study rather than using private funds. Even if NIDA does eventually agree to sell MAPS the marijuana, getting to that point will take extensive, time-consuming, and costly negotiations—while veterans continue to suffer.

For over 10 years, MAPS has been working with Professor Lyle Craker at the University of Massachusetts-Amherst to end the federal monopoly on marijuana for research by requesting a DEA license to start a MAPS-funded marijuana farm. On August 15, 2011, the DEA protected the monopoly by rejecting a 2007 DEA Administrative Law Judge's recommendation that it was in the public interest to grant Prof. Craker the license. MAPS is contesting DEA's rejection in the First Circuit Court of Appeals with generous pro-bono representation from major Washington, DC, law firm Covington & Burling LLP.

September 16 HHS Cover Letter:
http://www.maps.org/mmj/OASH_MAPS_Coverletter_Doblin.pdf
Annotated Reviewer Comments:
http://www.maps.org/mmj/HHS_Consolidated_Reviewer_Comments_Annot.pdf
MAPS Website:
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