Throughout 2012, MAPS worked tirelessly to cut through key areas of red tape in order to begin a clinical study on the use of marijuana as a treatment for symptoms of chronic posttraumatic stress disorder (PTSD). Medical doctors have reported anecdotal evidence for well over a century that patients who smoke or ingest the flowering buds of Cannabis sativa, or marijuana, have reduced physical pain as well as reduced insomnia, anxiety, and depression, all of which are common symptoms of PTSD.1-2 Recognizing the need for thorough scientific analysis of these claims, MAPS has taken the initiative to diligently support clinical research into the safety and effectiveness of marijuana as a therapy.

One such proposal is a MAPS-sponsored study to be conducted at the University of Arizona under the direction of Principal Investigator Dr. Sue Sisley, to examine the safety and efficacy of five potencies of smoked or vaporized marijuana for symptoms of PTSD in 50 US veterans.3 While MAPS gained approval to conduct the study from the FDA in April 2011, a host of competing federal and state policies have prevented its initiation and made it impossible for researchers to conduct a scientific analysis of the merits of marijuana as a medicinal therapy.

Marijuana is now legally available for eligible patients in 18 states and the District of Columbia, and two states legalized marijuana for recreational use in November 2012.4 In spite of this growing tolerance for medical marijuana at the state level, the federal government often blocks research into the medicinal applications of marijuana. It accomplishes this blockade through the Schedule I classification of marijuana combined with the maintenance of a monopoly on the control and distribution of marijuana for federal research by the National Institute of Drug Abuse (NIDA).

Even though marijuana was on the U.S. formulary prior to 1937 as an approved medical compound and was supported by the American Medical Association at that time as a useful therapeutic agent, the Cannabis Tax Act of 1937 raised numerous policy roadblocks that still obstruct marijuana research today. An assessment by The Boston Globe rings true: While clinical research rigorously validating the therapeutic benefits of the marijuana plant might be modest, “that says more about the difficulty of studying an illegal substance than it does about the inherent medical value of the plant.”5

The most significant blockade to MAPS’ marijuana research efforts has been NIDA’s refusal to provide the marijuana needed to conduct the study in Arizona. It is not currently possible to obtain marijuana for FDA-reviewed research studies from any source except NIDA, which grows, stores, and sells marijuana to researchers who...
study the adverse effects of the plant, from a single farm located at the University of Mississippi managed by marijuana scientist and entrepreneur Mahmoud ElSohly. In such a hostile climate for federally-reviewed marijuana research, it came as no surprise when—in September 2011, five months after the FDA cleared the study—NIDA and its parent agency the Public Health Service (PHS) conducted an independent review of the study protocol and decided it did not have scientific merit. One of the reasons the reviewers cited was that the protocol was not yet been scrutinized by an Independent Review Board (IRB), which reviews studies primarily with an eye for the safety of subjects.

MAPS has now secured approval of the proposed research protocol by the University of Arizona IRB in addition to the previous thorough review by the FDA. After careful assessment and three rounds of review, the IRB indicated their satisfaction with the overall study design and their assessment that the protocol provides sufficient safety measures for patients who enroll in the clinical trial. The final review of the study protocol by the IRB occurred on October 23, 2012. Now, with approvals from both the FDA and IRB clearly supporting the scientific merit of the study, there is mounting pressure on NIDA and the Drug Enforcement Administration (DEA) to reform their stance on these issues, to allow the much-needed research on alternative therapies for the 18-20% of young adult veterans and many others who suffer from PTSD after returning from combat duty in Iraq.6

*The pressure on the federal government to allow medical marijuana research is also mounting on a different front, in the case of Lyle E. Craker v. Drug Enforcement Administration. In many states, Cannabis plants can be grown for personal medicinal use and in Arizona, where the PTSD study would occur, it is now legal for eligible patients to grow up to 12 plants for medical uses. However, it remains illegal for an independent grower to supply marijuana for research into the medicinal qualities of the plant.

With support from MAPS, Lyle Craker, Ph.D., a professor of horticulture at the University of Massachusetts specializing in medicinal plants, spent nearly 11 years enduring internal DEA administrative reviews of his application to establish a production facility to grow marijuana with the controlled precision required for research purposes. These administrative proceedings ended on August 15, 2011, when DEA administrator Michelle Leonhart signed the final order denying Craker's request.

This final administrative denial opened the door for Craker's lawsuit, allowing him to take the case beyond the closed doors of the DEA and into the public forum of the U.S. Court of Appeals for the First Circuit in Boston, Mass. The opening brief was delivered in December 2011, and the court heard the first oral arguments in May 2012. The Appeals Court will be reviewing the rationale that the DEA used to reject an earlier 80-page report (issued by an Administrative Law Judge in 2007) recommending that it would be in the public interest for the DEA to issue a license to Professor Craker. A ruling in Craker's favor in the federal appeals court would force the DEA to reopen its administrative review of Craker's petition and conduct a new assessment of his request.

Dr. Craker is supported by MAPS along with pro bono legal services from Washington, DC-based law firm Covington & Burling LLP, one of the foremost law firms representing the pharmaceutical industry. The American Civil Liberties Union (ACLU) is also supporting Craker in the case.7

The U.S. Court of Appeals also heard testimony in October 2012 in the case of Americans for Safe Access v. Drug Enforcement Administration over the declassification of marijuana as a Schedule I
While the federal government stalls, a significant amount of state-level reform is underway that could facilitate the initiation of MAPS’ study of marijuana for veterans with PTSD, to be conducted by Dr. Sisley at the University of Arizona.

In 2010, Arizona voters approved Proposition 203, which allowed qualifying registered patients to obtain marijuana for specific debilitating medical conditions from 100 state-approved non-profit dispensaries. Unfortunately, legal opposition from Arizona Governor Janice Brewer and state Attorney General Tom Horne has prevented the bill from being fully implemented.

Since the passage of Prop 203, a $6 million surplus of voter-protected funds has accumulated to support the implementation of the bill, with $12 million projected for 2013. This capital could be used to conduct marijuana research in the state of Arizona if the Biomedical Research Commission, a committee controlled by Governor Brewer, specifically allocates these funds for these studies. At the time of this writing, no portion of these surplus funds has been allocated for research purposes.

In April 2012, in a separate initiative to block voter-approved Prop 203, Governor Brewer signed a bill into law that effectively banned marijuana studies from being conducted on university campuses. Dr. Sisley, the lead investigator of MAPS’ blocked study, is a vocal advocate for the credibility a university campus confers on a study of marijuana, and feels strongly that the university location would also provide benefits for the veterans suffering from PTSD who are waiting to enroll in the trial.

“Without the ability to conduct the study at an educational institution, this research can only legally be conducted at a location distant from a school campus. This does not provide the best options for patients, as many buildings will not rent space for a team to conduct a marijuana study, and others that will are not as clean and safe as we would like,” said Dr. Sisley. “I have worked with hundreds of combat veterans with PTSD who have admitted to using marijuana and tell me that it is the only thing that helps to ease their symptoms.”—Dr. Sue Sisley

With FDA and IRB support for MAPS-sponsored marijuana research as a treatment for PTSD, and with the increasing number of states attempting to ensure that patients have safe access to medical marijuana, the opportunity for the careful scientific assessment of marijuana as medicine will soon emerge.

REFERENCES

3. MAPS FDA-approved MJP-1 Study Protocol. March 9, 2011. maps.org
4. ProCon.org. 17 Legal Medical Marijuana States and DC: Laws, Fees, and Possession Limits. medicalmarijuana.procon.org/
Can war veterans with PTSD manage symptoms effectively with marijuana?

Up to 20% of Iraq combat veterans suffer from posttraumatic stress disorder (PTSD). 50% of PTSD patients who seek treatment with current therapies remain symptomatic.

**MAPS-sponsored study:** Enroll 50 PTSD veterans in a clinical trial to determine the safety and efficacy of 5 potencies of marijuana vs. placebo to control symptoms.

**FDA review and approval of clinical study protocol**
Fact: The Food and Drug Administration (FDA) is responsible for ensuring drugs are safe and effective.

**NIDA rejection of clinical study protocol**
Fact: The National Institute on Drug Abuse (NIDA) is responsible for studying drug abuse and addiction (not safety, efficacy, or medicinal uses for drugs).
Fact: NIDA is the sole supplier of marijuana for research purposes in the United States.

**Arizona IRB review and approval of clinical study protocol**
Fact: The Institutional Review Board (IRB) must ensure the safety of human research subjects and deemed this study to be sufficiently safe and scientifically worthy of investigation.

**Current Status:** Study on hold pending NIDA approval.

**Did you know?**
- Marijuana is available for medical use in 18 states and the District of Columbia.
- Colorado and Washington became the first states to legalize marijuana for recreational use on November 6, 2012, for anyone over the age of 21.

**Spotlight on Arizona**

**Sue Sisley, MD**
Professor, University of Arizona
Lead Clinical Investigator, Marijuana / PTSD Clinical Trial

- Proposition 203 approved by >50% of Arizona voters: 100 dispensaries for safe access to medical marijuana for qualified patients, up to 2.5 ounces.
- $6 million surplus of funds from stalled implementation of Prop 203 due to opposition from Governor Brewer.
- Convince Arizona state legislature to dedicate portion of Prop 203 surplus funds for research into safety and efficacy of marijuana & to allow clinical studies to occur at a school campus.