

# Marijuana study for veterans with trauma faces hurdle

BY BRIAN VASTAG

Getting pot on the street is easy. Just ask the 17 million Americans who smoked the federally illegal drug in 2010.

Obtaining weed from the government? That's a lot harder.

In April, the Food and Drug Administration approved a first-of-its-kind study to test whether marijuana can ease the nightmares, insomnia, anxiety and flashbacks common in combat veterans with post-traumatic stress disorder.

But now another branch of the federal government has stymied the study. The Health and Human Services Department is refusing to sell government-grown marijuana to the nonprofit group proposing the research, the Multidisciplinary Association for Psychedelic Studies.

The agency did leave the door open to eventually providing 13 pounds of the weed, which is grown at the University of Mississippi. But the HHS committee that rejected the request provided such conflicting criticisms that the person directing the study, MAPS Director Rick Doblin, is unsure how to address their concerns.

"Their goal at higher levels, I think, is to block the study," said Doblin, who for 25 years has been jumping through regulatory hoops to launch human studies of marijuana, LSD and MDMA, known as ecstasy, which are all illegal.

The HHS official in charge of the review, Sarah A. Wattenberg, declined to answer questions when reached by phone. Tara Broide, a spokeswoman for the agency, wrote in an e-mail that "the production and distribution of marijuana for clinical research is carefully restricted under a number of federal laws and international commitments."

The study proposes testing five doses of marijuana in 50 combat veterans with PTSD whose symptoms have not improved despite conventional treatments — typically talk therapy, antidepressants and anti-anxiety medicines.

Many veterans already use marijuana to calm their PTSD, said

Mary Tendall, a licensed therapist in Nevada City, Calif., who has treated "hundreds" of traumatized Vietnam, Afghanistan and Iraq veterans.

"It does mellow out the triggered response in a certain population," said Tendall, referring to hair-trigger anxiety reactions. "But with some, it made them very, very paranoid — it had the opposite effect."

For Paul Culkin, a 32-year-old Army veteran living in Albuquerque, small daily doses of pot offer a release from sleepless nights and high anxiety.

In November 2004, Culkin suffered neck injuries when a car bomb exploded 30 feet from him in southern Kosovo.

When Culkin returned home, he had "really bad nightmares and insomnia, lots of cold sweats," he said. He rarely left the house.

Culkin began taking anti-depressants, and he eventually received a medical separation from the Army. He now receives Veterans Affairs disability payments.

New Mexico is one of two states, along with Delaware, that explicitly allows the use of marijuana to treat PTSD. Culkin got state approval in 2008 to use it. "It really gets rid of your nightmares if you smoke before you go to bed," he said. "You feel like you got some rest finally."

Doblin thinks marijuana can help many more veterans. A 2004 study in the *New England Journal of Medicine* estimated that 18 percent of returning Iraq combat veterans had PTSD. And a 2008 report from the Rand Corp., a government contractor, estimated that up to 225,000 veterans will return from the Middle East clinically traumatized.

Medical marijuana is legal in 16 states and the District of Columbia. But obtaining it from the federal government for research requires surmounting an extra regulatory hurdle that is not required for any other drug.

That's because one government agency, the National Institute on Drug Abuse, controls the nation's supply of research marijuana. Any non-government researcher wanting access to it needs to satisfy the special HHS committee.

On Sept. 14, Wattenberg, the official in charge of the committee, wrote to Doblin detailing "a number of concerns relating to the proposal's approach, feasibility, and documentation of human subjects' protection."

But written comments from the five committee members paint a jumbled picture of sometimes contradictory concerns.

One member wrote that the study should exclude veterans who have previously smoked marijuana. And another committee member asked for the opposite, that the study should only include people who have smoked the drug, as those naive to it might suffer anxiety or panic attacks.

A third reviewer wrote that study participants should be monitored closely — presumably in a hospital — rather than letting them smoke the marijuana at home.

"Turning this into an in-patient study ends the study," Doblin said. "Nobody will live in-patient for three months, and that increases the study costs astronomically."

Other comments expressed skepticism that the marijuana in the study — given in weekly batches — could be kept from getting "diverted," meaning given or sold to non-participants.

In a phone interview, Doblin pointed out that the study's design satisfied FDA drug-diversion officials.

Participants will be required to videotape their every interaction with the weed, and will have to return any they do not smoke. In addition, a second person will have to witness the smoking and check in with the researchers weekly.

Doblin plans to modify the study and resubmit it to the committee, which will have to unanimously agree before the marijuana sale can move forward, Broide said. But even if HHS approves, another bureaucracy looms — that of the Drug Enforcement Administration. The nation's drug cops also have to approve the research.

"It's a long road," Doblin said. "But it's worth it. We're the mythical American trying to play by the rules."

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MARIO TAMAYO/GETTY IMAGES

Wall Street demonstrators, Brooklyn Bridge on Saturday.

## FORT HOOD

### Soldier not guilty in contractor's killing

A court-martialed U.S. soldier has been found not guilty by reason of lack of mental responsibility in the killing of a civilian contractor in Iraq, military officials said Saturday.

Pfc. Carl T. Stovall, 28, had pleaded not guilty in the March 2009 shooting of Hungarian laborer Tibor Bogdan near Camp Taji, just north of Baghdad. Bogdan was shot while digging a hole.

Stovall had allegedly told investigators that he thought Bogdan, who worked for a contractor specializing in waste removal, was a terrorist planting a bomb. Prosecutors, however, said Stovall, now 28, has changed his story multiple times, allegedly denying any involvement in one version.

Army psychiatrist Col. David M. Benedek testified Wednesday that Stovall is a paranoid schizophrenic and "not mentally responsible" for the shooting.

— Associated Press