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How the government limits valid scientific research on cannabis sativa

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The use of medical marijuana for millions of patients suffering from a wide range of health conditions and the subsequent therapeutic benefits has long been documented. Twenty-three states, the District of Columbia, Puerto Rico, and Guam, have determined that Cannabis sativa (a.k.a. marijuana) can benefit patients suffering from a wide range of conditions, including cancer, epilepsy, chronic pain, and post-traumatic stress disorder.

So given all the health benefits for people experiencing debilitating health issues, why does the federal government continue to stifle valid, externally valid scientific research on Cannabis sativa?

In a recent paper published in *Science*, researchers at The University of

New Mexico including Associate Professor Jacob Vigil in the Department of Psychology and Assistant Professor Sarah Stith in the Department of Economics, concluded that the federal government continues to make it extremely difficult to conduct any meaningful research on the risks and benefits of medicinal use of *Cannabis sativa*.

"Millions of patients have been granted the authorization to use medical Cannabis and Cannabis-based products by their respective state Health Departments and four states have begun taxing and regulating Cannabis sold for 'recreational' purposes," said Vigil and Stith. "However, the federal government continues to categorize Cannabis sativa as a Schedule I drug under the Controlled Substances Act, a more restrictive categorization than that used for cocaine, methamphetamine and PCP."

The definition of a Schedule I drug includes a "high potential for abuse," and "no currently accepted medical use," implying "a lack of accepted safety use of the drug or other substance under medical supervision, according to Vigil and Stith.

National Institute on Drug Abuse control

The National Institute on Drug Abuse (NIDA) controls the supply of Cannabis sativa to researchers. The active agent in Cannabis, Tetrahydrocannabinol or THC, has potency levels in the products that NIDA supplies that fall far below those of medical Cannabis sativa regularly sold and used in the U.S., significantly limiting the external validity of most clinical research designed to study the effects of Cannabis sativa on health, both positive and negative.

"This has created a truly unique and an unnecessary paradox in modern medicine, in which physicians are authorizing treatments to patients, and patients are regularly using medication without a scientific basis of knowledge on patient outcomes, forced rather to rely only on

scientifically invalid or anecdotal information," Vigil and Stith said.

Apart from following internal human subject protection procedures, such as Institutional Review Board (IRB) approval, a scientist designing a clinical trial on the effects of Cannabis sativa using human subjects must conduct several independent and lengthy procedures that include filing for an Investigational New Drug (IND) with the Food and Drug Administration (FDA), registering the study and obtaining approval from the Drug Enforcement Agency (DEA), and purchasing the Cannabis sativa to be used in the study through NIDA.

"An IND requires a level of specificity that may be difficult to achieve with a plant product or even undesirable when one takes into account the variation of natural phenotypes and the range of products used by patients, Vigil and Stith said. "In the case of new drug development with the intent to commercialize, such oversight may be prudent, but it is unclear why a study on, for example, the effects of smoked Cannabis sativa on driving impairment would also require an IND after receiving approval by a qualified Institutional Review Board."

DEA approval

After filing for and receiving IND approval from the FDA, the scientist must also register the study and receive approval from the DEA, an organization tasked with the conflicting interest of "enforcing controlled substances laws and regulations," which currently prohibit possession or distribution of Cannabis sativa, obvious components of any clinical investigation. The only exception is for Cannabis sativa purchased through NIDA. In other words, all Cannabis sativa used for research purposes must be purchased through NIDA, despite the fact that NIDA's stated mission is to bring "the power of science to bear on drug abuse and addiction." No mention is made of research related to therapeutic benefits or the potential for non-addictive recreational use.

Despite petitions from other universities, the NIDA Cannabis sativa supply is grown exclusively at the University of Mississippi since the passage of the Controlled Substances Act in 1970. It is not uncommon for researchers to invest several years navigating this system only to receive a rejection from one of the controlling federal entities, and typically the DEA, which carries a notorious record of stalling, impeding, or otherwise obstructing sound medical Cannabis research, according to the U.S. Drug Policy Alliance (Drug Policy Alliance, accessed January, 2016).

Potency issues

Another issue with what little research the U.S. government has approved is the limited potency of the Cannabis sativa products available through the University of Mississippi. Reliance on this single source completely restricts researchers from conducting clinical trials using products that match the potency levels of products used in vivo, i.e., studies that would enable scientists to assess the therapeutic benefits and negative side effects of the medicinal Cannabis sativa actually used by tens of millions of people in the U.S.

The highest level of THC currently available through NIDA is 12.4 percent (National Institute on Drug Abuse, accessed January 2016). As of December, 2015, out of all the currently funded NIH grants with the term 'Marijuana' (n = 51) or 'Cannabis' (n = 50) in the Project title, nearly every study addressed Cannabis use as a problem behavior, and only two studies measured the (analgesic) effects of Cannabis sativa in real time, each using products with potency levels between 3.5 percent and 7 percent THC. In contrast, a study presented by the owner of a state-certified Cannabis sativa testing laboratory at the 249th National Meeting and Exposition of the American Chemical Society found that the Cannabis sativa sold in Colorado averaged 18.7 percent THC levels with some strains registering as high as 35 percent THC.

In addition to dosing directly with the plant product, a variety of concentrates have been developed for vaporizing or ingesting edibles, both arguably healthier options than smoking. In New Mexico, the Department of Health has presently capped the THC potency levels in such products at 70 percent (a level that was widely protested as to low by visibly ill patients that attended a recent public medical advisory board hearing).

"Clearly, results from studies using Cannabis sativa obtained from the University of Mississippi offer little to no insight into the effects actually experienced by medical marijuana patients in terms of both therapeutic benefits and negative side effects, if any," Vigil and Stith said.

What physicians think

A recent poll conducted by the *New England Journal of Medicine* showed the vast majority of physicians in the U.S. believe that medical Cannabis is a safe and effective pharmacological agent for certain mental and physical health conditions (Adler & Colbert, 2013).

"With increasing morbidity rates associated with prescribed narcotic abuse (particularly among non-Hispanic Whites) there is a legitimate place for Cannabis sativa as an alternative and perhaps primary therapeutic option for patients with a broad range and severity of negative health symptoms," Vigil and Stith said.

The substitutability of Cannabis sativa for alcohol might also reduce the exorbitant number of deaths and costs associated with alcohol abuse and drunk driving.

"Unfortunately, both the costs and benefits of medicinal use of Cannabis sativa remain essentially unknown, and because the federal government effectively bans clinical research on Cannabis sativa, citizens, including

many severely ill individuals, may suffer and die unnecessarily from both the unknown risks and the unknown benefits of consuming Cannabis sativa," Vigil and Stith added.

Provided by University of New Mexico