Federal Obstruction of Medical Marijuana Research

Although 36 states and the District of Columbia have enacted medical marijuana laws, the Institute of Medicine's call for expanded clinical trials on marijuana's medical safety and efficacy remains largely unfulfilled.[1] As the American College of Physicians noted, research "has been hindered by a complicated federal approval process [and] limited availability of research-grade marijuana."[2]

Over a dozen recent small-scale Phase 2 clinical trials have found support for marijuana's medical efficacy.[3] However, the Drug Enforcement Administration's (DEA) previous refusal to license production of marijuana for medical research, federal obstruction of privately-funded research, and a lack of federal funding for research have created a catch-22: While millions of Americans find relief under state medical marijuana laws, they often hear that there is not enough large-scale Phase 3 research to make marijuana available by prescription. Yet, the deck has been stacked against that research happening.

NIDA's institutional bias results in lengthy delays and refusals to provide research material.
Prior to August of 2016, the DEA required that the National Institute on Drug Abuse (NIDA) have a monopoly on the supply of marijuana that could be legally used in federally approved research — unlike other Schedule I drugs. However, NIDA has an institutional bias against research intended to evaluate marijuana's medical efficacy. As NIDA's Stephen Gust testified, "it is not NIDA's mission to study medicinal uses of marijuana." Rather, the federal agency that had sole responsibility for supplying (or not) marijuana for research is charged with "support[ing] research on the causes, consequences, prevention, and treatment of drug abuse and drug addiction."[4]

The DEA's chief administrative law judge found, "NIDA's system for evaluating requests for marijuana research has resulted in some researchers who hold DEA registrations and the requisite approval from the Department of Health and Human Services being unable to conduct their research because NIDA has refused to provide them with marijuana."[5] In 2011, NIDA refused to supply the Multidisciplinary Association for Psychedelic Studies (MAPS) with cannabis for an FDA-approved PTSD study because of a separate hurdle known as the Public Health Service (PHS) review (later eliminated by the Obama administration in June 2015).[6] MAPS finally received approval from the PHS panel in 2014, but was then told the cannabis required for the study was not available. The study did not receive final approval until April 2016. [7]

On August 12, 2016, the DEA announced a new policy regarding cultivating marijuana for medical research. The DEA will no longer require all research marijuana to be grown and distributed via NIDA

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[1] "Marijuana and Medicine: Assessing the Science Base," *Institute of Medicine*, 1999, p. 3-5. "[R]esearch funds are limited, and there is a daunting thicket of regulations to be negotiated at the federal … and state levels."
[2] "Supporting Research into the Therapeutic Role of Marijuana," *American College of Physicians*, 2008.
[3] See, i.e., "Report to the Legislature and Governor of the State of California," Center for Medical Cannabis Research, Feb. 2010.
[4] "In the Matter Lyle E. Craker, Ph.D., Docket No. 05-16," Mary Ellen Bittner, ALJ, (DEA 2007) at 19.
[5] "In the Matter Lyle E. Craker, Ph.D., Docket No. 05-16," at 84.
[6] Brian Vastag, "Marijuana study of traumatized veterans stuck in regulatory limbo," *Washington Post*, Oct. 1, 2011.
[7] Press release, "MAPS receives $2 million grant from Colorado for study, and waits to receive marijuana from NIDA," Dec. 17, 2014. "DEA approves PTSD marijuana study," *Military Times*, April 21, 2016.

and will allow marijuana growers outside of that monopoly to apply for a registration with the DEA if they agree to only distribute marijuana with the prior, written approval from the DEA.[8] This change should result in easier access for researchers. However, the DEA did not grant preliminary approval for private production of cannabis until almost five years later — in May 2021.[9] As of this publication, all research conducted in the U.S. on botanical cannabis relied federal cannabis, which has involved lengthy delays and lower quality cannabis.

The federal government is not sufficiently funding research.
Despite the fact that over two-thirds of Americans live in jurisdictions that allow the medical use of marijuana, the federal government has provided very little funding for clinical studies on marijuana's efficacy since those state laws passed.[10] The federal government provided marijuana for free to more than a dozen patients for many years in its Investigational New Drug Program, but has failed to conduct any research on marijuana's efficacy in treating their conditions. The program closed to new patients in 1992, and only one patient remains in the program.. The only study of these patients was privately funded. It found, "[c]annabis smoking, even of a crude, low-grade product, provides effective symptomatic relief of pain, muscle spasms, and intraocular pressure elevations ... ."[11]

The NIDA monopoly created barriers to private research.
In addition to failing to provide marijuana to FDA-approved protocols, NIDA's monopoly deterred potential privately-funded researchers because financial sponsors will not invest millions of dollars in research until there is reliable access to a supply of marijuana that can be used both in research and — if it resulted in FDA approval — as a prescription medicine. NIDA is not authorized by Congress to sell marijuana for prescription use, yet the same strain would have to be used in research and as the approved drug.[12]

Another barrier is that pharmaceutical companies have a financial incentive to research isolated compounds of marijuana — which they can patent — rather than the whole plant, which they cannot.

When asked by Sen. Cory Booker whether she was concerned about NIDA's DEA-mandated monopoly and whether it acts as a barrier to research, Director Volkow answered that it was, and that ending the monopoly would lead to improvements in efficiency, effectiveness, and availability for research. She also indicated that the monopoly on marijuana exists for no other drug — including heroin — and that there was no scientific basis for this disparate treatment.[13]

At long last, the ability to conduct full-scale FDA-approved drug development research into a range of potential medical uses of cannabis should be greatly enhanced, with the imminent licensing of private

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[8] "Applications To Become Registered Under the Controlled Substances Act to Manufacture Marijuana To Supply Researchers in the United States." A Rule by the Drug Enforcement Administration, 08/12/2016.
[9] Meredith Wadman, United States set to allow more facilities to produce marijuana for research, *Science*, May 17, 2021.
[10] The only known instances of recent federal funding for research into the efficacy of whole plant marijuana are a $259,000 NIH grant to Dr. Barth Wilsey for a study on vaporized marijuana and spinal cord injury-related pain and possible funding by the VA of Northern California in a CMCR study, "Effects of Vaporized Marijuana on Neuropathic Pain." In comparison, California and Colorado have each provided about $9 million in funding for research into medical cannabis.
[11] Russo, et al., "Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis," *Journal of Cannabis Therapeutics* 2, no. 1 (2002).
[12] "In the Matter Lyle E. Craker, Ph.D., Docket No. 05-16," at 54.
[13] Senate hearing at 1:28:45.

production of cannabis for research. However, the process to make cannabis products available by prescription takes several years, and it is unlikely that every strain and preparation that patients find effective will go through this onerous process. State medical cannabis programs will remain essential to ensure safe access to a wide range of cannabis-based products that provide relief.