



**Marijuana Policy Project**  
236 Massachusetts Ave. NE, Suite 400  
Washington, DC 20002  
p: (202) 462-5747 • f: (202) 232-0442  
info@mpp.org • www.mpp.org

*“We change laws.”*

## **Federal Obstruction of Medical Marijuana Research**

Although 16 states and the District of Columbia have approved medical marijuana laws, the Institute of Medicine’s call for expanded clinical trials on marijuana’s medical safety and efficacy remains largely unfulfilled.<sup>1</sup> In 2008, the American College of Physicians noted that “research expansion has been hindered by a complicated federal approval process [and] limited availability of research-grade marijuana ... .”<sup>2</sup> In addition to the standard FDA and DEA approvals needed for all research using Schedule I drugs, researchers conducting trials with marijuana must receive approval through a National Institute on Drug Abuse/Public Health Service (NIDA/PHS) protocol review process that exists for *no other drug*.<sup>3</sup>

Over a dozen recent small-scale Phase 2 clinical trials have found support for marijuana’s medical efficacy.<sup>4</sup> However, NIDA’s monopoly on the federally approved marijuana supply, federal obstruction of privately-funded research, and a lack of public funding for research have created a catch-22: While more than 800,000 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 is stacked against that research happening.

### **NIDA’s institutional bias results in lengthy delays and refusals to provide research material.**

NIDA has a monopoly on the supply of marijuana that can be legally used in federally approved research — unlike other Schedule I drugs. NIDA also has a bias against research intended to evaluate marijuana’s medical efficacy. NIDA’s Stephen Gust testified “that it is not NIDA’s mission to study medicinal uses of marijuana ... .”<sup>5</sup> Rather, the federal agency that has sole responsibility for supplying (or not supplying) marijuana for research is charged with “support[ing] research on the causes, consequences, prevention, and treatment of drug abuse and drug addiction.”<sup>6</sup>

As 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.”<sup>7</sup> In 1995, Dr. Donald Abrams developed a research protocol to study marijuana’s potential benefits for HIV/AIDS wasting syndrome patients. Dr. Abrams received the requisite approvals, but NIDA denied his application to obtain marijuana after first refusing to respond for nine months. After Proposition 215 passed in California in 1996, NIDA asked Dr. Abrams to study the *risks* of marijuana use in HIV/AIDS patients, but NIDA insisted that subjects with AIDS wasting syndrome be excluded from the study. When Dr. Abrams accepted, NIDA not only provided the marijuana, it paid one million dollars for the study.<sup>8</sup> In 1999, NIDA refused to supply marijuana to Dr. Ethan Russo for a marijuana/migraine study that had been approved by the FDA.

In addition, the NIDA/PHS review has no deadlines and no formal appeals process, in contrast to the FDA’s 30-day deadline. The Institute of Medicine recommended the development of a smoke-free delivery system, yet NIDA has obstructed research on such a device. NIDA took more than two years before it rejected a protocol requesting to buy 10 grams of marijuana to study a smokeless vaporizer, without human subjects.<sup>9</sup> MAPS director Rick Doblin

<sup>1</sup> “Marijuana and Medicine: Assessing the Science Base,” Institute of Medicine, 1999 at p. 3-5. The report noted, “[R]esearch funds are limited, and there is a daunting thicket of regulations to be negotiated at the federal level (those of the Food and Drug Administration, FDA, and the Drug Enforcement Administration, DEA) and state levels.” p. 137.

<sup>2</sup> “Supporting Research into the Therapeutic Role of Marijuana,” American College of Physicians. Position Paper, 8. (2008).

<sup>3</sup> “In the Matter Lyle E. Craker, Ph.D., Docket No. 05-16,” Mary Ellen Bittner, ALJ, (DEA 2007) (*hereafter* ALJ Findings) at 49.

<sup>4</sup> See “Marijuana and Medicine: Assessing the Science Base” and “Report to the Legislature and Governor of the State of California,” Center for Medical Cannabis Research (Feb. 2010).

<sup>5</sup> ALJ Findings at 19.

<sup>6</sup> ALJ Findings at 19.

<sup>7</sup> ALJ Findings at 84.

<sup>8</sup> ALJ Findings at 43.

<sup>9</sup> See <http://www.maps.org/mmi/>

testified that developing marijuana into a prescription medicine “is MAPS’ explicit goal, so ... anything we do gets shut down.”<sup>10</sup> In 2011, NIDA refused to supply MAPS with marijuana for an FDA-approved PTSD study. MAPS can apply again, but approval requires unanimous consent from a committee that gave contradictory guidance.<sup>11</sup>

### **NIDA’s monopoly is a barrier to private research.**

In addition to failing to provide marijuana to FDA-approved protocols, NIDA’s monopoly deters potential privately-funded researchers because financial sponsors will not invest millions of dollars in clinical 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.<sup>12</sup> 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.

NIDA’s marijuana has often been freeze-dried for years. It has low concentrations of THC and includes virtually no cannabidiol, which has therapeutic value.<sup>13</sup> Other producers could produce marijuana with a better safety profile.

Since 2001, Professor Lyle Craker, Ph.D., University of Massachusetts-Amherst Medicinal Plant Program, has unsuccessfully attempted to acquire a license from the DEA to grow marijuana for research.<sup>14</sup> On February 12, 2007, DEA Administrative Law Judge Mary Ellen Bittner recommended granting Dr. Craker a license, finding that it would be in the public interest for the DEA to issue Dr. Craker a license, and that the DEA’s refusal to grant additional licenses to grow marijuana resulted in inadequate competition and a current supply that was inadequate for research needs.<sup>15</sup> However, the DEA delayed responding to Judge Bittner’s recommendation for almost two years, then rejected her recommendation on January 14, 2009, six days before the inauguration of President Obama.

### **The federal government is not sufficiently funding research and only one state has recently funded research.**

Despite the fact that 30% of Americans live in jurisdictions that allow the medical use of marijuana, the federal government has provided almost no funding for clinical studies on marijuana’s efficacy since those state laws passed.<sup>16</sup> 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. Four patients in the program, who have received marijuana for 19 or more years, survive today. The only study of these patients was privately funded. It found, “Cannabis smoking, even of a crude, low-grade product, provides effective symptomatic relief of pain, muscle spasms, and intraocular pressure elevations ... ”<sup>17</sup>

The California Legislature funded and created the Center for Medicinal Cannabis Research (CMCR) to study marijuana’s medical efficacy. In February 2010, the CMCR released a report on its 15 completed or ongoing studies, finding support for marijuana’s efficacy at alleviating pain and reducing spasms.<sup>18</sup> However, no further funding has been allocated, and, in this time of economic downturn, no other states are known to be funding similar studies. Due to the factors outlined in this memo, experts are aware of very few current clinical studies on the medical efficacy of smoked or vaporized whole plant marijuana in the U.S. — only the ongoing CMCR studies and one additional study. Non-profit organizations with private funding are ready and eager to fund full-scale FDA-approved drug development research into a range of potential medical uses of marijuana once the DEA is forced to end the NIDA monopoly on the supply of marijuana for research. Even then, the process to make marijuana available by prescription is expected to take about 10 years, so state laws are needed to protect patients in the meantime.

---

<sup>10</sup> ALJ findings at 44.

<sup>11</sup> Brian Vastag, "Marijuana study of traumatized veterans stuck in regulatory limbo," *Washington Post*, October 1, 2011.

<sup>12</sup> ALJ findings at 54.

<sup>13</sup> ALJ findings at 52-53.

<sup>14</sup> See <http://www.aclu.org/drug-law-reform/time-line-matter-lyle-craker>

<sup>15</sup> ALJ Findings at 85, 87.

<sup>16</sup> 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.”

<sup>17</sup> 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).

<sup>18</sup> Center for Medical Cannabis Research (February 2010).