

NIDA's Monopoly: GAME OVER?

Why is the federal government going to such lengths to stop MAPS and Prof. Craker?

Jag Davies and Rick Doblin, PhD

FOR THE FIRST TIME SINCE 1941, the federal government's monopoly on research-grade marijuana is in danger of coming to an end. If so, the window of opportunity for putting marijuana through US Food and Drug Administration (FDA) clinical trials would finally be open.

Professor Lyle Craker, PhD, director of the medicinal plant program in the Department of Plant, Soil and Insect Sciences, at the University of Massachusetts-Amherst, has been attempting for six years to obtain a Drug Enforcement Administration Schedule I license to manufacture marijuana exclusively for privately funded, federally approved research. The federal government has a monopoly over the supply of marijuana – but no other Schedule I drug – and uses that monopoly to obstruct privately funded research. Craker's case is the focal point of the struggle to bring medical marijuana before the FDA to determine whether it meets the FDA's standards for safety and efficacy.

On Feb. 12, 2007, following a comprehensive review of the available evidence from the 2005 DEA law hearing, DEA Administrative Law Judge Mary Ellen Bittner issued a decisive – but nonbinding – opinion and recommended ruling that Craker's application be approved. It is now up to the DEA to decide whether to accept or reject Bittner's recommendation.

Patients, doctors, and scientists are in a catch-22 because the Supreme Court has insisted that they to go to the FDA, but the DEA, NIDA, and the federal government have systematically obstructed their ability to perform FDA-approved research.

Those of you who have followed the drug policy reform movement since the 1980s will remember two decisive instances in which the DEA rejected the advice of its administrative law judge. First, in 1984, the DEA rejected a law judge ruling that MDMA be placed in Schedule III, rather than Schedule I. Then, in 1989, DEA famously rejected another law judge's ruling that marijuana be rescheduled, from Schedule I to Schedule III.

Because the drug policy reform movement has gained unprecedented direction and momentum during the past two decades, we actually have a fighting chance to pressure the DEA to accept this ruling. We're going to put the DEA on notice that there will be a political backlash if they continue to use politics to obstruct legitimate and highly demanded scientific research. The DEA will begin to process the judge's recommendation in May and has an unlimited amount of time to issue a formal response. In previous DEA law judge hearings, the DEA has taken anywhere between three and 14 months to respond.

We will use this intervening period to build on our congressional and organizational lobbying efforts to demonstrate to the DEA that there will be a price to pay for the continued political obstruction of science. A congressional sign-on letter is currently being circulated in the U.S. House of Representatives, sponsored by Rep. John Olver, D-MA, and Dana Rohrabacher, R-CA, (see the side bar on pg. 9 for details about contacting your representative). Since members of Congress are more likely to register support for an issue if the message is coming from their constituents, the role of grassroots activism could be the tipping point.

Craker's applications for regulatory approval, legal struggles, and proposed facility are sponsored by MAPS, which plans to design, fund, and obtain government approval for the clinical research necessary to develop marijuana into an FDA-approved prescription medicine. If successful, MAPS would bring smoked and/or vaporized marijuana to market under a nonprofit pharmaceutical model similar to Planned Parenthood's development and distribution of RU-486. DEA

licensing is the final regulatory hurdle in MAPS' quest to create the nation's first privately funded, federally approved medical marijuana production facility, which would pave the way for a drug development effort aimed at developing marijuana into an FDA-approved prescription medicine.

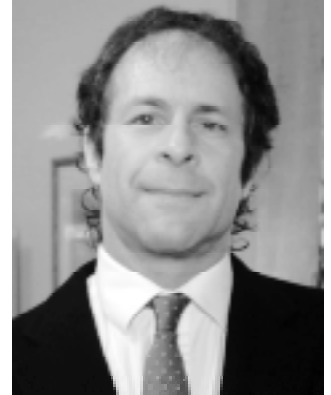
The Problem: NIDA's Monopoly

All you have to do is read NIDA's full name to see their inherent conflict of interest with medical marijuana research.

Since 1968, the federal government's National Institute on Drug Abuse (NIDA) has maintained a monopoly on the supply of marijuana, but no other Schedule I drug, that can be legally used in federally approved research. NIDA's monopoly makes very little sense given that the DEA has licensed privately funded manufacturers of methamphetamine, LSD, MDMA (ecstasy), heroin, cocaine, and virtually all other controlled substances.

Human studies on any Schedule I drug must gain approval from the FDA, yet for studies with marijuana, researchers must submit their protocols for an additional review process by NIDA and the Department of Health and Human Services (HHS) that exists for no other drug. This extra review process has been imposed on medical marijuana research as a result of NIDA's monopoly power, which persists despite federal law that requires adequate competition in the production of Schedule I drugs [21 USC section 823(a)(1); 21 C.F.R. section 1301.33(b)]. The HHS/NIDA review has no deadlines and no formal appeals process, in contrast to the FDA's 30-day deadline. Thus, NIDA's monopoly results in lengthy delays or refusals in providing research material.

NIDA has refused to supply marijuana to two FDA-approved protocols sponsored by MAPS, preventing these studies from taking place (Dr. Abrams, UC San Francisco, marijuana for AIDS wasting syndrome-IND #43-542; Dr. Russo, U. Montana, marijuana for migraines-IND #58, 177). In addition, for the last three-and-a-half years, NIDA has refused to sell 10 grams of marijuana to a MAPS/CaNoRML-sponsored laboratory study evaluating the effectiveness of a marijuana vaporizer, a nonsmoking drug delivery device that eliminates the products of



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combustion that patients would inhale after burning marijuana. NIDA has also prevented this study from taking place, despite the fact that the development of nonsmoking drug delivery devices was recommended by the Institute of Medicine in its 1999 report on medical marijuana.

For those researchers whose protocols it approves, NIDA provides inferior, low-potency marijuana. NIDA's marijuana has limited cannabinoid profiles, so researchers are unable to optimize the strain of marijuana they prefer to use for costly drug development efforts. The highest potency marijuana available from NIDA for research is 7 percent; the marijuana used by patients in states where it is legal has been documented to be between 10 percent and 20 percent.

NIDA's lone marijuana production facility is directed by Professor Mahmoud El Sohly, at the University of Mississippi. Another egregious conflict of interest for NIDA is that El Sohly has personal commercial interests in marijuana-based products. This includes both his THC suppository and his new DEA license permitting him to grow marijuana to extract THC for sale to the pharmaceutical company, Mallinckrodt, to manufacture generic Marinol. El Sohly would have a major conflict of interest if he were the sole supplier of marijuana to MAPS for prescription use, since marijuana would compete with products in which he has a personal financial interest.

NIDA cannot even guarantee that the same research material will be available for prescription use if FDA clinical trials determine that marijuana meets its guidelines for safety and efficacy. This makes any drug development effort using NIDA marijuana a futile exercise. As NIDA well knows, sponsors will not invest millions of dollars into research studies until there is reliable access to a supply of high-quality research material that can be used both in research and - if the research should prove successful - as an FDA-approved prescription medicine.

The Plan: Independent Supply, the "Holy Grail" of Marijuana Research

Considering the problems with NIDA's monopoly, for the past six years MAPS has prioritized creating an independent supply of legal research-grade

marijuana for use in FDA-approved studies. In June 2001, with support from MAPS and UMass-Amherst's approval, Craker applied to the DEA for a license to manufacture marijuana exclusively for use in federally approved research.

One of the DEA's primary tactics for stifling research is delay, and Craker's application has been a case in point. One year after the application was submitted, the DEA claimed it was lost. After the application was resubmitted in 2002, the DEA failed to respond for two-and-a-half years, forcing Craker to sue the DEA in federal court for unreasonable delay. This prompted the DEA to finally reject Craker's application in December 2004, three-and-a-half years after the original application was submitted. In turn, MAPS and Craker immediately requested an administrative law judge hearing, which took place over the course of 11 months in 2005.

Prior to the February 2007 ruling, organizations that had already written to the DEA in favor of Craker's application included the Multiple Sclerosis Foundation, the Lymphoma Foundation of America, the National Association for Public Health Policy, the United Methodist Church, Americans for Tax Reform, the American Medical Students Association, several state nurses' associations, the Massachusetts Department of Public Health, and the California and Texas State Medical Associations, the two largest U.S. state medical associations. Also, as a result of MAPS' congressional lobbying efforts, Massachusetts senators John Kerry and Edward M. Kennedy and 38 members of the U.S. House of Representatives have already previously written to the DEA in support of Craker's application.

Conclusion: The Strategic Benefits of the Federal Research Route

Of course, if the DEA still decides to reject Bittner's recommendation, this will only lend credence to state and local marijuana reform efforts. MAPS and Craker will appeal in the Circuit Court of Appeals, but that would tie the case up in the courts for several more years. If the DEA rejects the ruling, it will be clear that the appropriate administrative channels have been exhausted and that the FDA

drug development route is fundamentally blocked by NIDA's monopoly. In fact, considering the success of state and local reform efforts, one is almost led to wonder if FDA drug development is even necessary for marijuana. In the final paragraphs of this article, we would like to contextualize MAPS' FDA research strategy in light of state and local reforms.

Thirteen states and numerous municipalities have enacted laws protecting patients who use marijuana when prescribed by a doctor. Several more states, such as New York, Illinois, Minnesota, and Wisconsin are considering similar legislation this year. While recognizing the inspiring success of state and local initiatives over the past decade, it is also important to understand their historical context as it relates to NIDA and DEA's obstruction of the FDA drug development route, which, for better or worse, is the regulatory channel that all other prescription medicines must successfully endure in the United States.

While enforcement is generally left up to local authorities, there are no guarantees that the Feds will not intervene. The U.S. Supreme Court did rule in 2005 in *Gonzales v. Raich* that the federal government can arrest medical marijuana patients and enforce federal marijuana laws even in states where it is legal. Justice Stephen Breyer stated in oral arguments during the *Raich* case that medical marijuana patients should go through the FDA's regulatory process to get marijuana approved as a prescription medicine, rather than focusing on courts and referendums. Patients, doctors, and scientists are in a catch-22 because the Supreme Court has insisted that they go to the FDA, but the DEA, NIDA, and the federal government have systematically obstructed their ability to perform FDA-approved research.

As discussed earlier, clinical research with human subjects that meets the FDA's strict guidelines is costly. MAPS estimates that it would cost \$5 million to \$7 million to get marijuana approved as a prescription medicine, over the course of five to seven years, once there is an independent source of supply.

When compared to the costs of other forms of medical marijuana policy reform,

however, such as statewide ballot initiatives, the costs of research are minimal. One statewide ballot initiative can cost several million dollars; it would be many, many times more costly for all 50 states to pass medical marijuana laws than it would be to go for the whole ball of wax by gaining FDA approval.

Why is the federal government going to such lengths to stop MAPS and Craker? The federal government knows that if the FDA had the opportunity to evaluate medical marijuana based on science, not politics, it would likely approve it for medical use.

For the first time in six-and-a-half decades, since marijuana was removed from the U.S. Pharmacopia in 1941, there is a window of opportunity for the establishment of a privately funded source of research-grade marijuana. To take advantage of this unique opportunity, we need all supporters to contact their federal legislators. •

Help MAPS and Marijuana Research Succeed by Contacting Your Federal Legislators – Here's How:

Tell your federal legislators that you would like them to add their names to the congressional sign-on letter urging the DEA to follow the administrative law judge's recommendation by issuing a Schedule I license to Professor Lyle Craker, UMass-Amherst. Tell them that you would like to see the controversy over medical marijuana resolved through privately funded FDA-approved research. Individualized letters and phone calls are the best ways to get the attention of your legislators. E-mails are helpful, but phone calls and especially personal letters or faxes carry significantly more weight.

Call the congressional switchboard at (202) 224-3121 or toll free at (800) 962-3524.

For senators:

The Honorable: (full name)
Senate Office Building
United States Senate
Washington DC 20510

For representatives:

The Honorable: (full name)
House Office Building
United States House of Representatives
Washington DC 20515

For additional info: maps.org/mmj/DEAlawsuit.html