Feds Continue to Barricade Marijuana FDA Drug Development Research:
NIDA Rejects Vaporizer Protocol, DEA Continues Strategy of Delay

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Over the past twelve years, a dozen U.S. states have passed laws either through ballot initiatives or state legislation allowing for the use of physician-supervised medical marijuana, and a dozen more states--such as Illinois, Wisconsin, Minnesota, New York, and Michigan--have taken steps to pass similar laws that could pass over the next five years. To grasp the historically bizarre and unparalleled nature of state medical marijuana laws, one must remember that there is no other instance in recent history when states have regulated medicine–for better or worse, that has been the sole responsibility of the U.S. federal government's Food & Drug Administration (FDA) for most of the past century.

Thankfully, one nonprofit pharmaceutical drug development organization–MAPS–has been working diligently for the past two decades to go for the 'whole ball of wax' by attempting to design, fund, obtain government approvals, and conduct the clinical trials that are necessary to bring the marijuana plant itself to market as an FDA-approved prescription medicine in all 50 states. Unfortunately, rather than conducting research, MAPS has been drawn into lengthy legal and political battles with government agencies that have a vested interest in the status quo–the National Institute on Drug Abuse, also known as NIDA (a branch of the National Institutes of Health, or NIH), and the Drug Enforcement Agency, also known as DEA (an agency in the Department of Justice). DEA and NIDA are overseen by the White House's Office of National Drug Control Policy (ONDCP), a Cabinet-level office that coordinates all of the executive branch's "drug control" efforts.

The FDA itself is not officially opposed to medical marijuana research, but DEA and NIDA have the power to obstruct privately-funded clinical research aimed at evaluating whether smoked and/or vaporized marijuana meets the requirements to be developed into an FDA-approved prescription medicine. NIDA has refused to supply marijuana to two FDA-approved protocols sponsored by MAPS, preventing these studies from taking place.

NIDA has a monopoly on the supply of marijuana, but no other Schedule I drug, that can be legally used in federally-approved research--despite a federal law that requires adequate competition in the production of Schedule I drugs. Human studies on any Schedule I drug must gain approval from the Food and Drug Administration (FDA), yet for studies with marijuana, researchers must submit their protocols for an additional HHS/NIDA review process that also exists for no other drug. Moreover, the HHS/NIDA review has no deadlines and no formal appeals process, in contrast to the FDA's 30-day deadline, resulting in lengthy delays or refusals in providing research material. Furthermore, NIDA provides low-potency material with limited cannabinoid profiles for research, with researchers unable to optimize the strain of marijuana they prefer to use for costly drug development efforts. NIDA cannot even guarantee that the same material will be available for prescription use should FDA determine that safety and efficacy has been proven, rendering any drug development effort using NIDA marijuana impossible.

The end result is that NIDA's monopoly deters privately-funded researchers from proposing or conducting medical marijuana research, since financial 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.

Update: Vaporizer Protocol Rejected by NIDA

For the last five years, NIDA has refused to sell 10 grams of marijuana for a MAPS-funded laboratory study evaluating the effectiveness of a marijuana vaporizer. The goal of this study is to gather further information about the chemical constituents that are contained in the cannabis

vapor stream. A vaporizer is a non-smoking drug delivery device that eliminates the products of combustion that patients would otherwise inhale after burning marijuana. The Institute of Medicine recommended the development of non-smoking delivery devices in its landmark 1999 report on medical marijuana.

MAPS' initial vaporizer protocol was submitted to NIDA in June 2003. Although NIDA claims it will respond to protocols within 3-6 months (a far cry from FDA's 30-day deadline), NIDA failed to respond for over a year, forcing MAPS to sue for "unreasonable delay" under the Administrative Procedures Act. Although the suit was dismissed without prejudice, NIDA finally rejected the protocol in August 2005, more than two years after it was submitted. Less than a month later, MAPS responded to NIDA's rejection with specific objections to each of their critiques. More than 3 years later, NIDA still hasn't replied.

On January 16, 2008, MAPS submitted a redesigned protocol for scientific review by NIDA. The submission included three supportive letters from peer-reviewers urging NIDA's support and confirming the study's scientific merit. Five months later, on June 18th, NIDA responded by not only rejecting the protocol, but also by asking an exorbitant number of questions that appeared to be designed to delay us as long as possible. Chemic Laboratories, which would conduct the proposed study, responded to all of NIDA' s questions in August and is once again awaiting a response.

Update: Eighteen Months After Favorable Ruling from DEA Judge, No Response from DEA on MAPS-Sponsored Marijuana Production Facility

DEA, meanwhile, protects NIDA's monopoly by refusing to license alternative production facilities, such as Professor Lyle Craker's proposed MAPS-sponsored facility at the University of Massachusetts-Amherst. Craker, who is 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 over seven years to obtain a DEA Schedule I license to manufacture marijuana exclusively for privately funded, federally-approved research.

Thanks to the problems associated with NIDA's monopoly, MAPS' primary focus with marijuana research since 2001 has been sponsoring Craker's applications for regulatory approval and associated legal struggles.

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. Six months 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. (Dr. Craker was represented in those proceedings by ACLU attorney Allen Hopper and Julie Carpenter from the Washington D.C. law firm of Jenner and Block).

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 up to the DEA to decide whether to accept or reject Bittner's recommendation, but since there is no set deadline for DEA's decision, the agency appears content to continue its strategy of delay.

If the DEA rejects Bittner's recommendation, or if the delay continues so long as to be deemed "unreasonable" under the law, MAPS and Dr. Craker can appeal to the Federal Court of Appeals for the D.C. Circuit.

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Organizations that have written to DEA in favor of Craker's application include 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 efforts, last fall 45 members of the U.S. House of Representatives signed a letter to DEA in support of Craker's application. Massachusetts senators John Kerry and Edward M. Kennedy have also written to DEA in support of Craker's application.

DEA and NIDA are clearly scared of the truth about medical marijuana and are taking advantage of their lack of accountability to play politics with science and medicine. With nearly 80% of the public supporting outright legalization of medical marijuana, it's outrageous to make the case that simply researching medical marijuana is "not in the public interest" (as DEA has claimed).

In its statements on medical marijuana, the federal government justifies its concerted opposition and intervention with state laws (such as military-style raids on medical marijuana pharmacies and hospices in California) on the basis that marijuana has not been approved by the FDA as a medicine. Yet, as MAPS' efforts have demonstrated, DEA and NIDA have created a Catch-22 for researchers--on the one hand, denying that marijuana is a medicine because the FDA has not approved it, while on the other hand obstructing the very research that would be required for FDA to approve marijuana as a medicine.

Let's hope that the next administration in Washington will have the courage and common sense to implement evidence-based policies that value science and the human rights of drug users more than blind allegiance to political orthodoxy.