

DEA AND THE UMASS AMHERST MEDICAL MARIJUANA PRODUCTION FACILITY: AN UPDATE

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DEA Finally Replies After 18 Months

Since 1992, MAPS has been working to sponsor a privately-funded medical marijuana drug development research program. In late 1999, MAPS and Prof. Lyle Craker, Director of the Medicinal Plant Program, Department of Plant and Soil Sciences, UMass Amherst, began working together to establish a Massachusetts Department of Public Health and Drug Enforcement Administration (DEA)-licensed medical marijuana production facility. The facility is to be funded by a grant to UMass Amherst from MAPS and is intended to produce high-potency marijuana for use exclusively in federally-approved scientific research. In June 2001, Prof. Craker submitted his license applica-

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tion to the DEA, with full support from the UMass Amherst administration. For a complete, documented history of this effort, see <http://www.maps.org/mmj/mmjfacility.html>

On December 16, 2002, several DEA agents went to UMass Amherst to meet with Prof. Craker and several senior members of the UMass Amherst administration. Unfortunately, it turned out that the purpose of the meeting was to persuade Prof. Craker and UMass Amherst to withdraw the application, which they declined to do.

On March 4, 2003, DEA responded in writing for the first time to Prof. Craker’s application, more than 20 months after the application was originally submitted (it had been “lost” for over a year). The letter, from Frank Sapienza, Chief, Drug and Chemical Evaluation Section, stated that DEA was inclined to reject the application because it believed that NIDA

can supply marijuana “acceptable to the research community.” The testimony of Dr. Ethan Russo, who wrote to DEA to say that he found the quality of NIDA material to be substandard, was discounted since Dr. Russo “has not been registered by the DEA to conduct research with marijuana.” Ironically (at least to us), Dr. Russo was not registered with DEA to conduct human clinical research with marijuana (though he is registered with the DEA to conduct laboratory research with marijuana) because NIDA and the Public Health Service (PHS) didn’t like his privately-funded, FDA-approved protocol and refused to sell him marijuana, effectively preventing his study from taking place.

MAPS Response

MAPS responded in writing to the DEA letter by pointing out that while the poor quality of

NIDA material is an important consideration, there are other fundamental reasons why DEA licensing of the UMass Amherst facility is necessary to facilitate medical marijuana research. As long as NIDA retains its monopoly on the supply of marijuana that can be used in research, private sponsors of medical marijuana research 1) cannot select the exact strain of marijuana with the exact mix of cannabinoid content that the sponsors consider most likely to be safe and efficacious, 2) cannot manufacture the drug they wish to research and thus are not in control of either availability and cost, and 3) cannot supply the exact drug that was used in research for possible prescription use since NIDA is legally authorized to grow marijuana for research but cannot supply it on a prescription basis.

MAPS also emphasized a procedural reason why DEA support for NIDA's monopoly on supply serves to obstruct medical marijuana research. At present, NIDA will not sell marijuana to a researcher with a privately-funded and FDA-approved protocol unless the protocol is also approved by a NIDA/PHS review process. Since NIDA has a monopoly on the supply of marijuana, but not any other Schedule I drug such as MDMA, LSD or psilocybin, this additional review process exists only for marijuana research and has twice been used to prevent privately-funded, FDA-approved protocols from taking place.

As a result of NIDA's monopoly, no rational sponsor will invest millions of dollars in medical marijuana research while it remains dependent for its supply of research material on NIDA, whose institutional mission is diametrically opposed to exploring the beneficial uses of marijuana and which cannot legally provide marijuana for prescription use.

The fundamental question posed to the DEA by Prof. Craker's application for a license to produce marijuana is whether or not the DEA will open the door to a privately-funded medical marijuana drug development program. This is the model adopted by GW Pharmaceuticals in England, licensed by the British Home Office to

grow a variety of strains of marijuana as part of its privately-funded research into the medical uses of marijuana extracts. Unfortunately, DEA support for NIDA's monopoly seems to be more about controlling medical marijuana research than about controlling drug diversion, DEA's primary responsibility.

MAPS has asked the Marijuana Policy Project, the Drug Policy Alliance, the National Organization for Marijuana Laws, and Patients Out of Time to write letters to the DEA. These letters will point out, among other things, that as long as the DEA defends NIDA's monopoly, funders will not invest in scientific research they perceive as politically obstructed but will continue to prioritize state and federal legislative approaches and state initiatives. MAPS has also been in contact with Senator Edward Kennedy and his staff, who we are hoping will eventually take an active role in support of the UMass Amherst facility. DEA support of NIDA's monopoly effectively discourages privately-funded research, making federal calls for more research ring hollow. ■

Marijuana Research in Israel

MAPS is also working to facilitate medical marijuana research in Israel. The Israeli Ministry of Health has approved a small number (about ten) of physician-recommended patients for legal access to marijuana for medical purposes. MAPS has agreed to donate \$10,000 to cover the costs of a researcher to periodically evaluate the health status of these patients. Maripharm, a Dutch-government licensed medical marijuana growing company, is considering donating the necessary marijuana for the study. This project is tentatively scheduled to begin in mid-2003.