UMASS-AMHERST MEDICAL MARIJUANA RESEARCH FACILITY

BACKGROUND IN SUPPORT OF AN INDEPENDENT, PRIVATELY FUNDED SOURCE OF PRODUCTION

On February 12, 2007, DEA Administrative Law Judge (ALJ) Mary Ellen Bittner issued an Opinion and Recommended Ruling determining that DEA should grant the application of Professor Lyle Craker, University of Massachusetts-Amherst, for a Schedule I license to grow marijuana for distribution exclusively to federally approved researchers. Prof. Craker's proposed production facility would resolve the controversy over medical marijuana by determining whether it meets the FDA's standards for safety and efficacy.

Unfortunately, DEA is under no obligation to accept Judge Bittner's administrative ruling.

What is at issue?

Should DEA grant a Schedule I bulk manufacturer license to Prof. Lyle Craker, Director, Medicinal Plant Program, Dept. of Plant, Soil and Insect Sciences, UMass Amherst, to establish a privately funded facility to produce marijuana exclusively for federally approved and privately funded research?

What is the problem?

Despite the fact that federal law clearly requires adequate competition in the manufacture of Schedule I and II substances, since 1968 the National Institute on Drug Abuse (NIDA) has maintained an unjustified monopoly on the production of marijuana for legitimate medical and research purposes in the US. DEA helps to protect NIDA's monopoly by refusing to grant competitive licenses for marijuana production.

Currently, the only way for marijuana to be evaluated by the FDA to determine whether it meets the standards necessary to become a medicine under federal law is for privately-funded sponsors to conduct FDA-approved clinical trials. Unfortunately, NIDA's monopoly on the supply of legal marijuana is a fundamental obstruction to such privately funded research, which is currently not being conducted despite strong public interest.

The DEA wants to have it both ways, denying that marijuana is a medicine because the FDA has not approved it, while simultaneously blocking the appropriate administrative channels which would facilitate FDA clinical trials.

Arbitrary and Lengthy Delays: Despite the fact that it is not NIDA's mission to study the medicinal uses of marijuana or to advocate for such research, NIDA's monopoly on the supply of cannabis available for research results in arbitrary and lengthy delays. For example, Chemic Labs, a DEA-licensed analytical lab, was made to wait more than two years for a reply to its initial request to purchase 10 grams of marijuana for privately sponsored research into vaporizers, a non-smoking delivery system which the Institute of Medicine report recommended be developed. After two years of delay, the application was rejected. NIDA has also refused to provide marijuana to two other privately sponsored, FDA-approved protocols that sought to evaluate marijuana for AIDS wasting syndrome (IND #43-542) and for migraines (IND #58-177).

What is the resolution?

Congress should support and encourage DEA to accept the February 2007 Opinion and Recommended Ruling of Administrative Law Judge Mary Ellen Bittner. Furthermore, DEA should grant a Schedule I bulk manufacturer license to Prof. Lyle Craker, UMass Amherst, to establish a privately funded facility to produce marijuana exclusively for federally approved and privately funded research.

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