

## VAPORIZER RESEARCH: AN UPDATE

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MAPS and California NORML have completed a first, preliminary round of experiments demonstrating the feasibility of testing the Volcano vaporizer (www.vapormed.de). Conducted by Chemic Labs, this \$30,000 feasibility study indicated that the Volcano does produce remarkably clean vapor containing THC and other cannabinoids. We have raised an additional \$25,000 from a grant from the Marijuana Policy Project (first grant proposal rejected, second approved) and have just

completed a follow-up "protocol" study conducted according to FDA standards. This is the first vaporizer study designed to detect a broad spectrum of toxins in the gas phase of cannabis smoke or

vapor, and will provide the necessary quantitative data to apply for FDA approval of human trials using the vaporizer. The results show that the vapor contains no detectable levels of a wide range of toxins present in marijuana smoke, but does contain substantial amounts of cannabinoids.

This study was urgently needed to keep smoked and/ or vaporized natural cannabis on track for FDA approval in the face of competition from other, non-smoked delivery systems, notably GW Pharmaceuticals' oral spray. A human vaporizer study would likely be of interest to the California Center for Medicinal Cannabis Research (CMCR), of whose scientific advisory board I am a member. Dr. Donald Abrams, UC San Francisco, has worked closely with us to develop a research protocol which would for the first time demonstrate how effectively vaporizers deliver cannabinoids into the human bloodstream. This study, for which Dr. Abrams submitted a grant proposal to the CMCR on April 1, 2003, could in turn pave the way for further medical studies

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using the vaporizer. Dr. Abrams will submit the protocol to the FDA in early April.

In the meantime, however, the DEA is pushing to discourage CMCR from further research with the cannabis plant, on the grounds that smoking is an unsatisfactory method of drug delivery. Furthermore, GW Pharmaceuticals has shown interest in approaching the CMCR about conducting research with its cannabinoid extracts, as a substitute for the cannabis plant. If vaporization research does not proceed, there is a good chance that the DEA or NIDA will succeed in blocking additional Phase II and eventual Phase III efficacy studies using the cannabis plant, studies which are needed to obtain FDA approval for rescheduling cannabis for medical use.

Obtaining FDA permission to use a vaporizer in human clinical trials is the first of two critical milestones to be achieved prior to embarking in earnest on a medical cannabis drug development program. The second milestone is obtaining an independent, non-governmental source of high-potency cannabis for FDA-approved research. MAPS is developing a project of this kind in association with Prof. Lyle Craker, Director of the Medicinal Plant Program, Department of Plant and Soil Sciences, UMass Amherst (p. 12).