Drug Enforcement Administration
Office of Diversion Control
Federal Register Representative (ODL)
8701 Morrissette Drive
Springfield, VA 22152

November 23, 2007

Re: Docket No. DEA-308P; 72 Fed.Reg. 54226
Technical Amendment to Listing in Schedule III of Approved Drug Products Containing Tetrahydrocannabinols

I. Interest of MAPS

The Multidisciplinary Association for Psychedelic Studies (MAPS) is a membership-based non-profit research and educational organization. In essence, MAPS is a non-profit pharmaceutical company. MAPS' goal is to initiate and fund a serious drug development research program aimed at proving to the satisfaction of the FDA that marijuana is safe and efficacious for specific medical uses and should become a legal, FDA-approved prescription medicine.

II. MAPS' Position on the Proposed Change to 21 C.F.R. § 1308.13(g).

MAPS supports the removal of DEA rules and regulations that support any type of monopoly. The proposed changes would allow for adequate competition that would "provide a safe, effective, and low cost alternative to the American public." 72 Fed. Reg. at 54228. Allowing for adequate competition among pharmaceutical companies provides patients with more consistent access to medication that can improve the quality of their lives.

MAPS supports the proposed rule change which would allow the generic manufacture of MARINOL. The unique scheduling of dronabinol creates a monopoly on the manufacture and marketing of dronabinol, and the addition of competition benefits patients and research in general.

MAPS also supports DEA's decision to allow dronabinol to be derived from whole

plant material. The proposed change represents a modification in DEA policy that is consistent with current research that suggests marijuana can be developed into an FDA-approved medication.

A. The Proposed Change to 21 C.F.R. § 1308.13(g) Should be Enhanced by Removal of the NIDA Monopoly on Research Marijuana.

While MAPS applauds DEA's willingness to change policy and recognize that effective medicine can be derived from the marijuana plant, we demand that DEA take the next step and register Professor Craker as a bulk manufacturer of marijuana for use by DEA-registered researchers in FDA-approved protocols. The tenor of the proposed rule change is to remove the unfair monopoly that would be held by MARINOL once the patent has expired, improving competition and benefiting patients. Meanwhile, however, DEA has refused to register Professor Craker as a bulk manufacturer of marijuana, resulting in an unjustified monopoly and allowing a private producer to profit while blocking non-profit research.

Professor Lyle Craker has applied for registration by DEA as a bulk manufacturer of marijuana in order to facilitate necessary research into the medical benefits of marijuana. Under the current regime, the National Institute on Drug Abuse (NIDA) controls the only marijuana available for research purposes, and has refused to supply some researchers with marijuana, even though the protocols have FDA approval.[1] Professor Craker's non-profit facility would be located at the University of Massachusetts-Amherst, and has gained the support of numerous lawmakers and public officials.[2]

Adequate competition in the production of marijuana for medical, scientific, and research purposes is required by 21 U.S.C. § 823(a)(1). DEA's Administrative Law Judge Mary Ellen Bittner found that adequate competition in the manufacture of marijuana does not currently exist, and that Professor Craker's registration is required under the Controlled Substances Act and is appropriate under the Single Convention on Narcotics.[3]

Judge Bittner's decision came as a result of a lawsuit brought by Professor Craker after DEA initially denied his application (after over 3 years of delay). Judge Bittner's decision overwhelmingly supports an alternative source of supply for research marijuana. Unfortunately, DEA is not bound by Judge Bittner's decision, and can still choose not to

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[1] For more information, please see: http://www.maps.org/mmj/

[2] For more information, please see: http://www.maps.org/mmj/DEAlawsuit.html

[3] U.S. Dept. of Justice, Drug Enforcement Administration, "In the Matter of Lyle E. Craker, Ph.D., Docket No. 05-16, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of Administrative Law Judge," Mary Ellen Bittner, February 12, 2007, available at http://www.maps.org/mmj/DEAlawsuit.html.

register Professor Craker as a bulk manufacturer of marijuana, even though competition is required under the Controlled Substances Act. Every other schedule I substance is available from more than one supplier in the United States, and no other researchers are subjected to additional review in order to gain access to research materials—FDA-approval and DEA-registration is deemed adequate, even for substances such as Psilocybin ("magic mushrooms") and MDMA ("Ecstasy").

DEA's proposed new rule will allow for adequate competition in the marketing of dronabinol; DEA should also allow for adequate competition in the field of manufacturing marijuana for research purposes and register Professor Craker as a bulk manufacturer of marijuana.

B. The Proposed Change to 21 C.F.R. § 1308.13(g) Will Benefit One Private Producer to the Exclusion of All Others.

The proposed rule change purports to remove an unintended, unfair monopoly held by MARINOL once the patent has expired. MAPS supports the removal of this monopoly; however, the change in scheduling of dronabinol will benefit Professor ElSohly, as he is the only registered bulk manufacturer of marijuana in the United States. Professor ElSohly's private registration falls outside of his contract with NIDA. Once the proposed new rule goes into effect and the patent expires, companies who hold ANDAs for dronabinol will be allowed to purchase marijuana from Professor ElSohly for use in the creation of a generic MARINOL. Without competition in the supply of marijuana, Professor ElSohly will be able to set whatever price he deems necessary, and will handsomely profit from this rule change.

It is fundamentally unfair for DEA to create a new rule that will privately benefit one individual under the guise of removing a monopoly, all the while preventing non-profit production of marijuana for non-profit research purposes. DEA must register Professor Craker as a bulk manufacturer of marijuana to rectify this injustice.

III. Conclusion

DEA should enact the proposed change to 21 C.F.R. § 1308.13(g), and register Professor Craker a bulk manufacturer of marijuana. The proposed change reflects current data that shows that safe and effective medicine can be derived from the marijuana plant; it stands to reason that other safe and effective medicines can be created using the marijuana plant. DEA must register Professor Craker as a bulk manufacturer of marijuana in order to allow non-profit production of marijuana for use in federally approved research.