

Waiting But Not Idly:

An Update on Progress Toward Prof. Lyle Craker's MAPS-Sponsored Medical Marijuana Production Facility

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WE ARE NOW STARTING the sixth year of MAPS' efforts to sponsor a privately-funded facility to produce marijuana for FDA and DEA-approved research. When we wrote about University of Massachusetts-Amherst Prof. Lyle Craker's lawsuit against the DEA in the Spring 2006 MAPS Bulletin*, lawyers for both sides were working on the final legal briefings for this case. Both MAPS and the DEA filed final briefs to DEA Administrative Law Judge (ALJ) Mary Ellen Bittner on May 8, 2006.

MAPS has joined forces with MMPAP, a coalition of medical marijuana advocates who are working toward getting support from the American Medical Association for more reasonable medical marijuana policy.

Prof. Craker, Director the Medicinal Plant Program in the Dept. of Plant, Soil and Insect Sciences at UMass-Amherst, MAPS staff, and medical marijuana advocates and patients throughout the country are now eagerly awaiting a decision that will tell us a lot about the course of medical marijuana reforms over the next few years. Waiting and preparing, that is, because even if Prof. Craker receives a favorable recommendation, there's much more work to be done to ensure that Prof. Craker's facility becomes a reality, since DEA Administrator Karen Tandy can either accept or reject ALJ Bittner's recommendation.

For researchers seeking to perform FDA-approved clinical studies with most Schedule I substances, it is a relatively simple matter to obtain a license from the DEA to possess the actual research material, once the security of their laboratories has been demonstrated. Not so with marijuana. Marijuana alone is subject to a monopoly controlled by the National Institute on Drug Abuse (NIDA), a government agency whose mission is certainly *not* to examine the beneficial uses of controlled substances. Further,

Prof. Mahmoud El Sohly of the University of Mississippi, NIDA's producer of marijuana, has a personal financial interest that conflicts with smoked marijuana becoming a prescription medicine. Prof. El Sohly personally has patents on a marijuana suppository delivery system, and he has a DEA license to grow marijuana for his own private gain in order to supply THC extract under contract to a pharmaceutical company that produces generic Marinol. Both of these products would face direct competition from prescription marijuana, either smoked or vaporized.

The results of these several levels of conflict of interest are as one might imagine: NIDA's marijuana supply is of the low quality that befits NIDA's agenda to research the harms of marijuana, and, more importantly, NIDA's lack of competition produces arbitrary and total control over the supply. As a result, NIDA has been able to halt MAPS' medical marijuana research program for the last decade by refusing to sell marijuana to several of MAPS' FDA-approved studies. NIDA has even refused to sell 10 grams of marijuana for a MAPS-sponsored laboratory study of the chemical composition of marijuana

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vapors produced by the Volcano vaporizer, a non-smoking delivery system that successfully addresses FDA concerns about the inhalation of marijuana smoke.

MAPS and Prof. Craker are seeking to break this monopoly by opening a MAPS-funded production facility run by Prof. Craker. This facility would provide marijuana for all of MAPS' FDA-approved protocols and would spur additional new research, as the threat of a years-long bureaucratic nightmare is removed from MAPS' research-planning picture. More importantly, a private facility would create the possibility for MAPS to initiate its medical marijuana drug development clinical trials to evaluate whether marijuana can become an FDA-approved medicine. Clinical trials of a plant-based medicine must take place using the same strain of plant material that a drug developer plans to market, since the effects and side effects of another strain with different chemical concentrations could vary. No rational drug developer would invest millions of dollars in researching a low-potency, low-quality strain that is controlled by NIDA, a government body that could withdraw or refuse permission to use the strain at will, and that in any event is not permitted to be the supplier of marijuana for prescription medicine distribution, leaving the sponsor with the need to negotiate with Prof. El Sohly despite his major conflicts of interest. As one of our fellow medical cannabis advocates recently noted, this is like Pfizer spending millions of dollars researching a new pill that Merck owns the rights to, which would clearly be a foolish investment.

MAPS' final brief to the court, prepared by lawyers Julie Carpenter (Jenner & Block, LLP), Allen Hopper (ACLU Drug

Law Reform Project), and Emanuel Jacobowitz (Steptoe & Johnson, LLP) highlighted these and other arguments, and can be found with other information related the case at <http://www.maps.org/mmj/DEAlawsuit.html>. The DEA's reply brief, also filed on May 8, was rather empty of analysis and legal arguments and was padded, like a weak high school term paper, with a long reiteration of the contents of the testimony of each witness. Unfortunately but unsurprisingly, DEA lawyers resorted to *ad hominem* attacks on Rick Doblin for his personal marijuana use, despite the fact that he would never have access to any of the marijuana in Prof. Craker's facility. Since Rick had never sampled NIDA's supply of marijuana he had therefore not "diverted" legal marijuana to non-medical purposes. The DEA's brief can also be viewed on the MAPS website.

The final recommendation from ALJ Bittner is expected approximately four to six months after the brief filing date, which would be sometime between September and November. We've been spending these months preparing actively for the recommendation, because—unlike a decision in state or federal court—the DEA is not obligated to follow a recommendation from its own administrative law court. For comparison, some of you may be surprised to learn that DEA ALJs have *already* recommended rescheduling both marijuana and MDMA, and it is obvious how far that did not go!

With this historical trend in mind, the MAPS staff has been working hard to gather support from a broad range of individuals and organizations to put political pressure on the DEA to issue the license should Judge Bittner recommend

that course of action. Our supporters include 38 members of Congress, Senators Kennedy and Kerry of Massachusetts, the state medical associations of California and Texas, the state nurses associations of New Mexico, North Carolina, and Wisconsin, the Lymphoma Foundation of America, the National Association for Public Health Policy, the United Methodist Church, the Drugs and the Law Committee of the Association of the Bar of the City of New York, Grover Norquist, president of the conservative organization Americans for Tax Reform, and several other notable organizations. Efforts are continuing to get support letters from other organizations such as the American Nurses Association and the American Cancer Society.

MAPS has also just joined forces with the Medical Marijuana Policy Advocacy Project (MMPAP), a coalition of medical marijuana advocates who are working toward getting support from the American Medical Association (AMA) for more reasonable medical marijuana policy. The AMA House of Delegates already has a very positive resolution calling for further research into the use of marijuana as medicine**. MMPAP is working to find state delegations of the AMA who will help us propose a new resolution at the November House of Delegates meeting, calling for support for private production facilities like Prof. Craker's. The proposed resolution also supports protecting patients in medical marijuana states from criminal prosecution, in hopes that AMA support will assist the passage in Congress of the Hinchey-Rohrabacher amendment, which aims to codify such patient protection into federal law. The passage of our AMA resolution depends on support from

state medical associations, so if you have or know of good connections with any state medical associations, particularly in states that have medical marijuana laws, please contact me at kelly426@gmail.com.

We are hopeful that Judge Bittner will issue a favorable recommendation, and that the broad base of support that we have collected will convince the DEA to follow that recommendation. If the DEA does not follow a favorable recommendation, we can still pursue the case in federal court, arguing that the DEA's reasons for not following the recommendation are flawed. More litigation would delay Prof. Craker's facility from opening for many more years, so this is certainly not our desired outcome. However, if the DEA does fail to follow a favorable recommendation, or for that matter if the recommendation is unfavorable, it will only boost the efforts to pass state medical marijuana initiatives by providing even stronger evidence that the federal process for making marijuana into a medicine is blocked. What happens over the next few months in Prof. Craker's case will be a decisive factor in what sorts of medical marijuana reform efforts we see in the future, nationwide. We hope we'll have some good news for you on this front in an upcoming monthly email update and in the next *MAPS Bulletin!* •

* See Spring 2006 article at http://www.maps.org/news-letters/v15n4-html/dea_case.html

** See http://www.amaassn.org/apps/pf_new_pf_online?f_n=browse&doc=policyfiles/HnE/H-95.952.HTM

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