

## The Saga of MAPS' Lawsuit to Gain Approval to Sponsor a **Marijuana** Farm

By Rick Doblin, Ph.D., and Stephen Morseman

IN RECENT MONTHS, MAPS has increased our efforts to secure a DEA permit for Professor Lyle Craker, Ph.D., to cultivate marijuana under contract to MAPS, in order to break the government monopoly over the marijuana supply for FDA-approved studies. This campaign is of the utmost importance, because without breaking the monopoly over the marijuana supply, sponsors of research will never be able to secure the marijuana needed to justify the investment of millions of dollars into research. Without further research on this subject it will become increasingly difficult to provide the necessary body of clinical studies to justify developing marijuana into an FDA-approved prescription medicine.

At present, privately funded FDA-approved research with marijuana is fundamentally obstructed by the National Institute on Drug Abuse (NIDA), who is the sole provider of marijuana for FDA-approved studies. Even after researchers obtain FDA approval for their protocols, they must still contend with the NIDA review process in order to obtain their research materials. NIDA is not an objective judge as to who should receive marijuana for FDA-approved research because their mission is to study the harmful effects of illicit drugs. This has resulted in attempts to study the therapeutic potential of marijuana being met with delay or rejection. Thus, in order to facilitate research and give sponsors control over the marijuana being used in their studies, there needs to be an additional source of marijuana. Otherwise, sponsors will end up doing research with a drug controlled by NIDA that may not be available for prescription use or available only at outrageous monopoly prices.

Fortunately, we have the recommendation of DEA Administrative Law Judge Mary Ellen Bittner on our side. On February 12th, 2007, after extensive hearings and testimony, Bittner stated that it would be in the public interest to grant a DEA license to Prof. Craker at UMASS Amherst to cultivate marijuana under contract to MAPS. After a delay of almost two years, acting DEA Administrator Michelle Leonhart rejected this recommendation six days before President Obama was inaugurated. MAPS is working to influence Leonhart to reverse her decision and accept the ruling of Judge Bittner in order to finally break the federal monopoly over the marijuana supply. If this proves to be unsuccessful, we will continue our efforts in court to try to sue the DEA for unreasonable delay should they continue to ignore our pending motion to reconsider their rejection. Should our motion be rejected, we plan to sue the DEA in the U.S. Court of Appeals.

In an attempt to give this campaign wider recognition outside of the drug policy movement, we have reached out to over 200 different organizations throughout the medical community. Despite private support from these organizations, the current political environment has made them apprehensive about taking a formal position on this issue. We have had more luck with our public education campaign and have successfully gotten over a dozen letters to the editor published throughout the country, which has brought greater awareness to this issue. In order to try to influence all the different levers of power, we hired the Raben Group, a lobbying firm that helped persuade the Department of Justice to order the DEA to back off from prosecuting patient providers in medical marijuana states.

On November 17, 2010, the Senate Judiciary Committee held a confirmation hearing for Michelle Leonhart, who had been nominated by President Obama for Administrator of DEA. Leonhart has been in a leadership position at DEA since 2004 and was elevated under President Bush. She has been aggressively opposed to medical marijuana and led the DEA efforts to arrest providers and patients in states with medical marijuana laws. Shortly after President Obama took office, Attorney General Holder ordered the DEA to cease its enforcement activities in medical marijuana states of providers and patients acting in compliance with state laws. At the hearing, we'd hoped that some senators would urge Leonhart to respect medical marijuana laws and would support ending DEA obstruction of medical marijuana research. Unfortunately, that didn't happen. Instead, Senator Sessions (R-AL) obtained a commitment from Leonhart to actively oppose medical marijuana in non-medical marijuana states. Our only hope now is that the Obama Administration will find the courage to support resolving the controversy over the medical use of marijuana through scientific research and will order the DEA to accept Bittner's recommendation. Unfortunately, based on the lack of active support for medical marijuana from any senators at Leonhart's confirmation hearing, it's more likely that Prof. Craker will focus on legal challenges in court rather than on horticultural challenges in the greenhouse. •



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