June 10, 2003

Frank Sapienza
Chief, Drug and Chemical Evaluation Section
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

Dear Mr. Frank Sapienza,

I've reviewed your March 4, 2003 letter to Prof. Lyle Craker, Director, Medicinal Plant Program, UMass Amherst Department of Plant and Soil Sciences, concerning his application for a license to establish a facility to produce high-potency marijuana exclusively for federally-approved research. I'm writing now to comment on your letter as President of MAPS, the non-profit organization that has pledged to donate the funds to establish Prof. Craker's marijuana production facility when licenses are obtained.

I'd first like to thank you for being open to receive additional information about the need for the UMass Amherst facility, which is intended to produce high-potency marijuana exclusively for use in federally-approved research. I'd also like to thank you simply for responding at all, since your letter is the first written reply from DEA to Prof. Craker's license application initially submitted on June 24, 2001.

The fundamental question posed to the DEA by Prof. Craker's application for a license to produce marijuana is whether or not the DEA will open the door to a privately-funded medical marijuana drug development program. Ex-DEA Administrator Asa Hutchinson stated on November 28, 2001 that, "the question of whether marijuana has any legitimate medical purpose should be determined by sound science and medicine." Unfortunately, DEA support for NIDA's monopoly on the supply of marijuana that can be used in FDA-approved research seems to be more about controlling medical marijuana research than about controlling diversion, which is DEA's primary responsibility. Furthermore, DEA support for NIDA's monopoly also seemingly contradicts the intent of the Controlled Substances Act, which in 21 USCS, Section 823 A, states that the goal of DEA regulation of the manufacture of controlled substances is intended to limit "the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions [emphasis added] for legitimate medical, scientific, research and industrial purposes." NIDA's monopoly is the opposite of "adequately competitive conditions."

MAPS, as a non-profit research and educational organization, has been working for many years to sponsor FDA-approved clinical research with marijuana. However, MAPS will not be able to raise the substantial funds that will be needed for a medical marijuana drug development program until DEA removes the political and practical obstacles created by NIDA's monopoly on supply. Perhaps this is DEA's actual intent?

You stated in your letter that, “it appears that the basis of your application is the purported need for a higher potency and higher “quality” marijuana product than that currently available from the National Institute on Drug Abuse (NIDA).” While it is true that the poor quality of NIDA material is an important consideration, there are other fundamental reasons why DEA licensing of the UMass Amherst facility is necessary to facilitate medical marijuana research.

The core issue underlies all privately-funded pharmaceutical drug development. Private sponsors/funders of medical research seeking FDA approval for their drug are all able to select, manufacture or license, and supply for possible prescription use the drug they will invest millions of dollars to research. This is the model adopted by GW Pharmaceuticals in England, licensed by the British Home Office to grow a variety of strains of marijuana as part of its privately-funded research into the medical uses of marijuana extracts.

As long as NIDA retains its monopoly on the supply of marijuana that can be used in research, private sponsors of medical marijuana research 1) cannot select the exact strain of marijuana with the exact mix of cannabinoid content that the sponsors consider most likely to be safe and efficacious, 2) cannot manufacture the drug they wish to research and thus are not in control of either availability and cost, and 3) cannot guarantee to supply the exact drug that was researched for possible prescription use since NIDA is legally authorized to grow marijuana for research but cannot supply it on a prescription basis. No rational sponsor will invest millions of dollars in medical marijuana research while it remains dependent for its supply of research material on NIDA, whose institutional mission is diametrically opposed to exploring the beneficial uses of marijuana and which cannot in any case legally provide marijuana for prescription use.

There is also a procedural reason why DEA support for NIDA’s monopoly on supply serves to obstruct medical marijuana research. At present, NIDA will not sell marijuana to a researcher with a privately-funded and FDA-approved protocol unless the protocol is also approved by a NIDA/ Public Health Service (PHS) review process. This additional review process exists only for marijuana but not for any other privately-funded research with any other Schedule I drug such as MDMA, LSD or psilocybin. The only reason that such a policy can be imposed on privately-funded medical marijuana research is that NIDA retains a monopoly on the supply of marijuana, but not any other Schedule I drug.

This additional NIDA/PHS review is especially problematic because NIDA/PHS has already refused to supply marijuana to two FDA-approved protocols, thus preventing these studies from taking place. In your letter, you discounted Dr. Ethan Russo’s testimony about the need for the UMass Amherst facility because Dr Russo “has not been registered by the DEA to conduct research with marijuana.” This is quite a disingenuous argument since Dr. Russo “has not been registered by the DEA to conduct [FDA-approved] research with marijuana” precisely because NIDA/PHS refused to sell him marijuana for his FDA-approved protocol! Furthermore, Dr. Russo does possess a DEA Schedule I license for marijuana for laboratory research.

Sponsors investing private funds in medical marijuana research do not want to negotiate a Clinical Plan with FDA only to have NIDA/PHS decide for whatever reasons not to approve some of those studies. Until the unusual and unnecessary NIDA/PHS review of medical marijuana research is removed from the marijuana drug development process through the licensing of the UMass Amherst facility, sponsors will not invest a substantial amount of private funds into medical marijuana research.

Finally, the poor quality and low potency of NIDA marijuana is a significant problem that compromises medical marijuana research. Though you discounted his testimony, Dr. Russo complained about the poor quality of material that NIDA makes available for research and provides to the seven FDA-approved patients receiving marijuana on a compassionate basis. Unfortunately, several other researchers were reluctant to express in writing their complaints about the quality of NIDA material for fear of DEA retribution.

In your letter, you explained that NIDA has available a supply of 7-8% THC marijuana for bona fide research protocols, and that NIDA could produce marijuana of up to 15% if requested to do so for federally-approved protocols. Certainly, marijuana with 7-8% THC is a substantial improvement over the 3-4% THC marijuana that NIDA has previously provided to researchers. Nevertheless, the MAPS/ California NORML study of marijuana potency showed that the marijuana offered to patients at buyer's clubs around the country was often in the range of 12-15% THC, a product that NIDA does not currently offer. While NIDA claims it can provide marijuana up to 15% THC, such claims remain to be demonstrated. There are also other important aspects of quality including the considerable amount of seeds and stems that can be found in NIDA's cigarettes and the freshness of the product. Furthermore, specific strains vary in the amounts of other cannabinoids, such as cannabinol (CBN) and cannabidiol (CBD), that they contain, with these other cannabinoids offering potentially significant clinical advantages when synergistically combined with THC. Regardless of whether NIDA can improve the THC-content and overall quality of the marijuana it provides to researchers, sponsors of private research should not be forced to remain dependent on only those supplies that NIDA chooses to provide at a cost and availability solely to be determined by NIDA.

Finally, you indicated that DEA continued to have international treaty and legal concerns regarding the UMass Amherst application. I believe that all international treaty and legal concerns can be successfully resolved, as explained in more detail in the July 24, 2002 letter to DEA Administrator Asa Hutchinson from Peter Barton Hutt and Alexei Silverman, Covington & Burling, and Graham Boyd, ACLU Drug Policy Litigation Group.

Given the intense national controversy over the medical uses of marijuana, DEA should let research proceed in a fair and unobstructed manner, in exactly the same way that the medical use of any other drug would be researched. This means that sponsors should permitted to select and manufacture the exact product they choose to invest private funds to research. DEA should focus on diversion control, which Congress has empowered it to

regulate and control, rather than on actively working to sustain a government monopoly on supply that obstructs rather than facilitates medical marijuana research.

Sincerely yours,

Rick Doblin, Ph.D.
MAPS President

cc: John Ashcroft, Attorney General
John Walters, Director, ONDCP
William Simpkins, Acting Administrator, DEA