Frank Sapienza Chief Drug & Chemical Evaluation Section Drug Enforcement Administration Washington, D.C. 20537

Dear Mr. Sapienza:

Your March 4 letter to Dr. Lyle Craker at the University of Massachusetts at Amherst indicates that the Drug Enforcement Administration is blocking research that would allow the Food and Drug Administration to approve marijuana as a prescription medicine.

Amazingly, it took nearly two years for your office to respond to Dr. Craker's original inquiry to establish a privately funded, federally authorized marijuana production facility in Amherst.

You may or may not know that my organization controls one of the few funding streams that are available for medical marijuana-related activities in the United States. Until the DEA provides the necessary permissions for a private marijuana production facility to move forward, I am not inclined to authorize funding for medical marijuana research. Indeed, the DEA's attitude toward research reinforces my inclination to focus our resources on encouraging legislative changes, rather than promoting research. In sum, to the extent that the DEA delays or blocks medical marijuana research, the DEA will make it more likely that medical marijuana possession and cultivation will be legalized outright through voter initiatives and state legislatures.

In your letter, you claim that high-quality, research-grade marijuana is already available - or could be made available -- from the National Institute on Drug Abuse. You go on to say that you will need evidence that disputes this claim before you can consider Dr. Craker's application.

This appears to be a political attempt to block medical marijuana research, as your concern has no basis in law. Nowhere in the <u>Code of Federal Regulations</u> does it state that the DEA requires an applicant to prove a need for a different variety of marijuana or another Schedule I controlled substance before the DEA can grant permission to manufacture that substance for legitimate research.

Furthermore, a private research facility is actually required before the FDA can approve marijuana as a prescription medicine. (As you know, the National Institute on Drug Abuse's marijuana supply in Mississippi cannot be used on a prescriptive basis.)

As the National Academy of Sciences' Institute of Medicine (IOM) found in March 1999 in its landmark report, evidence indicates that marijuana is medically beneficial to certain

patients suffering from cancer chemotherapy treatments, AIDS, chronic pain, and other serious medical conditions. At the same time, IOM indicated in its report that additional clinical trials must be conducted before the FDA can decide whether to approve marijuana as a prescription medicine in the United States.

As things currently stand, not only are there no clinical trials using privately grown marijuana, but a private production facility doesn't even exist in the U.S.

IOM noted that it would take many years and untold sums of money to move marijuana through the FDA approval process -- even with the government's cooperation. Because of this hard reality, state legislatures and the U.S. Congress are moving to remove criminal penalties for patients who presently need to use marijuana for medical purposes.

Your letter of March 4 adds fuel to this movement. Because the DEA is stalling and proffering unsubstantiated arguments to thwart the development of a private production facility, it is all the more necessary for legislative bodies to remove criminal penalties for patients whose lives depend on using marijuana medicinally. I will be sure to communicate to elected officials who are looking at this issue the actions the DEA takes regarding medical marijuana research.

I strongly urge the DEA to approve the license for the privately funded medical marijuana production facility at the University of Massachusetts at Amherst.

Sincerely,

Rob Kampia
Executive Director