U. S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

JUL 01 2002

The Honorable Barney Frank
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Frank:

Thank you for your letter of June 6, 2002, regarding the cultivation of marijuana for research in the United States. You ask the Drug Enforcement Administration (DEA) "to license privately funded sources of marijuana for use in federally approved studies, in order to substantially facilitate the conduct of scientific research into the risks and benefits of the potential medical uses of marijuana." In this context, you also ask DEA to permit the cultivation of marijuana at locations other than the University of Mississippi.

Since the United States began in the late 1960s to investigate scientifically how humans are affected by smoking marijuana, the nation's sole source of research-grade marijuana has been the University of Mississippi. As your letter indicates, this research takes place under the strict oversight of the National Institute on Drug Abuse (NIDA). For the following reasons, it is essential that this arrangement continue.

For nearly a century, the United States has been a party to international treaties designed to establish effective controls over international and domestic traffic in drugs of abuse. The longest standing of such treaties currently in force is the Single Convention on Narcotic Drugs, 1961 ("Single Convention"), which the United States ratified in 1967. Several provisions of the Single Convention pertain specifically to the cultivation of marijuana. The Single Convention requires any party that permits the cultivation of marijuana for scientific purposes to ensure that such cultivation occurs only under the oversight of a national government agency, with the agency maintaining a monopoly over the distribution of all marijuana grown for research. Cultivation of marijuana by private growers not under the oversight of a national agency is prohibited by the treaty, as is distribution of marijuana by private entities. These requirements are necessary to minimize the likelihood that marijuana grown for research will be stolen or diverted into illicit channels, or that individuals will use their authority to cultivate for research as a subterfuge for illicit production and distribution. Such concerns are particularly heightened in the United States, where marijuana is the most widely used illegal drug.

The United States has long been the leader among nations committed to international drug control. Our country has recognized since the early 1900s that cooperative efforts among nations in combating drug abuse are critical to protect the health and general welfare of the American people as

well as citizens of all nations. Furthermore, the examples set by the United States in the area of drug control have often set the patterns followed by other nations. The United States must therefore demonstrate a continuing commitment to the Single Convention and other drug control treaties.

Congress recognized these principles when it enacted the Controlled Substances Act (CSA) in 1970. Included in the CSA are various provisions designed specifically to ensure compliance with the Single Convention and other drug control treaties. One such provision is that which governs the issuance of DEA registrations to manufacturers of controlled substances. In particular, when it comes to a substance listed in schedule I, such as marijuana, DEA may only register a person to manufacture such a drug if DEA determines that such registration is consistent with United States obligations under international drug control treaties. 21 USC 823(a). Thus, under the CSA, DEA may not grant registrations to private marijuana growers in a manner that would be inconsistent with the Single Convention.

Further, both the Single Convention and the CSA contemplate that domestic production of marijuana for scientific purposes must be limited to the minimum number of establishments that can produce an adequate supply. For more than 30 years, the University of Mississippi has produced an adequate supply to meet the entire United States demand for research-grade marijuana. There is no indication that this supply is currently inadequate or will become inadequate in the future. As long as the University continues to meet the nation's needs for research-grade marijuana while maintaining the highest level of safeguards against diversion, the Single Convention and the CSA dictate that it remain the sole domestic producer.

Your letter also suggests that marijuana should be made more available to researchers and that the federal government should not be the sole source of funding for marijuana used in research. In fact, this is already the case. In 1999, the Department of Health and Human Services (HHS) implemented a new policy to make marijuana more readily available to researchers. Among the changes made by HHS was that private funding can now be used to pay for the marijuana supplied by NIDA. The State of California has already utilized this new policy by providing funding to the University of California to conduct research into whether marijuana can be used safely and effectively as medicine. Pursuant to this state grant, there are several ongoing research projects using marijuana provided by NIDA, with the marijuana having been paid for by the researchers. (Prior to the commencement of each of these research projects, the research was deemed meritorious by both the Food and Drug Administration (FDA) and NIDA, and the researcher obtained a DEA registration to conduct such research.)

You state in your letter that "some claim that research has been impeded because of NIDA's refusal to supply marijuana to several FDA-approved medical marijuana protocols." Such claims are incorrect. In fact, it is DEA's understanding that, throughout the 32-year history of the CSA, there has been only one instance in which the FDA was willing to allow research involving marijuana to go forward but NIDA found the research protocol to be lacking in scientific merit (based on expert peer review) and therefore declined to supply the marijuana. That particular

researcher subsequently revised his protocol to correct the scientific flaws. Thereafter, both the FDA and NIDA found his protocol meritorious. Accordingly, he obtained a registration from DEA and conducted a clinical study using marijuana supplied by NIDA. It is simply a myth that the FDA, NIDA, or DEA has ever refused to allow scientifically valid clinical research involving marijuana to take place.

I share the sentiment expressed in your letter that any determination as to whether marijuana can be used safely and effectively as medicine must be based on reliable scientific evidence firmly grounded in sound clinical studies. The FDA approval process has protected the American public for decades and serves as the model of drug approval worldwide. Yet, recent efforts to legalize marijuana for purported "medical" use, either by ballot initiatives or legislative measures, seek to circumvent the FDA approval process and abandon science. For the United States to remain the safest country in which to purchase medicine, we must insist on the rigorous scientific criteria for drug approval mandated by federal law. No exception can be made for marijuana or any other schedule I drug.

I trust that this letter adequately addresses your inquiry. If you desire more specific information about the quality of marijuana supplied by NIDA to researchers or the procedures for obtaining such marijuana, you may wish to consult directly with NIDA.

Sincerely,

Asa Hutchinson
Administrator