July 24 , 2002

The Honorable Asa Hutchinson
Drug Enforcement Administration Administrator
700 Army Navy Drive
Arlington, VA 22202

Dear Administrator Hutchison,

Professor Lyle Craker of the Department of Plant and Soil Sciences at the University of Massachusetts, Amherst (UMass Amherst), asked the American Civil Liberties Union Drug Policy Litigation Project and Covington & Burling to review the United States international treaty obligations relevant to his application to the Drug Enforcement Administration (DEA) for a license to produce marijuana for federally-approved scientific research. To assist the agency in the process of reviewing this important application, Professor Craker requested that we send you the results of our analysis. Accordingly, we summarize those results below.

After reviewing your July 1, 2002 letter to Rep. Barney Frank, the text of the 1961 Single Convention on Narcotic Drugs and selected reports by the International Narcotics Control Board (INCB), the quasi-judicial entity that monitors compliance with the Single Convention and other international drug controls, it is our opinion that Professor Craker s proposed program does not contravene any of the United States international treaty obligations. Similar to the National Institute on Drug Abuse's (NIDA) current production facility at the University of Mississippi, the UMass Amherst project meets all relevant treaty obligations. Furthermore, the UMass Amherst project is fully consistent with your public statement of November 28, 2001, in which you declared that "the question of whether marijuana has any legitimate medical purpose should be determined by sound science and medicine.

I. Current System of Marijuana Production for Medical Research in the United States

As you are no doubt aware, both the Drug Enforcement Agency (DEA) and the Food and Drug Administration (FDA) currently regulate all aspects of medical marijuana production and use. Given this extensive agency oversight, they are in a position to impose the same regulations on the proposed UMass Amherst program as they currently do on the University of Mississippi program, with no diversion of supplies from medical to non-medical uses. The goal of the UMass Amherst facility is to produce a limited supply of 25 pounds in its first year.

At present, the University of Mississippi is the only location federally approved for marijuana production, and is licensed to do so by both the DEA and the Mississippi Department of Public Health. Under a contract from NIDA, the marijuana is produced under the direction of Professor Mahmoud A. Elsohy, Professor of Pharmacognosy. The marijuana is then shipped to the Research Triangle Institute (RTI) for processing into an FDA-approved dosage form (rolled

cigarettes of a standardized weight and potency). RTI is licensed through the DEA and the North Carolina Department of Health and Human Services. After RTI processes the marijuana into cigarette form, it stores the cigarettes until they are shipped to researchers approved by NIDA and licensed by DEA, and subject to an investigational new drug (IND) application that has become effective in accordance with FDA regulations, as well as to pharmacists working on behalf of the seven medical marijuana patients who receive marijuana pursuant to a compassionate access program under an effective IND. While federal government agencies license and regulate the University of Mississippi and RTI, at no point in this process do these agencies take physical possession of the cultivated marijuana.

The license furnished to the University of Mississippi s program renders NIDA the sole domestic source of marijuana for scientific research. The domestic monopoly on production enjoyed by the NIDA/University of Mississippi program imposes significant impediments to prompt and effective scientific research, especially privately-funded research seeking to develop marijuana into an FDA-approved prescription medicine. Accordingly, it is time for DEA to authorize an expansion of the channels for production and distribution of marijuana for scientific research, yet to do so with precisely the same regulatory safeguards against diversion or misuse as currently apply to the program at the University of Mississippi.

II. Advantages of the Proposed Alternate Source of Cannabis Production for Scientific Research.

The UMass Amherst project is to be funded by a grant from the Multidisciplinary Association for Psychedelic Studies (MAPS), a non-profit research and educational organization seeking to develop marijuana into an FDA-approved prescription medicine. The Massachusetts Department of Public Health, the state agency with regulatory oversight of such facilities, already has reviewed the UMass Amherst application and has expressed no objections in principle. It awaits DEA's agreement in principle before proceeding with its security evaluation and licensing process.

The UMass Amherst project would substantially expedite the evaluation of marijauna's efficacy and safety by meeting the needs of the sponsors of medical marijuana research and the researchers themselves. This is especially true when compared to the program administered by the University of Mississippi. Data in a New Drug Application (NDA) submitted to FDA must come from clinical trials that have been conducted with the identical product for which approval for marketing is requested. While NIDA can supply material from the University of Mississippi for FDA-approved clinical research, NIDA is not authorized to produce marijuana for possible prescription use. Any company, either for-profit or non-profit, that conducted a drug development program with NIDA's material would face the inherent limitations in the University of Mississippi program when it came time to provide material by prescription. As a result, NIDA-supplied marijuana is inadequate for use in any privately-funded drug development plan. Only an independent supply that is guaranteed to be available for research as well as possible

prescription use, such as would be produced at UMass Amherst, would suffice for a privately-funded sponsor of medical marijuana research to undertake eventual development.

Furthermore, NIDA's monopoly on supply forces researchers, even in the context of privately-funded studies, to submit to the lengthy procedures imposed by NIDA as a precondition to gaining access to a registered domestic source of cannabis. For instance, NIDA insists that even privately-funded studies that already have attained the approval of the FDA through an effective IND, undergo peer-review by a National Institute of Health advisory panel charged with reviewing applications for federal research grants. This additional layer of approval, which is required only for marijuana and not for any other Schedule I drug, introduces significant administrative delays and has twice resulted in the denial of a source for marijuana for scientific research for which there is an effective IND pursuant to FDA requirements.

Your letter of July 1, 2002 dismisses these concerns about the difficulty of obtaining marijuana for scientific research, stating that NIDA only once refused to provide marijuana to an FDA-approved protocol. Although you did not specifically identify the case you were relying upon for this statement, you appear to describe the well-known case of Dr. Donald Abrams' research protocol. It seems that DEA s review omitted consideration of the case of Dr. Russo's FDA-approved protocol (IND # 58,177), which was also denied by NIDA.

Furthermore, your letter appears to restrict the DEA s assessment of the need for additional domestic sources of marijuana to the issue of whether the University of Mississippi can produce an adequate supply, i.e., a quantity of material sufficient to meet domestic research demand. But sound scientific research necessitates that adequacy of supply be only one of several criteria weighed in the balance. The grade or potency of the material available is an important factor in obtaining the best clinical results. The UMass Amherst facility would produce medical marijuana of a higher potency than currently produced by the NIDA-contracted University of Mississippi program. While the University of Mississippi-produced marijuana has THC levels in the range of 2% to 7%, the University of Massachusetts would offer marijuana with THC levels from 8% to 15%. Higher potency marijuana would improve the risk/benefit ratio of marijuana consumption by reducing the amount of particulate material inhaled by participants in federally-approved medical research. Higher potency marijuana would also work more effectively in vaporizers, a non-smoking delivery device that does not burn the marijuana plant but instead heats it to the point where a vapor is produced that contains cannabinoids. Furthermore, the ratio of THC to other cannabinoids such as CBD and CBN can also affect therapeutic properties of marijuana. A privately-funded drug development program must be conducted with a product whose potency and variety of other cannabinoids the sponsor considers most likely to have a favorable risk/benefit ratio. The UMass Amherst facility would provide researchers with this essential choice.

Importantly, these significant advantages would not come at the expense of any reduction in the current scope of federal regulation of marijuana production. The DEA and FDA would

provide the exact same level of scrutiny to the proposed UMass Amherst program as they currently provide for the University of Mississippi program. With respect to both programs, the DEA would regulate all aspects of the production of cannabis. With respect to both programs, the DEA would also regulate security for the cannabis plants. Both programs would follow product purity and storage standards promulgated by the FDA pursuant to its administrative jurisdiction over research involving the medical applications of marijuana. And both programs would channel marijuana only to research programs approved and regulated by the DEA and the FDA. Thus, there is no substantive difference between the two academic programs in terms of the extent to which the federal agencies responsible for marijuana regulation would monitor the production and distribution of each program s products.

In short, The UMass Amherst proposal would permit medical marijuana to be produced in a manner that would greatly facilitate privately-funded, FDA-approved research and the eventual development of medical products.

III. International Treaty Obligations Relevant to Domestic Cannabis Production.

The United States is a signatory to the Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, T.I.A.S. No. 6298 (ratified by the United States in 1967, see 21 U.S.C./ 810(7)). As the International Narcotics Control Board (INCB) succinctly stated, the Single Convention as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: *to ensure adequate availability of narcotic drugs for medical and scientific purposes,* while at the same time preventing the illicit production of, trafficking in and use of such drugs. Report of the INCB for 1995, Availability of Opiates for Medical Needs, prepared pursuant to United Nations Economic and Social Council Resolutions 1990/31 and 1991/43, at 1 (emphasis supplied). Cannabis, which is listed in Schedules I and IV, is among the narcotics subject to the Single Convention s controls.

After reviewing the text of the Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the specific policies adopted by the INCB to monitor compliance with the treaty, we are of the opinion that the UMass Amherst plan to cultivate marijuana for medical research purposes would not contravene any provision of the treaty. To the contrary, the UMass Amherst plan would have the salutary purposes of facilitating the privately-funded investigation of marijuana and of adding to the international body of scientific knowledge concerning the medical usefulness of marijuana. In its official publications, namely its most recent annual report, the INCB has emphasized the importance of research regarding medical marijuana and urged that those scientific results be furnished to it and to the World Health Organization pursuant to the treaty.

The Single Convention clearly approaches the issue of drug production not from the perspective that all drug production and consumption is illegal, but from the position that drugs must be available for medicinal purposes. For instance, though the Single Convention considers

the *abuse* of such drugs to pose a danger, the preamble to the Single Convention sets forth that, the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and adequate provision must be made to ensure the availability of narcotic drugs for such purposes. Id., Preamble.

In keeping with the spirit of this language of the Preamble, the production of narcotics for medical and scientific research is expressly excepted from the Single Convention s recommended prohibitions on production and distribution of narcotics. Article 2, which applies to drugs listed under Schedules I and IV, including cannabis, provides: A Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, and possession or use of any such drug *except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to direct supervision and control of the Party*. Art. 2/5(b) (emphasis added).

As regards control of cannabis, the treaty permits nations to cultivate the cannabis plant for the production of cannabis or cannabis resin so long as the nation adopt[s] such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant, and appli[ies] thereto the system of controls as provided in article 23 [of the Single Convention on Narcotic Drugs] respecting the control of the opium poppy. Single Convention, Art. 28// (1) & (3). The system of controls mandated in Article 23 requires principally that a nation create a government agency to operate controls and that the agency designate the land where the drug will be cultivated, license the drug s cultivators, purchase and take physical possession of the drug crop, and maintain the exclusive right of importing, exporting, wholesale trading and maintaining stocks [of the drug] . . . . Single Convention, Art. 23//1-2. (The full text of Article 23 is attached for your reference.)

Your July 1 letter asserts that the Single Convention and the federal Controlled Substances Act (CSA) dictate that [the University of Mississippi program] remain the sole domestic producer. Our review of the relevant language of the Single Convention and the CSA, however, disclose no textual basis for this assertion. Indeed, there is no requirement in the CSA or the Single Convention that the agency to which a government grants the the exclusive right of importing, exporting, wholesale trading and maintaining stocks enjoy a perpetual monopoly on domestic production and maintenance of stocks for scientific research. Art. 23/2(e). Instead, the Single Convention expressly authorizes alternative sources of domestic production for licit purposes: stating that the exclusive right granted to such a government agency *need not extend* . . . to medicinal [cannabis]and [cannabis] preparations. Id (emphasis added). The Single Convention thus specifically contemplates that marijuana stocks will be maintained by parties other than a government agency so long as those parties are holding those stocks for the purpose of medical research and scientific use.

The fact that the Single Convention does not foreclose a Government from permitting a private company to produce cannabis for medicinal purposes is best illustrated by the case of GW Pharamaceuticals. GW Pharmaceuticals is a British corporation that currently produces its own cannabis plants at a secure facility, processes those plants, and then ships cannabis extracts to its own affiliated medical cannabis research projects. See http://www.gwpharm.com. Just as the UMass Amherst project would be supervised by the DEA and the FDA, GW Pharmaceuticals cultivates its cannabis crop with the support and regulation of the United Kingdom s Home Office and the Department of Trade and Industry. Although the INCB reports frequently single out nations that are engaging in practices that violate their Single Convention obligations, its 2001 Report makes no reference to GW Pharmaceuticals as an instance of international noncompliance. The operation of GW Pharmaceuticals demonstrates that it is possible under International law for a nongovernmental organization to cultivate medical cannabis in a manner that is easy for its government to regulate and that complies with international treaty obligations. To reiterate, the Single Convention clearly contemplates that such production and research will occur.

The consistency of the UMass Amherst application with the requirements of International law is further demonstrated by the fact that the INCB clearly contemplates that drugs, including marijuana, will and should be cultivated for medicinal purposes, and that the problems this poses for controlling traffic in illicit drugs should be resolved through maintenance of careful controls. One need look no further than its most recent annual report to the United Nations to validate this conclusion.

- Addressing opioids, covered by the same Single Convention provision as cannabis, the Board noted recently that [c]ases involving the diversion and abuse of opioids, in particular methadone . . . have been identified in several countries, and urged parties to the Treaty to take the necessary measures to prevent diversion. International Narcotics Control Board, 2001 Report, II (C) (*f* 123). The necessary measures the Board contemplated, however, were supervised consumption, short dispensing intervals and central registration of all opioids prescribed for treatment purposes, rather than elimination of opioid cultivation or distribution. Id. In fact, even while recognizing that opioid diversion posed problems, the Board urged all Governments that have not yet done so to examine their national policies, legislation, regulations and administrative procedures to identify and remove any obstacles to ensuring the adequate availability of opioids for treatment of moderate to severe pain. Id. at F (*f* 197).

- Addressing cannabis, the Board noted that Scientific research on the efficacy of medical use of cannabis or cannabis extracts has been initiated or is planned in several countries, including Canada, Germany, the Netherlands, Switzerland, the United Kingdom and the United States in order to assess the efficacy of cannabis in treating AIDS wasting, glaucoma, multiple sclerosis and pain and in alleviating the

side effects of cancer chemotherapy. Id. at II(D)(*f* 158). Rather than criticizing this research, the Board stated that it welcomes sound scientific research into the possible therapeutic properties and medical uses of cannabis or cannabis extracts. Id. Again, rather than urging nations to avoid research on cannabis or refrain from cultivating cannabis for medical research purposes, the Board simply reminded nations of the control requirements set by the relevant provisions of the 1961 treaty to reduce the risk of [cannabis] diversion and abuse. Id. at II(D)(*f* 159).

- Later in the 2001 annual report, the Board observed that [S]hould present and future scientific studies reveal medical usefulness of cannabis, WHO should be informed in accordance with Article 3 of the 1961 Convention. Id. at II (G) (*f* 228).

In sum, there is nothing in the text of the Single Convention or its enforcement history that would counsel an operative legal distinction under International law between the University of Mississippi program that currently operates with a DEA license and the proposed UMass Amherst program: both programs would be federally licensed, and hence subject to government agency control as mandated by the Single Convention; both programs would produce marijuana only for medicinal research purposes, as the Single Convention permits; and both would deliver marijuana from its site of cultivation to the site where it would be researched, rather than passing the product to a government agent.

IV. Conclusion.

After reviewing the United States international treaty obligations relevant to Dr. Craker's application to produce marijuana for federally-approved research at UMass Amherst, we conclude that the treaty clearly permits the United States to license privately-funded, government-regulated production facilities. When such a facility is permitted, the medical utility of marijuana will be investigated through scientific research with a commercial product of the sponsor s choice, manufactured by or under contract to the sponsor, and with a review process identical to that for all other Schedule I drugs.

Respectfully submitted,

Signatures on original document sent to DEA Administrator Asa Hutchinson on letterhead from Covington & Burling.

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Alexei M. Silverman

Graham Boyd
American Civil Liberties Union,
Drug Policy Litigation Project

Enclosures

cc: Professor Lyle Craker, Plant and Soil Sciences, University of Massachusetts
Rick Doblin, Ph.D., MAPS