

A Case Study on the Drug Enforcement Administration Marijuana Growers Program

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Executive Summary

This case study was constructed in Fall of 2019 to bring attention to the Drug Enforcement Administration (DEA): Marijuana Growers Program. In 2016, the Drug Enforcement Administration announced the use of federal resources to construct the marijuana growers program which aims to increase the quantity of licensed marijuana growers to research and examine the effects of marijuana. Since the announcement of this program, cannabis growers across the country sprang into action to submit applications. However, in its initial stages the statutory landscape complicated the approval process due to the U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). It is recommended that the DEA routinely analyze regulatory guidelines to improve regulatory policy. Additionally, I recommend compliance centers to be instituted in this program to equip the DEA with the components needed to advance the regulatory objectives of the program and increase accountability. Lastly, I recommend the preparation of an administrative team to provide a clear pathway for trust and confidence as this program develops.

Background

Cannabis is the botanical word for a hemp plant derivative that's been called by many names. That word's origins are linked with a Mexican word used for the plant in the early 1900s that was spelled and pronounced "mariguana." This term evolved to marihuana and eventually to the modern spelling of marijuana (Mcdivitt 2018). For almost a century in the U.S, the public and policymakers debated the legality of Cannabis, widely known as marijuana. By the early 20th century the federal government has placed punitive restrictions on use, sale, and manufacture of marijuana. The mid 20th century saw calls for national legalization and decriminalization of marijuana. In recent years, growing support for cannabis legalization presents an opportunity to reclassify the substance in federal law.

Growing public support provoked state-level initiatives to grow out of the dissenting conclusion regarding marijuana reclassification. Supporters and opponents have different views on the appropriate classification of marijuana. Nonetheless, in November of 2011, Governors Lincoln D. Chafee of Rhode Island and Christine O. Gregoire of Washington submitted a petition to the Drug Enforcement Administration (DEA) requesting that proceeding be initiated to repeal the rules and regulations that place marijuana in Schedule I of the Controlled Substances Act (CSA) on November 30, 2011 (DEA: Proposed Rule, 2016). The DEA denied the petitions of two top state level officials to reclassify marijuana. To support their decision, the DEA stated, "marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision and further issued recommendation that marijuana remains in Schedule I and the DEA Administrator likewise so concluded" (DEA: Proposed Rule, 2011).

The petition aimed to make its case for marijuana reclassification, stating "cannabis has an accepted medical use in the United States, is safe for use under medical supervision, and has a relatively low abuse potential compared to other Schedule II drugs." Additionally, the petition requested that marijuana and "related items" be rescheduled in Schedule II of the CSA (DEA: Proposed Rule, 2011).

In accordance with rescheduling provisions under the Controlled Substance Act (1971), The United States Department of Health & Human Services (HHS) concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, the HHS recommended that marijuana remain in Schedule I and in agreement the DEA Administrator likewise so concluded (DEA: Proposed Rule, 2011).

In spite of this, public support for national marijuana reclassification continued to grow despite the DEA's decision. California established the Center for Medicinal Cannabis Research (CMCR) in 2000 "in response to scientific evidence for therapeutic possibilities of cannabis and local legislative initiatives in favor of compassionate use." State-level public referendums and laws in support of the use of medical marijuana cultivated massive interest in the medical community. Additionally, the desire for high quality clinical investigation as well as comprehensive safety and effectiveness data (DEA: Proposed Rule, 2011).

Statutory Landscape

The DEA announced a policy change aimed at expanding the number of DEA registered marijuana manufacturers to provide researchers with a more varied and robust supply of marijuana. At present, there is only one entity authorized to produce marijuana to supply researchers in the United States: the University of Mississippi, operating under a contract with National Institute on Drug Abuse consistent with the Controlled Substance Act and U.S. treaty obligations, DEA's new policy will allow others to apply to become registered with DEA so that they may grow and distribute marijuana for FDA-authorized research purposes (DEA, 2016 [Press Release]).

A. Communication of requirements

According to the federal register filing, Under section 823(a), for DEA to grant a registration, two conditions must be satisfied: (1) The registration must be consistent with the public interest (based on the enumerated criteria listed in section 823(a)) and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). Parties to the Single Convention are obligated to maintain various control provisions related to the drugs that are covered by the treaty. Among these is a scheduling provision, 21 U.S.C. 811(d)(1). Section 811(d)(1) provides that, where a drug is subject to control under the Single Convention, the DEA Administrator (by delegation from the Attorney General) must "issue an order controlling such drug under the schedule he deems most appropriate to carry out such [treaty] obligations, without regard to the findings required by [21 U.S.C. 811(a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811(a) and (b)]." (DEA: Proposed Rule, 2016)

In 2016, the DEA administrator wrote that the total number of individuals registered with the DEA to research marijuana, marijuana extracts, marijuana derivatives, and THC has doubled from 161 in 2014 to 354. However, program inaction promulgated on 25 applicants for the program since 2016 (DEA, memo, 2016). Currently, applications are being approved for the program on the basis of alignment with the requirements, but the concern is that many applications are still pending for unknown and unclear reasons.

While the number of applicants indicates popular support for the marijuana growers program, Attorney General Jeff Sessions soon halted its expansion. Mr. Sessions was concerned about political blowback from Single Convention treaty guidelines, costs and lack of supervisory ability in the program. The unique nature of this program could produce conclusive research evidence that alters the regulatory trends of marijuana. The DEA anticipates that registering additional qualified marijuana growers will increase the variety of marijuana available for these purposes. Since August of 2019 further announcements have not been made and pending applicants are at a standstill.

Life-Cycle of DEA Marijuana Growers Program

The publication of the 2016 policy statement from the Department of Justice engaged a review process to ensure that the marijuana growers program is consistent with applicable laws and treaties. In consultation with other federal agencies, this process remains ongoing; however, it has progressed to the point where DEA is able to issue Notices of Application (DEA: Notice of Applications, 2019).

Due to the political blowback and instability of the DEA marijuana growers program, the method for dispute resolution & monitoring of activity/behavior and compliance is unclear. Nevertheless, the

denial of Lyle E. Craker's (2013) application provides a potential framework for the DEA's method of resolving disputes and checking compliance.

A. Compliance

The Drug Enforcement Administration (DEA) program administrator ultimately concluded that any one of three negative findings could provide a "compelling" basis to deny the application: conflict with the Single Convention; existing adequate supply and competition; and Mr. Doblin's, who was a colleague of Dr. Craker, conduct and involvement. Availing himself of the opportunity, Dr. Craker filed a motion for reconsideration in January 2009 and on February 13, 2009, Dr. Craker filed a petition for review of Craker II in this court. (Howard 2013).

The inability to comply with the guidelines orchestrated by the DEA constituted grounds for denial for a license to grow marijuana. Further, if an entity is denied entry into the program and they sue the Drug Enforcement Administration it is likely any judge will turn to these proceedings to adjudicate if the denial was reasonable. With that in mind, compliance with the outlines announced by the program is essential. Lyle E. Craker's twelve year ongoing litigation reveals the procedures that the DEA is likely to follow for monitoring of activity/behavior, compliance.

B. Enforcement

In the event an applicant submits paperwork for entry into the DEA marijuana growers program and they are approved and responsibilities are disregarded legal penalties will be faced. The same goes for applicants that apply to the program and they are denied. According to the U.S Code of Federal Regulations § 822(a), the manufacture of a schedule I substance is a criminal offense unless the manufacturer has registered with the Attorney General. Id. § 822(a)(1). The Controlled Substance Act (CSA) provides that the Attorney General "shall register an applicant to manufacture substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions or protocols in effect on May 1, 1971." Applicants will face legal repercussions if they neglect to follow the law or abandon their legally binding responsibilities stated in U.S Federal Code.

Alternatives not considered

Upon enacting the marijuana growers program policy, the program administrators found themselves overwhelmed with the level of public interest. In August of 2019, Scottsdale Research Institute sued the DEA in the D.C. Circuit U.S Court of Appeals for inaction on their pending application submitted to the marijuana growers program in 2016. The court dismissed the case since the Scottsdale Research Institute application was in the process of being reviewed as stated in the DEA 2019 press release.

Continuous ongoing litigation over different aspects of the program highlights a barrier of administrative compliance for applicants. Former Attorney General Jeff Sessions pointed out several reasons for the gradual action taken within the program on applications. As pointed out, one of the reasons, "lack of supervisory ability" demonstrates a viable opportunity for the DEA to advance its regulatory schism and institute compliance centers for assistance with the program.

Compliance centers will equip the DEA with the components needed to advance the regulatory objectives of the program and increase accountability. Dr. Craker felt there was institutional bias due to the barriers that prevented his application from being granted. Similarly, Scottsdale Research Institute wanted the DEA to take action on their application that was pending since 2016. Regulations that stipulate a clear and timely standard for compliance such that all improper behavior can be specified or reasonably inferred in advance will be more effective than those that do not (Wilson 1980). If compliance centers are set up at the early stages of the regulatory process, then it would provide clarity for denied and pending applicants. Further, it would resolve the issue of "lack of supervisory" ability by providing applicants with the regulatory knowledge and requirements for the DEA marijuana growers program.

The conclusions of *Lyle v DEA* could help applicants understand that the purpose of the program is to provide researchers with a more varied and robust supply of marijuana from applicants. “Finding the right fit can make a big difference in reducing confusion over regulatory requirements and incentives for regulated entities to shirk their responsibilities” (May 2007). With this new approach, the DEA will increase the fluidity of the program and thoroughly guide applicants through the treaty guidelines.

Management Tasks & Skills

Preparing an administrative team to take on this task will increase transparency and provide a clear pathway for trust and confidence as this program develops. The DEA marijuana growers program has a meticulous process for approval. The tasks are assigned to the administrative team through stages. **(1)** Consistent with subsection 823(a)(1), DEA will evaluate each application it receives to determine whether adding such applicant to the list of registered growers is necessary to provide an adequate and uninterrupted supply of marijuana (including extracts and other derivatives thereof) to researchers in the United States. **(2)** As with any application submitted pursuant to section 823(a), in determining whether the proposed registration would be consistent with the public interest, among the factors to be considered are whether the applicant has previous experience handling controlled substances in a lawful manner and whether the applicant has engaged in illegal activity involving controlled substances. **(3)** given the in-depth nature of the analysis that the CSA requires DEA to conduct in evaluating these applications, applicants should anticipate that, in addition to the information requested in the application itself, they will be asked to submit other information germane to the application in accordance with 21 CFR 1301.15.

In order to accomplish the outlined tasks, the DEA administrative team needs high level management skills and trained legal specialists to contend with potential lawsuits and disputes from denied applicants.

The ongoing litigation suggests the marijuana growers program has faults in its foundation. Applicants desire to gain access into the program range from commercial to public motivations, however the meticulous process doesn't provide access to everyone. As the program develops, the DEA should institute a legal team or a legal specialist who will tightly examine the legal ramifications of every decision made regarding the marijuana growers program.

However, public participation alone in a program of this caliber does not adequately measure the success of the program. “The evaluation community needs to ask not whether participants are satisfied, but whether the public’s collective interests would likely be more satisfied with the results of a given” (Coglianese 2002). With this, I recommend that more well grounded measures of success be implemented when assessing objectives, effectiveness, and equity. This program should be focused on providing researchers with a varied supply of marijuana as opposed to the satisfaction of making it through the applicant process. Further, I recommend comparing the ease and effectiveness of procedures for all applicants. The DEA should compare the applicants that were approved against the applicants that were not approved for the marijuana growers program and see if this comparison is accomplishing what they set out to achieve.

Conclusion & Recommendations

Presently there is legislation before both houses in Congress to modify the status of marijuana in the U.S. For example, the Marijuana Freedom and Opportunity Act aims to remove cannabis from the Controlled Substances Act and to establish a marijuana opportunity trust fund. Opponents of legalization and reclassification argue that it would be unreasonable to legalize marijuana through Congress because the research does not support acceptable safety levels. Whether the DEA marijuana growers program has had an impact on the national conversation surrounding legalization of the drug is unknown. Despite the controversy, the program has increased the number of federally licensed marijuana researchers.

Moving forward, it is recommended that the DEA routinely analyze regulatory guidelines to improve regulatory policy. According to authors Hahn and Hird, the DEA can do this in three steps: (1) Evaluate the cost and benefits of proposed regulatory changes. (2) Design the program to promote more effective regulation. (3) Reflect on the actual design of specific policies.

The public perception of the regulatory program is crucial, because it is essential that applicants participate in this program for the government to appropriately conclude their efforts in marijuana legalization are legitimate. As disclosed in *Craker v. Drug Enforcement Admin*, claims of institutional bias can hinder the growth of the program due to public dissatisfaction. When the program sets out to implement new regulatory objectives, its past performance can surmount its efforts and suggest resources are better used elsewhere. With approximately 350 researchers enrolled in the program, for now the goals of the program are being accomplished. As the program develops, the Agency should focus on providing clear and transparent information to applicants, and should make more effort to be responsive to questions and criticisms.

Many of the issues that arose with respect to the DEA marijuana growers program can be traced back to the lack of attentive detail with information. According to “An Agenda to Improve Administrative Rulemaking, Information Management”, the success of any administration in using information to advance a policy agenda and produce quality rules depends in large part on their ability to manage another central element of rulemaking. Therefore, this study proves that it is incumbent upon the Drug Enforcement Administration to improve its information management to communicate about the program in a more smooth manner.

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