

Federal DEA Guidance Impacts Pennsylvania Medical Cannabis Research

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On August 12, the U.S. Drug Enforcement Administration (“DEA”) published a series of decisions impacting both state and federal medical marijuana law and policy. In its Policy Statement: Applications to Become Registered Under the Controlled Substance Act to Supply Researchers in the United States (the “Policy Statement”), DEA stated that it will allow marijuana growers to apply for registration to supply marijuana to researchers, changing a fifty year policy that permitted only one entity nationwide, the University of Mississippi, to do so.¹ DEA also issued a Statement of Principles on Industrial Hemp, which we will address in a future publication.² At the same time, and in contrast to its statements supportive of research into the potential medical utility of marijuana, DEA rejected two requests dating back many years to reclassify marijuana from its Schedule I status.³



DEA’s decision to expand registration of growers of research-grade marijuana will substantially affect research operations in Pennsylvania by providing potential new sources of marijuana for research purposes authorized under Pennsylvania’s Medical Marijuana Act, Act of Apr. 17, 2016, P.L. 84, No. 16 (“the Act”). DEA’s refusal to change marijuana’s Schedule I classification status, on the other hand, and its current approval process for research involving marijuana, impede research, as will be discussed further in this article, and underscore an ongoing tension between current state and federal medical marijuana regulatory schemes.

¹ See DEA Policy Statement, Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 Fed. Reg. 53846.

² 81 Fed. Reg. 53395. *The Statement of Principles on Industrial Hemp* explains how Federal law applies to activities associated with industrial hemp that is grown and cultivated in accordance with the Agricultural Act of 2014, and authorizes the growth and cultivation of industrial hemp within an agricultural pilot program established by a State department of agriculture or agency responsible for agriculture, under certain conditions.

³ See DEA, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53767; Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688.

I. DEA Ends the NIDA-Monopoly

Historically, researchers seeking marijuana for research purposes have only been able to access the substance from a single source - the University of Mississippi, which is licensed by DEA and funded and overseen by the National Institute on Drug Abuse ("NIDA"), within the National Institutes of Health ("NIH").⁴ The DEA-mandated "NIDA-monopoly" has been criticized for unnecessarily limiting the supply of marijuana for research, and as potentially reflecting bias against medical marijuana use and research.⁵

This arrangement was the result of DEA's longstanding view that contracting with a single entity was the best way for the federal government to satisfy its treaty obligations – in particular, to limit diversion - under the Single Convention on Narcotic Drugs, 1954 ("Single Convention").⁶ Under articles 23 and 28 of the Single Convention, a signatory to the treaty that allows the cultivation of cannabis for lawful uses (e.g., FDA-authorized clinical trials) must, in pertinent part, license, regulate, and control the production quota of cannabis cultivators.⁷

DEA's Policy Statement departs from this historical approach by allowing new entities to apply for a registration to become a bulk manufacturer of marijuana to supply legitimate researchers. A registered grower will be permitted to operate independently, provided the grower agrees through a written memorandum of agreement with DEA that it will only distribute marijuana with prior written approval from DEA.⁸ Registered growers will only be authorized to supply marijuana to DEA-registered researchers whose protocols have been determined by

the Department of Health and Human Services (HHS) to be scientifically meritorious.⁹ Registered growers will be subject to all applicable requirements of the Controlled Substances Act ("CSA") and DEA regulations, including those related to quotas, record-keeping, order forms, security, and diversion control.¹⁰



DEA will evaluate grower applicants based on two conditions, provided by the CSA:

- Registration must be consistent with the public interest (based on enumerated criteria listed in 21 U.S.C. 823(a)); and
- Registration must be consistent with U.S. obligations under the Single Convention.¹¹

In determining whether the proposed registration would be consistent with the public interest, DEA will consider "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."¹² Importantly, the DEA Policy Statement expressly states, "[i]n this context, illegal activity includes any activity in violation of the CSA (regardless of whether such activity is permissible under State law) as well as activity in violation of State or local law."¹³

⁴ Prior to 2014, only 21 kilograms per year of marijuana were produced for research. DEA approved increases in the production quota in 2014 and 2015. Currently about 650 kilograms per year are available for research through the University of Mississippi. See 80 Fed. Reg. 34694.

⁵ See, e.g., John Hudak, Ph.D. and Grace Wallack, "Ending the U.S. government's war on medical marijuana research," Brookings Institution, October 2015, available at <https://www.brookings.edu/research/ending-the-u-s-governments-war-on-medical-marijuana-research/>.

⁶ See, e.g., 74 Fed. Reg. 2101, 2114-118 (denying an application for registration as a bulk manufacturer of marijuana, and explaining that limiting the potential for diversion was a key factor).

⁷ 81 Fed. Reg. 53847.

⁸ 81 Fed. Reg. 53848.

⁹ 81 Fed. Reg. 53848 (citing 21 U.S.C. 823(f)).

¹⁰ *Id.*

¹¹ 81 Fed. Reg. 53847 (citing 21 U.S.C. 823(a)).

¹² 81 Fed. Reg. 53847.

¹³ 81 Fed. Reg. 53847.

II. DEA Rejects Petition to Reclassify Marijuana

While DEA's Policy Statement addresses one longstanding barrier to research involving marijuana, additional obstacles remain. At the same time as it endorsed research into the potential medical utility of marijuana, and its chemical constituents, DEA rejected two requests to change marijuana's Schedule I status under the CSA. DEA's denial was based on a recommendation from HHS, which 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.¹⁴ The HHS recommendation incorporated a review of available scientific data on marijuana conducted by FDA, in which FDA noted that no published studies conducted with marijuana meet the criteria of an adequate and well-controlled efficacy study.¹⁵ Nor did any adequate safety studies exist. In the FDA's view, without an accepted therapeutic indication for medical marijuana, there is no way for the FDA to perform a risk-benefit analysis to determine whether its risks are outweighed by its benefits for a particular indication.¹⁶

DEA also stated that, given its obligations under the Single Convention, it would not consider changing the classification to anything less restrictive than Schedule II.¹⁷ DEA would not reclassify marijuana as a Schedule II drug because drugs with the potential for abuse that have "no currently accepted medical use in of the current absence of an accepted medical use in treatment in the United States" and lack "accepted safety for use under medical supervision" must be classified as Schedule I drugs under the CSA.¹⁸

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III. Pennsylvania Medical Marijuana Act Research Provisions

Before analyzing the impact of the DEA announcements on the research provisions in the Act, it will be helpful to lay out the provisions designed to encourage research into the potential medical utility of marijuana. The Act contains two provisions designed to encourage medical marijuana research within the Commonwealth. First, the Act creates a state-funded and administered medical marijuana research program that will study the impact of marijuana on the 17 serious medical conditions enumerated within the Act. Second, the Act creates a state permit process for academic clinical research centers, in partnership with grower/dispensaries, to grow and/or dispense marijuana for purposes of research.

A. State-Funded Medical Marijuana Research Program

The most significant contribution of the Act on medical marijuana research may ultimately be its provision of funding of state-administered studies through a tax on the state medical marijuana industry. DEA's Policy Statement expresses DEA's view that funding, rather than regulation (or the absence thereof), may be the most important factor in whether medical marijuana research takes place. The Policy Statement notes that the "California Marijuana Research Program" enacted by law in 1999 appropriated a total of \$9 million for at least 17 state-sponsored studies. However, once California stopped funding the research, the studies ended.¹⁹

Under the Pennsylvania state-funded and administered medical marijuana research program:

- The Department of Health ("DOH") will create a database of all serious medical conditions, including comorbidities, which are cited by practitioners in their certification of patients for medical marijuana.²⁰
- The database will also include the form of medical marijuana certified to treat each serious medical condition.²¹

¹⁴ 81 Fed. Reg. 53688.

¹⁵ 81 Fed. Reg. 53701.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ 81 Fed. Reg. 53688.

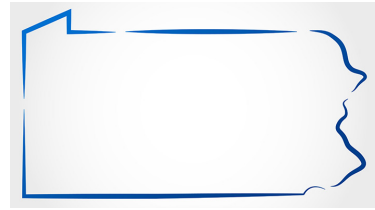
¹⁹ 81 Fed. Reg. 53846 n. 2.

²⁰ Act of Apr. 17, 2016, P.L. 84, No. 16, Section 1902(B)(1),(2).

²¹ *Id.*

- When the database contains 25 or more patients with the same serious medical condition, DOH is required to petition the FDA and DEA for approval to study the condition and the impact of medical marijuana on the condition.²²
- At the same time, DOH shall publicly announce the formation of a research study, and will solicit requests for participation from a vertically integrated health system²³ and a university within the Commonwealth.²⁴
- Upon approval of the research study by the FDA and DEA, DOH will select a vertically integrated health system(s) and university to conduct the research study.²⁵

According to the Act, a vertically integrated health system may be approved by DOH to dispense medical marijuana, or grow and process medical marijuana, or both, in accordance with a research study under the chapter (a vertically integrated health system that obtains such approval is called a “health care medical marijuana organization” under the Act).²⁶ Health care medical marijuana organizations will be subject to tracking, security, and record-keeping requirements issued by DOH.²⁷ Approval by DOH of a vertically integrated health system as a health care medical marijuana organization will authorize access to medical marijuana for all patients included in the research study.²⁸



If FDA and DEA reject the proposal, DOH will collect and collate data on the serious medical condition and use of medical marijuana in its treatment,

and consider submitting an additional request for federal approval of the research study.

B. Permit Process for Clinical Registrants/Academic Clinical Research Centers

In addition, under the Act, DOH may approve up to eight permits to “clinical registrants.” A “clinical registrant” is an entity that (1) holds permits as both a grower/processor and a dispensary under the state regulatory system, and (2) has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entity regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances.²⁹ DOH, through a permit, may approve the dispensing of medical marijuana by a clinical registrant to the academic clinical research center for the purpose of conducting a research study.³⁰

Clinical registrants must comply with all other requirements of the Act regarding growing, processing, and dispensing medical marijuana, and must have a minimum of \$15,000,000 in capital.³¹

²² Section 1902(B)(3).

²³ A “vertically integrated health system” is a health delivery system licensed under the Health Care Facilities Act, in which the complete spectrum of care, including primary and specialty care, hospitalization, and pharmaceutical care, is provided within a single organization. See section 1901.

²⁴ Section 1902(B)(4).

²⁵ Section 1902(B)(5). The division of duties between the vertically integrated health system/university and DOH also raises interesting questions. Currently, under Act 16, it appears that DOH will select the vertically integrated health system/university after obtaining approval for the study, and will notify them of the data which is required to meet the FDA’s and DEA’s approval for the study. Section 1902(B)(5); Section 1903(2). It would seem that the university would be in the best position to design an effective and approvable study, rather than DOH.

²⁶ Section 1901; 1903(A). If a vertically integrated health system is approved as a health care medical marijuana organization which dispenses, but does not grow, medical marijuana, it must

²⁷ Section 1906.

²⁸ Section 1904.

²⁹ Section 2001 (“clinical registrant” definition).

³⁰ The clinical registrant shall disclose information about the strain and strength of the marijuana to be used in the research study, and evidence of approval of the trial by an IRB, and any other required regulatory approval. DOH may not require disclosure of any information that would infringe upon the academic clinical research center’s exclusive right to intellectual property or legal obligations for patient confidentiality. Section 2003(1).

³¹ Section 2002.

IV. Analysis of the Pennsylvania Medical Marijuana Act Research Provisions in Light of the Federal Regulatory Scheme

The DEA's Policy Statement removes some uncertainties that previously existed under the Act. For instance, while the provision permitting up to eight clinical registrants to obtain permits to grow and dispense marijuana for research would have conflicted with the prior NIDA-monopoly in this area, now there is a path for these entities to obtain federal approval for their activities. As described previously, DEA still must evaluate an application for registration by a grower pursuant to the criteria set forth in 21 U.S.C. 823(a), focusing on whether granting the registration would be in the public interest. The fact that a parallel state regulatory regime exists would seem to enhance the argument that granting registration to such entities would be in the public interest. Similarly, under the state-funded and administered medical marijuana research program provisions, the Act permits a vertically integrated health system to obtain approval as a health care medical marijuana organization to dispense or grow and process medical marijuana, or both, for the ultimate purpose of making it available for research under the state program. This provision also would have conflicted with the NIDA-monopoly in this area. Following the DEA policy shift, it appears that vertically integrated health systems can partner with a grower which has obtained registration from DEA to supply marijuana for research, or seek DEA registration itself to grow medical marijuana for research.

The Policy Statement, however, did not eliminate all burdens on researchers and other entities seeking to participate in research authorized by the Act. Research involving Schedule I substances require a separate DEA researcher registration, and federal review of the research protocol through the FDA Investigational New Drug ("IND") process.³² And, researchers seeking NIH-funding for research involving marijuana must go through an additional NIH review process.³³

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And, while the DEA Policy Statement provides a path for researchers to obtain research-grade medical marijuana from entities other than the University of Mississippi, it is not clear at this time how many registered growers DEA will approve. DEA quotas for research-grade medical marijuana will apply to registered growers as well as the University of Mississippi.³⁴ DEA has stated that it will not register an unlimited number of marijuana growers, and will register only the number that is necessary to "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes."³⁵

The DEA announcements also highlight ongoing tension for participants in the state-authorized medical marijuana industry. DEA's Policy Statement endorses medical marijuana research while maintaining that an applicant's history as a grower or dispenser under a state regulatory system would count as illegal activity, that could undermine eligibility for registration under 21 U.S.C. 823(a). This criteria for evaluating applications would seem to disadvantage any grower that has prior experience growing marijuana under a state-approved process. In this respect, growers based in Pennsylvania may be in a unique position to apply for registration pursuant to the Policy Statement. Because Pennsylvania has not yet issued permits for grower/processors, no Pennsylvania-based grower/processors will have engaged in the kind of state-approved but federally prohibited activities that DEA advised would constitute "illegal activity" from its perspective.

More importantly, though, DEA's refusal to reclassify marijuana expresses a view that marijuana has no accepted medical value, despite the fact that this characterization is part of what makes it difficult for researchers to demonstrate its medical value. DEA's less-than-enthusiastic approach to medical marijuana raises additional challenges for researchers, IRBs, institutions, and seeking to participate in the options that the Pennsylvania law has made available.

³² 80 Fed. Reg. 35960.

³⁴ 81 Fed. Reg. 53848.

³³ *Id.*

³⁵ *Id.* (quoting 74 Fed. Reg. at 2127-2130).

Conclusion

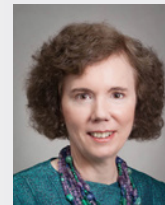
While Pennsylvania's efforts to encourage and make state funding available for research into marijuana's effects on serious medical conditions is promising, researchers are still limited by DEA's refusal to reclassify or declassify marijuana, and by uncertainty in the relationship with the state and federal regulatory schemes. It seems that DEA has created a classic "catch-22" by refusing to remove legal barriers to clinical research based on the absence of the clinical research DEA says is needed to remove those barriers. While the hurdles are not insurmountable, DEA's restrictive approach will continue to present many challenges for medical marijuana research programs.

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