May 20, 2020

VIA ELECTRONIC SUBMISSION—REGULATIONS.GOV

Documents Management Staff Drug Enforcement Administration
Re: Docket No. DEA-506
RIN 1117-AB54

Request for Information on Controls to Enhance the Cultivation of Marijuana for Research in the United States

Dear DEA:

On behalf of the nearly 2,000 members of the National Cannabis Industry Association (NCIA), we appreciate the opportunity to submit comments regarding the Drug Enforcement Administration's (DEA) *Request for Information on Controls to Enhance the Cultivation of Marihuana for Research in the United States*. The information herein constitutes NCIA's public comments. Should the DEA have any follow up questions, or if you would like to meet to discuss, please do not hesitate to contact us at the email address below.

Thank you.

Respectfully submitted,

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Overview

The Drug Enforcement Administration (DEA) issued a notice of proposed rulemaking in the Federal Register on March 23, 2020 at 85 FR 16292. Public comments remain open until May 22, 2020. The proposed rulemaking states in pertinent part:

> *"The Drug Enforcement Administration is proposing to amend its regulations to comply with the requirements of the Controlled Substances Act, including consistency with treaty obligations, in order to facilitate the cultivation of cannabis for research purposes and other licit purposes. Specifically, this proposed rule would amend the provisions of the regulations governing applications by persons seeking to become registered with DEA to grow cannabis as bulk manufacturers and add provisions related to the purchase and sale of this cannabis by DEA."* [1]

If adopted, these new rules would radically overhaul how medical cannabis can be researched.

With over a decade of advocacy, the National Cannabis Industry Association (hereinafter referred to as "NCIA") represents nearly 2,000 cannabis and ancillary businesses and is the preeminent trade association for the state-legal cannabis industry. It is the view of NCIA that instead of facilitating research, this proposed rulemaking (and any subsequent rules that codify DEA's plans) will serve only to further hinder research and indefinitely delay any potential positive outcomes. It is for this reason, and the reasons articulated below, that NCIA opposes this rulemaking process in its entirety.

Most significantly, a law enforcement agency should not be in charge of any aspect of this process. One of the many qualified public health agencies in the federal government (i.e. Health and Human Services, National Institutes of Health, etc.) should manage all of the processes related to research into the medicinal benefits of cannabis, including making decisions about who might qualify to grow and sell the product to researchers. This is perfectly consistent with U.S. treaty obligations under the 1961 United Nations Single Convention on Narcotic Drugs of 1961 (as amended by the 1972 Protocol, the "Single Convention"). Furthermore, the U.S. should adopt a regulatory framework that encourages and facilitates further research, rather than chilling it.

The American public has repeatedly made clear its desire for greater unimpeded, evidence-based research to be conducted on the public health benefits of cannabis. By way of background, voters across the political spectrum overwhelmingly support medical cannabis legalization. In 2017, a Quinnipiac University poll showed 94% approval for medical cannabis, including 96% of Democrats and 90% of Republicans.[2]

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[1] 85 FR 16292 (emphasis added)

[2] *U.S. Voter Support For Marijuana Hits New High,* Quinnipiac University (April 20, 2017), https://poll.qu.edu/national/release-detail?ReleaseID=2453

On more comprehensive reform, a 2019 Gallup Poll showed two-thirds (66%) of Americans support legalizing cannabis for adult use.[3] Medical cannabis is an important staple of our economy, with 47 states having legalized medicinal cannabis and 33 states allowing for higher levels of THC. As of June 2019, Americans for Safe Access estimated there are over 3 million medical cannabis patients in the U.S.[4] There is no putting the genie back in the bottle; it is clear the American public wants regulated, tested and safe cannabis. And American entrepreneurs, American consumers and American lawmakers deserve to know the scientific truths about the medicinal properties of cannabis. It is time for the federal government to facilitate and not hinder research into these popular products.

Qualified Public Health Agencies Should Oversee All Qualification and Registration of Bulk Manufacturers of cannabis for Medical/Scientific Research

The success of modern medicine is dependent on sound implementation of evidence-based medicine, defined by the NIH as "*the integration of individual clinical expertise with the best available research evidence from systematic research and the patient's values and expectations*."[5] Evidence-based medicinal research guides practicing clinicians on medications use, dosing, and monitoring. These decisions combine anecdotal evidence supported by unbiased empirical data in the form of clinical research.

Despite the fact that over 3 million patients in the U.S. use cannabis legally as medicine to treat a variety of conditions and symptoms (chronic pain being the most prevalent), key research is stifled due to its current Schedule I status. The high-risk demographics of some patients like the elderly and veterans who use medical cannabis demand that research-based evidence guide cannabis use for these populations.

Unreasonable barriers placed on research, including limiting the number of qualified applicants or further delays in the process, increases the risks to millions of patients who use cannabis, contributing to ongoing uncertainties related to inaccurate dosing, inappropriate formulation application, interactions with pharmaceutical drugs and botanicals, and basic safety monitoring. High-quality research supports informed and safe decision-making in medicine. This is absolutely essential in all fields of medicine, including cannabis.

Expanding research capability is of critical importance for NCIA's nearly 2,000 members who serve Americans across the nation and who have a vested interest in knowing as much as possible about the medicinal properties of the cannabis plant, particularly for important therapies such as the treatment of PTSD in veterans. NCIA's members share

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[3] *U.S. Support for Legal Marijuana Steady in Past Year,* Gallup (October 23, 2019), https://news.gallup.com/poll/267698/support-legal-cannabis-steady-past-year.aspx

[4] *2019 State of the States Report: An Analysis of Medical Cannabis Access in the United States,* Americans for Safe Access (2019), https://american-safe-access.s3.amazonaws.com/sos2019/sos19web.pdf

[5] *Evidence-Based Medicine: New Approaches and Challenges,* Journal of Academy of Medical Sciences of Bosnia and Herzegovina (December 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789163/

the DEA's stated goal to "*facilitate the cultivation of cannabis for research purposes*," but strongly disagree that the DEA's proposed rulemaking will best accomplish that stated goal.

The cannabis industry has been waiting for three years for the release of this Federal Register Notice with the hope that the proposed regulations were drafted to advance the goal of facilitating much-needed research. If adopted in its current form, however, this proposal would have just the opposite effect; it would impose another level of unnecessary regulatory and bureaucratic obstacles in the path of valid medical-cannabis science. In fact, these proposed rules would actively obstruct research into the medicinal properties of cannabis. Most significantly, DEA is not the proper agency to act as gatekeeper for such important public health research. Indeed, this mandate is entirely outside the agency's expertise.

DEA is a law enforcement agency, not a public health agency. The agency has an inherent conflict of interest in promulgating these regulations and applying them fairly. For example, DEA announced on April 15, 2020 that the agency seized 4 million cannabis plants through its domestic cannabis suppression and eradication program in 2019. That is a 42% increase from 2018. DEA has also inexplicably failed to take action on any previous cultivation applications, dating back four years. These acts and omissions are inherently at odds with any conclusion that the agency can provide effective oversight of cannabis research.

It is our collective view that one of the many qualified public health agencies in the federal government like HHS or NIH can more effectively manage all of the processes related to research into the medicinal benefits of cannabis, including making determinations on who may qualify to grow and sell the product to researchers. Below we offer our specific rationale for objecting to the proposed rule as drafted and offer suggestions for how to best facilitate this important research.

History

In August 2016, the DEA published a policy statement indicating that the agency wished to support expanding research into the potential medical utility of cannabis and its chemical constituents by increasing the number of entities registered to cultivate cannabis for research and the lawful supply of cannabis available for researchers—within the framework of the Controlled Substances Act (CSA) and the Single Convention.

Prior to 2016, DEA authorized a single cannabis supplier (University of Mississippi) to supply cannabis for research purposes under a contract at the National Institute on Drug Abuse (NIDA). This significantly limited the available supply of high-quality cultivated cannabis for research purposes. Rather than have NIDA be the exclusive registrant for cannabis cultivation, DEA's 2016 policy statement announced an intent to accept new applications for cannabis cultivators, as long as the newly registered growers would sell their cannabis exclusively to DEA-licensed cannabis researchers.

Although the cannabis industry strongly supports the addition of new cultivators to bolster the limited research conducted on this subject, the industry does not support expanded DEA authority. Our public health agencies are far better suited to determine the qualifications of parties engaged in medical or scientific research.

Since the DEA's announcement four years ago, over 30 entities have applied to be registered to manufacture cannabis to supply researchers. Yet, no action has been taken by DEA on any of the applications to date. A lawsuit filed by one of the applicants recently asked the courts to force the DEA to act on their application. As a result, the D.C. Circuit subsequently ordered the DEA to provide an explanation. The DEA responded that regulations were forthcoming, and this NPRM was the result.

The Single Convention on Narcotic Drugs (1961)

In promulgating these new rules, DEA has stated that it is bound by the dictates of the Single Convention in how it licenses cultivators of cannabis for medical research. In doing so, DEA proposes new regulations that require licensed growers to transfer all of their output to DEA and, with limited exceptions, gives DEA exclusive control over the import, wholesale trade and maintenance stocks of cannabis. To obtain a registration to manufacture, applicants must prove that their registration would be consistent with the public interest and U.S. obligations under the Single Convention. The proposed new regulation, if adopted, would exclude medical cannabis which is defined narrowly as cannabis or its derivatives (but not hemp) that can be legally marketed under the Food, Drug and Cosmetic Act.

To our knowledge, compliance with the Single Convention has never previously been raised as a requirement to obtain a registration. While we believe that the adherence to international treaties is important, DEA's new focus upon the Single Convention is curious to say the least. In recent years, including under the current Administration of President Donald J. Trump, the U.S. has removed itself from multiple international organizations and stopped or limited funding of international organizations. President Trump has not hidden his frustration with international trade groups and security alliances when he has concluded that American national interests required contrary action. Specifically, the Trump Administration has relinquished our responsibilities under numerous international treaties like the Paris Accord, NAFTA, Intermediate Range Nuclear Forces Treaty, Trans-Pacific Partnership, UNESCO, Iran Nuclear Deal, among others. Moreover, the current Administration has regularly railed against international bodies like the United Nations, NATO, World Health Organization, and the UN Human Rights Council that he has concluded were injuring American interests. It is therefore confusing to see how the Administration, which has repeatedly eschewed international treaties over the past four years, is now relying upon an international treaty to justify the transfer of authority over cannabis production for research to law enforcement.

Importance of Research into the Medicinal Benefits of Cannabis

Under the CSA, cannabis (other than hemp and pharmaceutical drugs approved by FDA) is classified as a Schedule I drug, meaning that the substance is considered to have a high potential for abuse, the substance has no accepted medical use, and there is a lack of accepted safety for the use of the substance under medical supervision.[6] Of course, the logic of that classification for cannabis is fundamentally irreconcilable with the reality of today's science.

With respect to potential for abuse, there is no such consensus in the scientific community. To the contrary, non-scheduled substances such as alcohol and tobacco are widely considered by substance abuse experts to have a much higher potential for abuse than cannabis. With respect to accepted medical use, there is no serious debate on the subject. There is substantial evidence within the medical community demonstrating that numerous cannabinoids have accepted medical applications. One blatant example of this contradiction is the patent in the hands of the federal government. In 2003, the U.S. Department of Health and Human Services was awarded a patent entitled "Cannabinoids as Antioxidants and Neuroprotectants."[7] Therefore, despite cannabis having been classified as having no medicinal use, the U.S. government itself has a patent on its medicinal use. Finally, with respect to safety, 33 states now effectively regulate the medicinal properties of cannabis in their respective state medicinal programs. While hundreds of thousands of Americans safely use cannabis medically or for adult recreation at present, the federal government continues to take the position that cannabis "has no currently accepted medicinal use." Ironically, this is largely due to limited federal government research into its medicinal efficacy.

The reasons why the U.S. lacks sufficient data on the medicinal use of cannabis are simple—supply and quality. Plainly, there is not enough cannabis being grown by the University of Mississippi for meaningful research by NIDA. The quality of the cannabis produced is also objectively unsuited for medical research or rigorous clinical trials. In fact, DEA has resorted to granting authority to Canadian cannabis companies to export cannabis for research purposes.[8] Better quality cannabis and more easily accessible supply are greatly needed. Research is also needed to make better decisions about the myriad potential uses of cannabis and for better policy-making, including legislation and drug scheduling decisions. The attempted rulemaking here would do nothing to solve either of those problems. In fact, it is more likely that these proposed rules would, in fact, obstruct research by leaving the most experienced cultivators on the sidelines.

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[6] *Drug Scheduling*, Drug Enforcement Administration, https://www.dea.gov/drug-scheduling.
[7] U.S. Patent No. 6,630,507 (filed Apr. 21, 1999).
[8] *Canadian Marijuana Company allowed to Legally Export Medical Cannabis to the U.S.,* Newsweek *(September 18, 2018),* https://www.newsweek.com/canadian-cannabis-company-allowed-legally-export-medicinal-cannabis-us-1127133

Objections to Provisions in the New Notice of Proposed Rulemaking

While we have numerous objections to the plan as outlined in the proposed regulations, we focus here on a few critical pieces that are highly objectionable to the industry. Below, we highlight a few of these objections and the public policy rationale behind them.

1. It is the strong view of NCIA that the DEA should withdraw its rulemaking. Instead, Congress should modify the CSA to allow for a public health agency to license the production of cannabis for medical and scientific research purposes. Because of the importance of scientific and public health considerations at play in overseeing the manufacture of controlled substances for research, federal public health agencies should lead the program that the DEA promotes for itself in this NPRM. DEA's proposal to strip the authority of several public health agencies and to place itself in charge of nearly every aspect of this important regulatory scheme is entirely outside its traditional role as a law-enforcement agency. NCIA believes that one of the many qualified federal public health agencies such as NIH or HHS should be responsible for this essential scientific research. This important oversight should not be placed under the authority of a federal law enforcement agency responsible for the investigation and prosecution of federal narcotics offenses.

2. Numerous parties to the Single Convention regulate the production, export/import, and distribution of medical cannabis (i.e. Canada, Uruguay, Israel, United Kingdom, Germany and Lesotho, etc.) and do not follow Article 23 of the Single Convention to the letter of the law or the degree to which DEA believes that the U.S. must comply. NCIA does not believe that such a narrow reading of our treaty obligations is warranted, given the reality that 33 states currently regulate commercial supply chains (including cultivators and distributors) to safely produce, store and transport any cannabis needed for medical or scientific research.

3. As noted above, the Trump Administration has publicly pulled out of multiple treaties and repeatedly chastised international organizations when it has concluded those treaties or organizations were allegedly running contrary to U.S. national interests. It is not clear why the Administration suddenly believes that an outdated narcotics treaty should take precedence over the will of the American people in at least 33 states (or, for that matter, established federal administrative procedure with respect to the physical custody of medical cannabis stocks). There is a simple procedural solution. The most obvious path for the Trump Administration would be to withdraw from the Single Convention and rejoin the Convention with a formal reservation opting out of the cannabis-related provisions of the Convention. Such an action by the U.S. would bring us into compliance with our international treaty obligations under the Single Convention, while keeping the door open for American cannabis companies in the private sector to provide high-quality cannabis for medicinal and scientific research.

4. The NPRM commentary specifically notes that it will consider prior compliance with federal (not state) narcotics laws (CSA) in granting or denying the registration. This threatens to exclude many of the nation's most qualified applicants, namely, state-compliant grow operations. Without stipulating the accuracy of the legal conclusion, we assume that the DEA will assert that those operating in compliance with current state law are violating federal law. These companies in the cannabis industry have been growing medical grade cannabis for decades, and their skills are essential for America to lead the international race to unlock cannabis's substantial economic and medicinal potential. Excluding these companies because the DEA believes they have technically been operating in violation of federal law has no good public policy rationale. In fact, the opposite is true. If the DEA only allows inexperienced growers to participate, there are no assurances that the new growers will have the required expertise in growing quality cannabis for research purposes. Growing cannabis is not like growing pumpkins or potatoes. There is a great deal of complex technology and learned technique that goes into cannabis growing and extraction practices. The U.S. needs to leverage the expertise of growers with 20-30 years of experience, rather than relying on growers with limited experience growing cannabis. NCIA would prefer to see a greater emphasis on other factors, like compliance with state laws, expertise in growing cannabis, and demonstrated ability to grow research-grade cannabis. Strict reliance on past compliance would also naturally tend to abdicate U.S. leadership on these issues in favor of foreign operators.

5. This proposed rule shifts the burden of proof that a registration should be granted from the DEA to the applicant. This new requirement differs from other registration provisions which stipulate that if a registration application is denied by the DEA, the Administrator shall issue an order to show cause and provide reasons why the registration has been denied. This new provision and the burden of proof language suggests that the DEA may simply deny the application by concluding that the registrant has not met its burden of proof. NCIA firmly believes that the regulating agency should be required to provide notice and a hearing in instances of registration denial, as is the case with other registration applications under the CSA.

6. The new NPRM provides that no new application for manufacture will be considered until all of the applications that were accepted for filing before the effective date of the rule have been granted or denied. Given the nearly four-year backlog of pending applications, this plan appears likely to cause further delays to much needed research which could help Americans. There is no rationale given for precluding new applications while pending registration applications are considered.

7. The NPRM also suggests cumbersome and expensive procedures for inspection of crops and harvests, as well as physical security at harvest locations, that are likely to discourage applications to cultivate cannabis for research.

8. Finally, DEA's NPRM also makes rulemaking retroactive and thus very likely incompatible with the Administrative Procedure Act.

Conclusion

The federal government should be incentivizing research, not discouraging it. On behalf of its nearly 2,000 members, NCIA hereby requests that these proposed regulations be amended and/or withdrawn in accordance with our concerns as articulated herein and that a qualified public health agency be appointed to serve as the coordinating agency instead. We also request that the applicant pool be expanded to include companies that are or have cultivated cannabis in accordance with the laws of any state, regardless of whether the DEA concludes such actions did or did not technically violate the CSA. Most importantly, NCIA requests that the U.S. Government incentivize research and create a pathway for less restrictive means by which the country can access important information about the medicinal properties of cannabis.