

## Docket No. RIN 1117-AB54/Docket No. DEA-506

### Controls to Enhance the Cultivation of Marijuana for Research in the United States

Americans for Safe Access (ASA) respectfully submits the following comments in response to the DEA's notice published in the [Federal Register](#). We would like to call specific attention to the recommendations outlined in our justifications for the changes to proposed regulations (2) and (3). While we can appreciate the work that DEA has done to protect the health and safety of US citizens, we feel it is important that a new agency be established that has no history in prosecution of the activities that DEA seeks to become the sole enforcer of. This new agency, the Office of Medical Cannabis Control, would be tasked with overseeing not only the requirements of the research program but also set standards for states that permit medical cannabis. This would enable cultivators that are licensed in medical cannabis states to provide high quality medical cannabis to researchers thereby increasing the diversity of products that can be used in research studies and clinical trials.

#### DEA solicits comment on the following issues:

- Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information shall have practical utility.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Regulation

(1) All registered manufacturers who cultivate cannabis shall deliver their total crops of cannabis to DEA. DEA shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest. DEA may accept delivery and maintain possession of such crops at the registered location of the registered manufacturer authorized to cultivate cannabis consistent with the maintenance of effective controls against diversion. In such cases, DEA shall designate a secure storage mechanism at the registered location in which DEA may maintain possession of the cannabis, and DEA will control access to the stored cannabis. If DEA determines that no suitable location exists at



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the registered location of the registered manufacturer authorized to cultivate cannabis, then DEA shall designate a location for the authorized grower to deliver the crop as soon as possible, but not later than four months after the end of the harvest. However, in all cases the registrant must comply with the security requirements specified in [21 CFR part 1301](#).

### **ASA Suggested Change**

- (1) All registered manufacturers who cultivate cannabis shall register their crops with the DEA through the tracking system. DEA shall track all crops through this system and perform audit activities for compliance. DEA shall approve the transfer of research grade medical cannabis through the tracking system and either take possession and make the transfer or approve the direct transfer between cultivator and researcher. Registered manufacturers will designate a secure storage area to be used only for research grade medical cannabis which is approved by DEA. This secure storage area will be monitored by video surveillance and accessible to DEA at all times. However, in all cases the registrant must comply with the security requirements specified in [21 CFR part 1301](#).

### **Justification for Change**

At present, the USDA is tasked with implementing a tracking program for hemp cultivators. States with medical or adult-use cannabis programs require that all producers track the plants and products made therefrom, from seed to sale. There are a number of compliant software programs currently available that can achieve this purpose. Rather than expend valuable resources on developing a new tracking system, it is suggested that a system that is already in use be put in place, or the system implemented by USDA. By using this type of a system, overhead costs are reduced while compliance is maintained with both the CSA and the Single Treaty.

Should the need for research grade medical cannabis be greater than the current available supply, ASA suggests allowing medical cannabis cultivators that are currently operating under highly regulated conditions be considered for application as providers. State compliant producers are already operating under highly regulated conditions to prevent diversion, are already subject to extensive background checks, have been developing experience in manufacturing, have an interest in public health, and are by definition compliant with state and local law. State regulators have worked towards protecting the general public, and especially children.



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In the context of the manufacture of controlled substances, according to the law referenced by the DEA in their proposal, factors included in the considerations of *public interest* include:<sup>1</sup>

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
- (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
- (6) such other factors as may be relevant to and consistent with the public health and safety.

By allowing state licensed medical cannabis cultivators to provide additional research material, the needs of researchers will be met faster and through already available channels, rather than wait for an approved manufacturer to cultivate and develop chemovars that meet the researchers' needs. In this case, both the cultivator and the DEA fulfil all of the consideration of public interest.

## Proposed Regulation

(2) DEA shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. Such exclusive right shall not extend to medicinal cannabis or cannabis preparations. DEA may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. DEA will require prior written notice of each proposed importation, exportation, or distribution of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorizing the importation, exportation, or distribution. All importation and exportation shall be performed in compliance with [21 CFR part 1312](#), as applicable.

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<sup>1</sup> [USC Title 21 Chapter 13 Subchapter 1 Part C §823\(a\)](#)



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Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express written authorization of DEA.

### **ASA Suggested Change**

- (2) DEA shall, with respect to cannabis, have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations. DEA may exercise its exclusive right by authorizing the performance of such activities by appropriately registered persons. This authorization shall include review of applications within 30 days of receipt and publication of applicant scores and applications (all intellectual property and private information will be redacted). Authorization will be issued to all applicants who score at least ninety percent (90%) of points available.

DEA will approve each proposed importation, exportation, or distribution of cannabis that specifies the quantity of cannabis to be imported, exported, or distributed and the name, address, and registration number of the registered manufacturer or researcher to receive the cannabis before authorization of the transfer in the tracking system. All importation and exportation shall be performed in compliance with [21 CFR part 1312](#), as applicable. Under no circumstance shall a registered manufacturer authorized to grow cannabis import, export, or distribute cannabis without the express authorization of DEA via the tracking system.

### **Justification for Change**

The Single Treaty calls for the importing, exporting, wholesale trading, and maintaining of stocks to be done by a single entity. ASA recommends transferring that authority to a single entity that does not currently exist within the framework of the federal government. Some entities may view the DEA negatively and in order to present a consistent front that is aimed at solely focusing on the needs of cannabis researchers, that has no history in prosecution of those who are participating in the activities that DEA is seeking to control, we propose the creation of the Office of Medical Cannabis Control (OMCC).

In tandem with taking on the functions of the Agency in administering research, the OMCC will also be responsible for bringing the regulation of cannabis across the states under one roof; to establish national oversight of operating licences, minimum standards for labeling and packaging, standards for cultivation, and standards for testing for pesticides, heavy metals, contaminants, adulterants, and other potential threats to health and public safety. States with more stringent rules than the federal guidelines would be allowed to keep them in place, while those which fall behind would have to improve their testing



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requirements to meet the new federal standards. Creating one central authority to ensure conformance with these standards should simplify the regulatory environment nationwide. See Attachment I *Ending the Federal Conflict: Changing the Paradigm on Medical Cannabis* for a full overview of how the proposed OMCC would function.

Additionally, by making license application review occur within 30 days, there is no wondering on behalf of applicants when they will be approved or denied a license. By redacting proprietary and personal information, the OMCC presents a transparent licensing process and allows the public to be aware of the reasoning behind licensing decisions. Not placing a cap on the number of producers gives researchers a broader range of products available to them to use in their research, and setting a high minimum score ensures that only the most qualified applicants will be approved.

### **Proposed Regulation**

(3) A registered manufacturer authorized to grow cannabis shall notify DEA in writing of its proposed date of harvest at least fifteen days before the commencement of the harvest.

### **ASA Suggested Change**

(3) A registered manufacturer authorized to grow cannabis shall update the tracking system whenever cultivation activities occur such as harvesting, drying, and curing. Harvest batch records will be updated to include the date(s) of harvest, the weight of cannabis harvested, and the location of where the cannabis will be dried and cured.

After drying, the cannabis will be weighed and the weight recorded in the tracking system to account for weight loss from moisture and to identify trends that could potentially identify diversion of research grade medical cannabis. After curing, the cannabis will be weighed and recorded in the tracking system. Samples of each cultivar will be collected to ensure they are representative and sent to an accredited testing laboratory for confirmation that the batch meets established criteria for health and safety.

### **Justification for Change**

The fifteen day harvest window, after which the controlling agency would be expected to take possession of the cannabis, does not provide a large enough window for drying, curing, and testing of the product to ensure safety and conformity to desired conditions, such as expected cannabinoid or terpenoid concentrations. It also does not provide enough time for further processing into oils, concentrates, or



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other preparations to be used by researchers. The average drying time for Cannabis Sativa L. is typically 5-15 days, while curing times can range from 2-3 weeks, sometimes up to 8 weeks<sup>2</sup>.

Should our earlier recommendation that registered manufacturers utilize a seed to sale tracking system be implemented, the controlling Agency would be able to track all batches and know which stage each one is in. This system would also track testing results for easy identification of passing and failing batches. Should our additional suggestion that registered manufacturers use video surveillance monitoring of their secure storage areas, the controlling Agency will be able to visually monitor storerooms for any activities of diversion.

The recommendation that the cannabis and cannabis products be tested for safety and health is to ensure that subjects involved in clinical trials do not receive products that may be deleterious to their health. Additionally, researchers may have specific cannabinoid and terpenoid needs for the areas they are studying and, if they are not producing their own research grade medical cannabis, they should have prior knowledge of the products they are taking possession of.

The types of testing and required acceptance criteria would be established, monitored, and enforced by the OMCC via the electronic tracking system and on-site auditing of operations. This testing and acceptance criteria would then be required for medical cannabis products that are not considered research grade medical cannabis, in the event that researchers require additional cannabis products outside of what is available within the research supply network. At present, testing requirements differ by state and medical cannabis patients cannot be assured that products are consistent or safe. By establishing a framework for health and safety standards that is , the interests of the public are maintained.

## Additional Considerations

### Remove NIDA from the Process of Research

The scientific process seeks to discover new ways of understanding the natural world through experimentation designed to test the integrity of a hypothesis. In this process, the observation of replicable data which defies the nature of this pre-existing hypothesis is where we find this new understanding. The public interest has always encompassed the realm of public health, which greatly benefits from reputable research seeking to advance treatment options available to the public. In NIDA director Nora Volkow's own words: "it's not NIDA's mission to study the medicinal use of marijuana or to

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<sup>2</sup> <https://www.leafly.com/news/growing/drying-curing-cannabis>



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advocate for the establishment of facilities to support this research." NIDA's stated mission "to lead the Nation in bringing the power of science to bear on drug abuse and addiction".

By expanding the number of approved researchers whose goal it is to find uses for cannabinoids, terpenoids, and the various combinations thereof, the US will be able to catch up to researchers in other countries that have been performing this kind of research for decades. This will also allow NIDA to continue their mission of fighting drugs of abuse and focusing on health issues such as those related to the abuse of both licit drugs such as opioids and illicit drugs such as heroin.

### **Place a Cap on the Wholesale Value of Cannabis**

With the proposed reforms, the DEA advances taking over the duties outlined in Single Treaty Article 23(2) (d: physically possessing the crop on behalf of gov't) and (e: conducting wholesale trading and maintaining federal stockpiles). With their wholesaling scheme, the DEA must ensure affordable access to research grade cannabis for investigators. We recognize a necessary consideration for bulk prices may include the labor value of DEA special agents as well as the costs of transportation and storage.

DEA estimates this program's total annual cost to be \$607,644.<sup>3</sup> To cover these expenses, DEA's plan outlines administrative fees of \$304 per kg (2.2 lbs/kg) on top of the agreed wholesale price of the flower. This is estimated by dividing the cost of the program by the amount of cannabis produced, with 2000kgs being the model estimate. This equates to roughly \$750/pound, with the average wholesale cost of a pound (2.2kgs) roughly \$2000-\$4000, meaning a tax of 25-50% on a single pound of research grade medical cannabis. ASA proposes to use a tax that doesn't present such a financial burden to researchers. This is particularly important for researchers that are producing their own cannabis, who simply need DEA to approve the transfer of product from the cultivation to the research site. With the use of an electronic tracking system, the time and resources needed to make this approval are reduced, thereby justifying a reduction in the tax rate and associated costs for researchers.

### **Classification of Cannabis**

ASA recognizes that much of the DEA's proposed framework revolves around the fulfillment of our obligations to uphold the *Single Convention on Narcotic Drugs* ("Single Convention" or "Treaty") of 1961 and the *Controlled Substances Act* (21 U.S.C. 13 §801 et. seq. or "CSA") of 1970. ASA submits that the current domestic and international classification of cannabis is improper, and supports the removal of cannabis and cannabis resin from Schedule IV of the Single Convention and from Schedule I of the CSA. This removal will open the doors for researchers to work directly with legally operating, licensed

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<sup>3</sup> [Federal Register Controls to Enhance the Cultivation of Marijuana Research in the United States Table 2](#)



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producers, to cultivate and generate cannabis and cannabis products that are meaningful to the researchers' needs.

## Public Interest

The DEA's proposal leans heavily on the idea of *public interest*: "section 823(a) provides that the registrations to manufacture controlled substances in schedule I or II must be 'consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.'" ASA contends that over the past 50 years, American public interest has shifted overwhelmingly in favor of cannabis. To date, 33 states, DC, and four of the five permanently inhabited U.S. territories have passed laws to create comprehensive medical cannabis programs, and 14 states have passed more limited reforms allowing for the medical use of cannabidiol (CBD). With these reforms at the state level, 91% of American adults now live in territories with some form of access to medical cannabis.

Increased access, exposure, and broader normalization of cannabis have deeply affected the American consciousness. Cannabis has become a more popularized form of medicine; a CBS News poll of doctors showed that 88% of doctors were in favor of recommending cannabis as a treatment to patients. Doctors aren't the only ones taking note, legislators have found medical cannabis programs to be one of the most popular policy platforms. A random sampling of Americans polled by Quinnipiac in 2018 reported 94% in favor when asked if they supported legal access to medical cannabis with a doctor's recommendation. In addition to an increasing trend of exposure and acceptance, we estimate there are some 3 million Americans registered as medical cannabis patients throughout the country.

## Background

Americans for Safe Access ("ASA") was founded in 2002 with a mission to ensure safe and legal access to cannabis (marijuana) for therapeutic use and research. With over 100,000 members in the United States, ASA is the largest national member-based organization of patients, medical professionals, scientists, and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research. ASA works to overcome political, social, and legal barriers by working to create policies that improve access to medical cannabis for patients and researchers through legislation, education, litigation, research, grassroots empowerment, advocacy and providing services for patients, governments, medical professionals, and medical cannabis providers.

## Commitment to Health and Disclaimer

For nearly two decades Americans for Safe Access (ASA) has strived to help the health outcomes of individuals improve through the use of doctor recommended medical cannabis. ASA acknowledges that



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when it comes to discussions surrounding cannabis research, politics are often put before patient needs. ASA does not believe that medical cannabis is appropriate for all patients, nor does it believe that cannabis and its derivatives are completely devoid of side effects. However, for many patients, the use of medical cannabis leads to reduced reliance on traditional pharmaceuticals and an improved quality of life.

Americans for Safe Access appreciates the opportunity to provide comments to assist in formulating a new framework for supplying researchers in the United States with the highest quality cannabis used to conduct studies advancing our understanding of cannabinoids and terpenoids, the primary active ingredients in cannabis. ASA, its members, and its affiliates share a deep commitment to providing safe and effective cannabis and cannabis derived medicines to those who need it most in lawful state-based programs.



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