May 22, 2020

VIA ELECTRONIC SUBMISSION—REGULATIONS.GOV

Re: *Comments from LA NORML Regarding DEA Proposed Rule "Controls to Enhance the Cultivation of Marijuana for Research in the United States"*
[RIN 1117-AB54/Docket No. DEA-506]

We write as the LA Chapter of the National Organization for the Reform of Marijuana Laws (LA NORML).

LA NORML respectfully submits its comments on the Drug Enforcement Administration's (DEA) notice of proposed rulemaking (NPRM), entitled "Controls to Enhance the Cultivation of Marihauna for Research in the United States," issued in the Federal Register on March 23, 2020 at 85 FR 16292. LA NORML appreciates the opportunity to submit these comments. Should the DEA have any questions or wish to discuss any of the information discussed below, please do not hesitate to contact us.

One of the oldest NORML chapters in the country, LA NORML was founded in 1973 and is a regional chapter of the National Organization for the Reform of Marijuana Laws. NORML's mission is to repeal the prohibition of cannabis at the local, state and federal level by educating those in our community about cannabis and hemp and their potential medical and industrial uses.

The DEA's proposed rulemaking would require licensed cannabis cultivators to transfer title and physical possession of their total crops to the DEA within four months of harvest, and require the DEA to exercise the "exclusive right" of importing, exporting, wholesale trading, and maintaining stocks of cannabis. The DEA has clarified that these new rules have been promulgated to bring the licensing framework for the cultivation of cannabis for medical research into compliance with U.S. treaty obligations under the United Nations Single Convention on Narcotic Drugs of 1961, 18 U.S.T. 1407 (Single Convention).

The NPRM also expresses the DEA's intention to promote the advancement of cannabis research, explaining: "DEA believes that these changes will enhance and improve research with marihuana and facilitate research that could result in the development of marihuana-based medicines approved by the Food and Drug Administration (FDA)."

However, it is LA NORML's view that rather than enhancing, improving, or facilitating medical cannabis research, the agency's proposed rulemaking would only serve to further stifle and impede the progress of cannabis research in the United States. More specifically, LA NORML believes the proposed rulemaking is problematic in many respects, including:

1. The proposed rulemaking contains no provisions to safeguard against future undue delays in the processing of applications. There is no clear timeline for the approval or denial of the more than 30 pending applications, or for subsequent applications. Proposed rule 21 CFR § 1318.03(a) provides that the Administrator may grant an application for a registration to manufacture cannabis only if the Administrator determines that such registration is consistent with the public interest and with United States' obligations under the Single Convention. Further, proposed rule § 1318.05 sets forth the six public interest factors to be evaluated by the Administrator. However, there are no provisions setting forth a timetable for the Administrator's evaluation of the public interest factors, and LA NORML is concerned that the rules may leave too much leeway and discretion for when the evaluation process must be completed. Accordingly, LA NORML proposes that the DEA add deadlines to its proposed rulemaking that would cover the approval or denial of applications accepted for filing both before and after the effective date of the final rule. LA NORML believes a reasonable deadline would consist of a requirement that the overseeing agency act on an application within six (6) months of its submission.

2. With respect to applicants seeking to grow cannabis that would be purchased and used by other DEA-registered researchers, the proposed rulemaking would require such applicants to obtain from each end user a "bona fide supply agreement," defined under § 1318.02(g) as "a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act." The NPRM explains that the bona fide supply agreement should list the "name and address of the end user, the end user's DEA registration number, the quantity of marihuana to be supplied, and the price that the end user and grower have mutually agreed upon[,]" and explains that the "DEA will consider this information, along with additional information, when establishing an individual manufacturing quota for the grower." The proposed rulemaking, however, does not include any deadlines by which the DEA must review or approve bona fide supply agreements. LA NORML is concerned that this may result in undue delays for researchers and thereby hinder research progress. To address this concern, LA NORML believes that the proposed rulemaking ought to include reasonable deadlines by which the DEA must review and approve bona fide supply agreements following their submission and make quota determinations based upon them.

3. The proposed rulemaking would grant the DEA broad immunity from liabilities arising out of the performance of its duties under the newly proposed framework. Specifically, proposed rule 21 CFR § 1318.07, entitled "Non-liability of Drug Enforcement Administration," provides that "[i]n the event that a buyer deems the delivered cannabis to be defective, the buyer's sole remedy for damages shall be against the grower and not the Administration." LA NORML believes this proposed rule creates a risk of entirely stripping away a buyer's legal remedies. For example, in a situation where the DEA is solely at fault for a loss or damage to a crop that occurs while the crop is under the

agency's ownership, possession, and exclusive control, this immunity protection would leave the buyer without a damages remedy. This, in turn, implicates constitutional concerns and the buyer's due process rights. To that end, LA NORML respectfully recommends that the proposed rulemaking be revised to provide for a more limited form of agency immunity. Further, LA NORML recommends that the DEA add stricter guidelines and mandatory duties that DEA agents must follow after taking possession of the cannabis and during transport and delivery to buyers. LA NORML suggests that these guidelines and duties be designed to minimize risk of loss or defects in the cannabis between the time the DEA takes possession of the cannabis and its delivery.

4. The proposed rulemaking includes an administrative fee structure that is likely to inhibit the proper development of a robust system of approved cannabis cultivators. The draft rules propose charging fees to applicants at a level that would ensure the DEA's recovery of the full costs of operating the new program, in accordance with the agency's obligation under 21 U.S.C. § 886a(1)(C). However, LA NORML believes this proposed rulemaking needlessly drives up the cost of operating the program. For example, proposed rule § 1318.04(a) would require the DEA to establish and oversee offsite storage facilities in the event the agency determines that no suitable secure location exists at the registered location to store harvested cannabis. However, this requirement would necessitate additional construction, maintenance, transportation, and quality control costs. Pursuant to the DEA's financial obligations under the proposed rules, all of these costs would then get passed on to registrants. This, in turn, could chill applicants from entering the program, and thereby limit the amount of cannabis available for researchers. This would cause researchers to have less than full access to the variety of strains and cultivars necessary for developing a full body of research. LA NORML respectfully recommends that the DEA develop a rule that would require the agency to work with registrants to ensure their on-site facilities have proper security measures in place to prevent diversion.

For these reasons, LA NORML opposes the proposed rulemaking in its current format and encourages the DEA to implement changes to the framework before such rulemaking is finalized. While the NPRM indicates that we are headed toward a healthy and robust cannabis cultivation program, the current version of the rule requires several changes to achieve that goal. Until such changes are made, we believe there is a significant chance the program will not successfully allow for an adequate and uninterrupted supply of cannabis to support scientific study. Thank you again for the opportunity to submit these comments.

Respectfully submitted,

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