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Digging Deeper: Examining DEA Proposed New Rule to Enhance Cultivation of Marijuana for Research Exposes Conflict of Interest for the DEA

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On March 23, 2020, the Federal Register published a Drug Enforcement Administration (DEA) Notice of Proposed Rulemaking, which allegedly aimed to establish "Controls to Enhance the Cultivation of Marijuana for Research in the United States."[1] The DEA's Notice offered for the first time, an outline of operational details under the newly proposed scheme, once effective.[1] As recent as 2019, DEA signaled that ensuring "transparency and public participation [in this process, … would provide [the] general public opportunity to comment on regulations that [would]… govern … growing marijuana for scientific and medical research.[2] For those who have followed developments in the marijuana landscape closely, the proposed new rule is long overdue. To be kind, a fair reading of its text alongside the many public comments published in the Federal Register is disappointing, and quickly exposed the title for the proposed new rule is at best, misleading.

First, assuming it is implemented as written, DEA estimates under the new rule anticipate approval of at most between three to 15 applications to manufacturers seeking to produce marijuana for research.[1] The DEA has acknowledged that in the entire 50 year history of the Controlled Substance Act,[3] only a single marijuana producer had been authorized to grow marijuana for research, and hence only a single producer had provide the entire supply of marijuana used for research in the US.[4] In other words, from a DEA perspective, federally approved marijuana manufacturers, and accordingly, marijuana production, will be enhanced, though in reality, only enhanced incrementally.

Second, back in August 2016, the DEA announced a policy shift stating an intent to begin accepting applications from companies wanting to become DEA-licensed marijuana researchers,[5,6] yet DEA actions contradict the agency's public statements. The DEA explained it would "expand the number of federally approved [marijuana] manufacturers, and promote [marijuana] research" because, according to the DEA; "in recent years" … there has been "greater public interest in expanding marijuana related research."[6] In direct contradiction, the agency received 35 applications for registration as bulk marijuana manufacturers since the 2016 DEA stated policy change, those applications remain currently pending.[1,6] Further, the agency defends the limits imposed on the number of approved marijuana manufacturers under the new rule as "necessary to produce an adequate and uninterrupted supply under adequately competitive conditions."[1]

Third, under the proposed new rule, the DEA, a law enforcement agency, would operate under, if not create, an actual conflict of interest by inserting itself into the US marijuana industry as "purchaser" and "repository" of all marijuana grown and produced for research by federally licensed manufacturers for which DEA would have exclusive enforcement and oversight.[1,4,5,6]

Lastly, researchers investigating marijuana's clinical and therapeutic efficacy assert that even the current DEA regulations impose an undue burden on researchers, while also reporting that marijuana grown by the single DEA-approved producer lacked quality assurance control in its potency and contamination by mold.[5,7,8] Those complaints highlight the lack of research-grade marijuana from the current single DEA-approved producer of marijuana for research in the US.

There may be a variety of solutions to these and yet other cited deficiencies. A large number of those submitting comments attacking the DEA and the proposed new rule, have offered at least several well-laid out arguments based on known historical facts, evidence-based literature; intellectually straightforward reasoning:

- There is a need "to prove the medical benefits of marijuana" and thus a need for proliferation and "diversity in research" which must be done quickly;[5]
- Robust investigations into the therapeutic value of cannabis requires the availability of hundreds of [approved marijuana producers];[5]
- The "DEA should be removed" from … [this newly proposed role] because it has failed to adequately administer the marijuana research program, and "despite promises to expedite and streamline the process, failed to deliver."[5]
- "Current scheduling of marijuana in Schedule I—along with heroin—does not allow for proper research" of its medicinal value.[5]
- Historically, a "large portion of the DEA budget derived from that which it receives to fight marijuana... [and] ensuring marijuana remains in Schedule I (thereby illegal under federal law), [basically] guaranteeing the DEA continues to receive those funds" and these facts present "a clear conflict of interest," underscoring yet another reason why the DEA has no place in the "business of marijuana."[5]

Similarly themed comments argue marijuana's medical merits; hence, the need to advance medical research to obtain data, and remind the public the DEA has historically stymied such research.[5] Yet other voices echo the discriminatory impact on minority communities because of marijuana's placement in Schedule I and the DEA's willfully blind enforcement of the Controlled Substance Act passed in 1970.[2,3,4]

The prescribed 60-day comment period following Notice of Proposed New Rule officially closed on May 22, 2020.[1,5] Within the comment period, 247 comments were received; some additional comments were submitted after the comment

period ended.[5] The DEA is presently considering the comments. However, it remains to be determined whether, or not, the "opportunity for comment" has any impact, whether or not the DEA will amend the proposed rule, and whether or not the DEA is listening…

About the Author

Ettie Rosenberg, PharmD, JD, has previously published original research articles on the evolution of marijuana legislation in California and the US, and presented on this topic nationally and within California. Her contributions on developments in marijuana laws, and the national and statewide legislative policy landscape on marijuana have appeared in previous issues of the Journal. Dr. Rosenberg currently serves as Assistant Dean of Student Affairs, and Professor, Department of Pharmacy Practice, at West Coast University School of Pharmacy. Dr. Rosenberg is a member of the JCPhP Editorial Advisory Board. Dr. Rosenberg has no conflicts of interest to report.

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