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INSIGHT

Drug Enforcement Administration Set to Increase Registered Marijuana Manufacturers for Research Purposes

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On May 14, 2021, the Drug Enforcement Administration (DEA) announced that it would soon register additional manufacturers to cultivate marijuana for research purposes. For over 50 years, the National Center for Natural Products Research at the University of Mississippi has been the only DEA-registered manufacturer of marijuana for research purposes, operating under a contract administered by the National Institute on Drug Abuse (NIDA). While marijuana is also cultivated in states that allow for its recreational and medical use, the federal government considers the University of Mississippi to be the only lawful source, as Schedule I controlled substances may *only* be manufactured for research purposes under the Controlled Substances Act (CSA), and manufacturers must register with the DEA.

Marijuana Supply for Researchers

Under the CSA, marijuana and its derivatives are classified as Schedule I controlled substances, unless an exception applies. This means the manufacture (or cultivation), possession, and distribution of marijuana are illegal, *except* for the purpose of DEA-sanctioned research. DEA (as delegated by the Attorney General) is required to register an applicant who would like to manufacture Schedule I or II controlled substances if it "determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." DEA thus seeks to balance the demands from researchers for a larger, more diverse supply of marijuana against the United States' obligations under international treaties. Further, the supply of marijuana and other Schedule I and II controlled substances is subject to production quota limitations determined by DEA based on an annual assessment of need.

In recent years, both Congress and the executive branch have acted to address marijuana supply issues.

- In 2015, the Improving Regulatory Transparency for New Medical Therapies Act (P.L. 114-89) amended the CSA and imposed deadlines on DEA to issue notice of each application for a registration to manufacture Schedule I substances for research and then act on the application.

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- In August 2016, DEA announced a policy change "designed to foster research by expanding the number of DEA-registered marijuana manufacturers." Under the new policy, DEA stated that it would register additional growers 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." In addition, under the new policy these growers would only be permitted to supply marijuana to DEA-registered researchers whose protocols have been determined to be "scientifically meritorious."
- Despite the CSA amendment and announced policy change, the delay in issuance of new registrations continued. The delay may be related to a 2018 finding by the Department of Justice (DOJ), Office of Legal Counsel (OLC) that DEA must change its current practices to adopt a framework in which it purchases and takes possession of the entire marijuana crop of each registrant after the marijuana is harvested. Further, the OLC stated that DEA "must generally monopolize the import, export, wholesale trade, and stock maintenance of lawfully grown marijuana" to comply with the Single Convention on Narcotic Drugs.
- In August 2019, former Attorney General William Barr announced that DEA was "moving forward with its review of applications for those who seek to grow marijuana legally to support research." DEA published a notice in the *Federal Register* (1) providing notice of the 33 applications it had received to manufacture Schedule I controlled substances for research purposes and (2) announcing its intent to promulgate regulations governing the manufacture of marijuana for research purposes.
- In December 2020, DEA published a final rule that, among other things, requires all registered manufacturers who cultivate marijuana "to deliver" their total crops to DEA with limited exception; however, the crops may remain at the manufacturers' registered locations. DEA is to purchase and take possession of such crops (not later than four months after harvest ends) by designating a secure storage mechanism at the registered location and controlling access to the marijuana.

These actions were precursors to DEA's recent announcement that it would soon be registering additional manufacturers of marijuana. As outlined in the announcement, DEA has provided Memoranda of Agreement (MOAs) to multiple manufacturers pending final approval of their registration applications.

Future Sources for Marijuana Researchers

As stated, the University of Mississippi has been the only registered manufacturer of marijuana for over 50 years. Some have referred to this as a "federal marijuana monopoly," and researchers have long objected to the quality and quantity of marijuana available for research. For example, issues raised by researchers regarding the National Center for Natural Products Research marijuana include

- mold found in the samples of bulk marijuana,
- excessive age of the samples,
- lower THC potency compared to local products, and
- lower number of product options compared to what is available elsewhere.

Of note, NIDA states there is currently no universally accepted standard for levels of mold on marijuana, and NIDA's Certificates of Analysis for their marijuana state that NIDA may store marijuana for up to 10 years prior to shipment. NIDA provides marijuana to researchers with a range of potencies.

Additional registrations to manufacture marijuana may increase the quantity and improve facets of marijuana research, and may contribute to future debate on rescheduling marijuana. Both the Food and

Drug Administration (FDA) and DEA identified lack of research as a significant factor in denying marijuana rescheduling petitions in 2016. It remains unclear if the additional manufacturers of marijuana will satisfy concerns raised by researchers. For instance, researchers in states with state-authorized marijuana have expressed interest in using the wide range of marijuana products available at local dispensaries rather than the more limited NIDA supply that is subject to strict federal regulation because NIDA's products have lower potency and are not representative of the wider variety and higher quality available at local dispensaries. DEA's change to add registrants is not to allow for dispensary use, as the marijuana grown by new registrants, like that of the University of Mississippi, is *only* to be grown for research purposes as authorized under the CSA.

Author Information

Lisa N. Sacco
Analyst in Illicit Drugs and Crime Policy

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