King & Spalding

Client Alert

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For more information, contact:

D. Kyle Sampson
+1 202 626 9226
ksampson@kslaw.com

Lisa M. Dwyer
+1 202 626 2393
ldwyer@kslaw.com

Melis A. Coraggio
+1 202 626 5457
mcoraggio@kslaw.com

Christina R. Young
+1 202 626 2395
cyoung@kslaw.com

David J. Farber
+1 202 626 2941
dfarber@kslaw.com

Amanda J. Klingler
+1 202 626 9255
aklinger@kslaw.com

Jesse Snyder
+1 202 383 8925
jsnyder@kslaw.com

Jackson M. Grubbe
+1 202 626 8980
jgrubbe@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue
Suite 900
Washington, D.C. 20006
Tel. +1 202 737 0500

DEA's Proposed Rule to Reschedule Marijuana Could Reduce Obstacles to Medical Research but Public Input Is Needed to Fill in Knowledge Gaps

On May 16, 2024, the U.S. Drug Enforcement Administration ("DEA") issued a Notice of Proposed Rulemaking ("NPRM") to reclassify marijuana[1] from Schedule I to Schedule III under the federal Controlled Substances Act ("CSA")[2] and provide the public an opportunity to submit comments. The proposed rule applies only to botanical marijuana, and it does not impact hemp, synthetic tetrahydrocannabinol ("THC"), or cannabis-derived products previously scheduled outside of Schedule I (*e.g.,* Marinol and Syndros). Enacted in 1970, the CSA established five drug schedules, or categories, that determine applicable restrictions on controlled substances.[3]

Since 1970, marijuana has been regulated as a Schedule I controlled substance. Schedule I substances are considered to have "no currently accepted medical use and a high potential for abuse," whereas Schedule III substances have "a moderate to low potential for physical and psychological dependence" and "a currently accepted medical use in treatment in the United States."[4] DEA's proposed rule would remove marijuana from the Schedule I class of drugs that includes heroin, 3,4-methylenedioxymethamphetamine ("MDMA" or Ecstasy), peyote, methaqualone, and lysergic acid ("LSD"), and reclassify it among Schedule III substances like ketamine, anabolic steroids, testosterone, and products containing less than 90 mg codeine per dosage.

The proposal follows President Biden's October 2022 request for DEA and the U.S. Department of Health and Human Services ("HHS") to review marijuana's scheduling and an August 2023 HHS recommendation to move marijuana to Schedule III.[5]

I. HHS'S AND DEA'S EVALUATIONS OF MARIJUANA

In general, when assessing whether marijuana should be rescheduled, HHS and DEA consider marijuana's chemical profile, accepted medical uses, potential for and history of abuse, and public health risks.[6]

In its August 2023 report, HHS concluded that credible support exists for a currently accepted medical use for marijuana in treating pain and nausea, vomiting, and anorexia related to a medical condition.[7] DEA deferred to some of HHS's scientific and medical findings for purposes of initiating rulemaking proceedings but believes more data about marijuana abuse liability is needed.[8]

Not surprisingly, given its mission, DEA seems especially concerned about human abuse potential. For example, DEA emphasized that marijuana's pharmacology complicates consistent interpretations of clinical data and suggested that additional data on effects, potency, and routes of administration are needed. DEA noted that state and federally sanctioned drug channels may be causing marijuana diversion and that data on seizures of marijuana by law enforcement may help assess abuse potential, and it recognized the limitations of comparing data on adverse outcomes across drugs. It also emphasized that driving under the influence of marijuana remains a serious concern. Although the proposed rule refers to some post-2016 data, it repeatedly refers to data and DEA conclusions from 2016.[9]

Rescheduling is not guaranteed. Typically, DEA-proposed rules are signed by the DEA Administrator. This proposed rule, however, was signed by Attorney General Merrick Garland rather than DEA Administrator Anne Milgram, suggesting perhaps some reluctance by DEA to go forward with a final rule without more information (including on human abuse potential). Of course, DEA is an agency of the U.S. Department of Justice, which is headed by the Attorney General who answers to the President—who has indicated clearly his desire that marijuana be rescheduled, provided that rescheduling is supported by the scientific evidence.[10]

Via the public comment process, stakeholders have an opportunity to fill in these gaps in the scientific evidence with more recent data on marijuana's safety, public health risks, chemical profile, and potential for abuse.

II. RESCHEDULING MARIJUANA COULD SPUR MARIJUANA PRODUCT DEVELOPMENT

The proposed rule makes clear that even if moved to Schedule III, "marijuana would remain subject to the limitations within the Food, Drug, and Cosmetic Act" ("FD&C Act").[11] For example, under the FD&C Act, before a drug product can enter the market, the U.S. Food and Drug Administration ("FDA") must approve a New Drug Application showing that the drug is safe and effective for its intended use.

Due to the restrictions associated with researching a Schedule I drug, most of the current data on marijuana was obtained through observational studies. Observational studies, however, do not provide definitive evidence, as various external factors can impact the data. Moving marijuana to Schedule III will allow for better research by making it easier to access marijuana for use in Randomized Control Trials ("RCTs"), which are considered the "gold standard." RCTs are double-blinded studies where subjects do not know if they receive the drug or placebo. These types of controlled clinical trials reduce bias and minimize the impact of external variables through randomization.

If marijuana is rescheduled, then restrictions on medical researchers seeking to study the substance for specific medical uses would be significantly eased, which could lead to smoother FDA approvals of marijuana-based pharmaceuticals. The reduced research burdens could be an opportunity to expand the FDA-approved therapeutic uses of marijuana-related products beyond treatment for certain condition-related seizures (*i.e.,* Epidiolex); anorexia associated with weight loss in patients with AIDS (*i.e.*, Syndros and Marinol); and nausea and vomiting associated with cancer chemotherapy (*i.e.,* Syndros, Marinol, and Cesamet).[12]

Entities interested in advancing their marijuana research and product development should consider providing comments to the DEA rulemaking docket.

a. Federal Research Funding

Federal law limits the use of federal funding for research on Schedule I substances. A 2024 appropriations law prohibited using federal funds for such research except "when there is significant medical evidence of a therapeutic advantage to the use of such [Schedule I] drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage."[13] Currently, marijuana researchers are faced with a catch-22: they cannot receive these federal funds to produce more evidence of therapeutic benefits of marijuana because there is not already significant evidence of such therapeutic benefits. Rescheduling marijuana would make it easier to secure funding to conduct much needed clinical research because research on Schedule III substances is not similarly restricted.

b. DEA Registration

Entities seeking to conduct research on controlled substances must first register with DEA, which involves submitting information on their qualifications, proposed research, and the security measures at their research sites.[14]

Although there are specific rules designed to expedite marijuana research approvals,[15] the requirements for Schedule I research registrations are still far more stringent than for Schedule II-V research registrations.[16] For example, Schedule I applicants must submit a separate research protocol for each study, which is not the case for Schedule II-V applicants.[17] In addition, unlike Schedule II-V applications, Schedule I research applications are subject to a separate HHS review.[18] Moreover, registered Schedule III researchers have broader authority than Schedule I researchers to perform chemical analysis and conduct instructional activities with controlled substances.[19]

c. Procurement and Storage

Registered entities are limited to producing a DEA-determined quota of each Schedule I and Schedule II substance.[20] Schedule III substances, however, typically do not have such quotas. Although the DEA recently increased the production quota for marijuana and its extract,[21] rescheduling marijuana would likely allow more consistent marijuana production, which could assist entities seeking to conduct marijuana research.

The CSA requires DEA to approve every order of a Schedule I or II substance.[22] Registrants must retain copies of each order form and keep them available for inspection for two years.[23] In addition, storage requirements are more stringent for Schedule I substances.[24] Rescheduling marijuana would allow for more standard purchase orders and ease some of these recordkeeping and storage requirements.

d. Open Questions for Researchers

Currently, DEA controls who may grow marijuana for research purposes. Marijuana provided to researchers by DEA-sanctioned growers, however, is not representative of all the varieties and potencies of marijuana available on the market. Marijuana contains over 500 different compounds, including cannabinoids, terpenes, and flavonoids.[25] Even if marijuana is rescheduled, it is unclear that DEA will approve marijuana with the variety and concentration of compounds researchers seek to study.

In sum, rescheduling marijuana will ease research barriers, which could invite investment by pharmaceutical companies with robust research and development capabilities to discover new FDA-approved therapeutic uses for marijuana and its many compounds. To guide product development efforts, companies exploring marijuana research should take the

opportunity to submit comments to clarify marijuana-specific research requirements concerning registration, protocols, procurement, and storage.

Given DEA's concerns about the potential for marijuana abuse, comments related to data from clinical studies that may have been conducted under state-legal medical marijuana operations would be especially helpful in closing the gaps in the proposed rule.

III. STATE-LEGAL CANNABIS COMPANIES COULD SEE INCREASED PROFITABILITY, YET ENFORCEMENT QUESTIONS REMAIN

The state-legal cannabis industry has functioned under a patchwork of state laws and regulations for decades now. Despite marijuana being illegal under federal law, 38 states, the District of Columbia, and four federal territories have legalized the use of marijuana for medical purposes.[26] Indeed, 24 states and the District of Columbia have legalized adult-use of marijuana (also known as "recreational" use).[27]

At the federal level, Section 280E of the Internal Revenue Code prohibits tax deductions for business expenses incurred "in carrying on any trade or business . . . [that] consists of trafficking in controlled [Schedule I and II] substances."[28] Section 280E applies even if a cannabis business operates in a state where marijuana use has been legalized.[29] Moving marijuana to Schedule III would allow cannabis companies to take federal tax deductions for ordinary business expenses, such as payroll and rent. This could enhance the profitability of cannabis companies and attract investment into the sector. And the added attention from investors may allow companies to capitalize on the reduced research barriers, accelerating the development of marijuana-based therapies. Increased profitability also will likely increase marijuana marketing, leading to a greater prevalence of use, which may generate useful insights into marijuana's public health impact, including human abuse potential.

Despite the potential profitability, enforcement questions persist for state-legal cannabis companies. DEA's proposed rule notes that even if rescheduling is finalized, "the manufacture, distribution, dispensing, and possession of marijuana would remain subject to the applicable criminal prohibitions of the CSA."[30] In response to HHS's recommendation to reschedule marijuana, a group of 30 former U.S. Attorneys sent an open letter to DEA expressing concern that rescheduling may harm the government's ability to pursue drug cartels.[31] In contrast, some experts argue that state-legal cannabis programs have decreased marijuana trafficking. Moreover, even if rescheduling is finalized, marijuana products remain subject to the numerous requirements of the FD&C Act.

While state-legal cannabis operations have survived for years, the public comment period is an opportunity for state-legal cannabis companies to comment and seek clarity on potential financial impacts and DEA's planned enforcement policy.

IV. NEXT STEPS IN THE ADMINISTRATIVE PROCESS

Rescheduling marijuana likely is months away. The CSA requires rescheduling decisions to be made through formal rulemaking. DEA's publication of the NPRM in the *Federal Register* kicked off a 60-day public comment period, which ends on July 22, 2024.[32] Interested parties may request a hearing before an Administrative Law Judge, where they can introduce evidence and expert testimony about the pros and cons of rescheduling. In fact, nine former DEA administrators and 18 attorneys general have formally requested such hearings. In two separate letters to DEA Administrator Anne Milgram, these officials described rescheduling marijuana as "likely the most consequential rulemaking" DEA has ever undertaken.[33]

After the public comment period closes, DEA will review the record, which may take months. The NPRM has already drawn thousands of public comments. Following DEA review, DEA may terminate the rulemaking, amend the rule, or proceed to issue a final rule. DEA has already forecast that it may amend the rule based on public comments.[34]

V. CONCLUSION

Rescheduling marijuana would ease legal constraints for DEA registrants, especially for researchers, which could impact product development and the public health. Yet companies would still need to navigate complex regulatory and compliance issues at the federal and state levels.

As written, the proposed rule leaves crucial questions about the impact on marijuana-derived product development and state-legal cannabis businesses unanswered. Such companies still face uncertainty related to potential federal enforcement actions because cannabis remains illegal under federal law and has not been approved by the FDA for the treatment of any disease.[35]

DEA has previously considered rescheduling marijuana, but that consideration was initiated by outside parties, and the DEA denied both petitions. Now DOJ has, for the very first time, initiated the process to reschedule marijuana. Stakeholders have the opportunity to submit comments on the proposed rule by July 22, 2024. Public input will clarify regulatory outcomes for a promising and growing industry.

King & Spalding LLP regularly counsels on issues related to FDA and DEA-regulated products. Please let us know if you have any questions regarding the proposed rule, or if we can be of any assistance in creating comments or preparing for a rapidly evolving and volatile regulatory landscape.

[1] Marijuana is defined as the plant *Cannabis sativa L.* and its parts, compounds, or products—excluding "hemp," which is the plant and its products that are low in delta-9-tetrahydrocannibinol, one psychoactive cannabinoid in marijuana. *See* DEA, Notice of Proposed Rulemaking, *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44,597 (May 21, 2024) (Docket No. DEA–1362), *available at* https://www.govinfo.gov/content/pkg/FR-2024-05-21/pdf/2024-11137.pdf [hereinafter "*Proposed Marijuana Rulemaking*"].
[2] *See* U.S. Dep't of Justice, Press Release, *Justice Department Submits Proposed Regulation to Reschedule Marijuana* (May 16, 2024), https://www.justice.gov/opa/pr/justice-department-submits-proposed-regulation-reschedule-marijuana.

[3] *See generally* 21 U.S.C. § 812. The current list of scheduled substances can be found at 21 U.S.C. § 812 and 21 C.F.R. § 1308.
[4] DEA, *Drug Scheduling* (last visited June 21, 2024), https://www.dea.gov/drug-information/drug-scheduling; *see also* 21 U.S.C. § 812(b)(1), (3).
[5] *See Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,599-600.
[6] *See generally* HHS, *Basis for the Recommendation to Reschedule Marijuana to Schedule III of the Controlled Substances Act* (Aug. 29, 2023) (recommending to DEA "that marijuana should be placed in Schedule III"), *available at* https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf [hereinafter "HHS Rescheduling Recommendation"]; *Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,601-15; *see also* 21 U.S.C. § 811(b)-(c) (establishing factors in scheduling decisions).
[7] *See* HHS Rescheduling Recommendation at 1, 28, 63-65.
[8] *See Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44603 ("DEA believes that additional data . . . may be appropriate for consideration in assessing marijuana's actual or relative potential for abuse"); *id.* at 44,610 ("DEA believes that additional data on marijuana's pattern of abuse may be appropriate for consideration"); *id.* at 44,613 ("DEA also believes that additional information regarding the scope, duration, and significance of marijuana abuse may be appropriate for consideration"); *id.* at 44,615 ("DEA anticipates that additional psychic or physiological dependence liability may be appropriate for consideration"); *id.* at 44,619 (expressing deference to HHS findings).
[9] *See, e.g.*, *Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,600, 44,602, 44,603, 44,610, 44,612, and 44,615.
[10] *See* The White House, Statement from President Biden on Marijuana Reform (Oct. 6, 2022), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/ (calling for HHS to evaluate marijuana's scheduling and describing historical marijuana policy as "failed"); *see also* President Joseph R. Biden, Jr. (@POTUS), X (May 16, 2024, 1:03 PM), https://x.com/POTUS/status/1791152464617431389 (describing the rescheduling NPRM as "an important move toward reversing longstanding inequities").
[11] *Proposed Marijuana Rulemaking*, 89 Fed. Reg at 44597.
[12] *See* Label for EPIDIOLEX® (cannabidiol) oral solution, FDA (rev. July 2020), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210365s005s006s007lbl.pdf; Label for SYNDROS® (dronabinol) oral solution, CII, FDA (rev. May 2024), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/205525Orig1s013lbl.pdf; Label for MARINOL (dronabinol) capsules, for oral use, CIII, FDA (rev. Jan. 2023), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/018651s033lbl.pdf; Label for Cesamet® (nabilone) capsules, FDA (rev. Apr. 2022), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/018677Orig1s017lbl.pdf.
[13] The Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, div. D, tit. V § 509 (118th Cong.).
[14] *See* 21 U.S.C. § 822; 21 C.F.R. §§ 1301.11(a) & 1301.13.
[15] 21 U.S.C. § 823(c).
[16] *See* 21 C.F.R. § 1301.13(e)(1)(v), (vi).
[17] *See id.* § 1301.18.
[18] *Compare id.* § 1301.32, *with id.* § 1301.31.
[19] *See id.* § 1301.13(e)(1)(v), (vi); *accord* DEA, *Researcher's Manual: An Informational Outline of the Controlled Substances Act* 19-21 (rev. 2022), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-057)(EO-DEA217)_Researchers_Manual_Final_signed.pdf.
[20] 21 U.S.C. §§ 823(d) & 826.
[21] *See*, DEA, Final Order, *Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2024*, 89 Fed. Reg. 407, 415 (Jan. 3, 2024), https://www.govinfo.gov/content/pkg/FR-2024-01-03/pdf/2023-28962.pdf.
[22] *See* 21 U.S.C. § 828(a); *see also* 21 C.F.R. § 1305.03.
[23] *See* 21 C.F.R. § 1305.17.
[24] *See id.* § 1301.72(a), (b).
[25] *See* HHS Rescheduling Recommendation at 10, 19.
[26] *See Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,600.
[27] *See* Congressional Research Service, *Legal Consequences of Rescheduling Marijuana* 2 (updated May 1, 2024), https://crsreports.congress.gov/product/pdf/LSB/LSB11105.
[28] 26 U.S.C. § 280E.
[29] *See Canna Care, Inc. v. Comm'r*, 694 F. App'x. 570 (9th Cir. 2017) (affirming Tax Court decision denying business expense deductions for a marijuana dispensary operating in California); *see also* De Lon Harris, Internal Revenue Service, *Providing Resources to Help Cannabis Business Owners Successfully Navigate Unique Tax Responsibilities* (last visited June 21, 2024), https://www.irs.gov/about-irs/providing-resources-to-help-cannabis-business-owners-successfully-navigate-unique-tax-responsibilities.
[30] *Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,597.
[31] *See* Jonathan Capriel, *Group Of Former US Attys Urges DOJ Not To Reschedule Pot*, *Law360* (Dec. 15, 2023), https://www.law360.com/articles/1777208/group-of-former-us-attys-urges-doj-not-to-reschedule-pot.
[32] *See Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,597; *see also* 21 U.S.C. § 811(a)(2).
[33] *See Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,598; Sam Reisman, *Ex-DEA Heads Echo GOP AGs' Call For Pot Rescheduling Hearing*, Law360 (June 20, 2024), https://www.law360.com/articles/1850013/ex-dea-heads-echo-gop-ags-call-for-pot-rescheduling-hearing.
[34] *See Proposed Marijuana Rulemaking*, 89 Fed. Reg. at 44,598 (stating that "DOJ recognizes this [rescheduling] action may have unique economic impacts. . . . DOJ is specifically soliciting comments on the economic impact of this proposed rule. DOJ will revise this section at the final rule stage if warranted after consideration of any comments received.").
[35] *See* FDA, *FDA and Cannabis: Research and Drug Approval Process* (updated Feb. 24, 2023), https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process.