CLIENT ALERTS & INSIGHTS

Is There a Shortcut to Cannabis Rescheduling?

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In the next 2 months or so, the Drug Enforcement Agency (DEA) is likely to announce that it will reschedule cannabis under the Controlled Substances Act (CSA)[1] from a Schedule I highly dangerous and addictive drug with no medical purpose (where it currently sits next to heroin), to a Schedule III drug that has a medical purpose and is less addictive (like Tylenol with codeine). It could be a long road, however, to get from DEA’s announcement to the effective date of rescheduling. What if there was a way (or ways) to short-cut this process?

The typical process after a rescheduling announcement would be for DEA to publish a (~60 day) notice of proposed rulemaking in the Federal Register with a public comment period, during which time it could also hold hearings with interested parties (“Public Comment Period”). These hearings would proceed before administrative law judges and are designed to gather input from stakeholders, evaluate evidence and arguments, and make an informed decision.[1] Should DEA nevertheless move forward with rescheduling cannabis to Schedule III, the parties who opposed rescheduling during the Public Comment Period would likely be considered “aggrieved” and would therefore have standing to request judicial review (essentially, an appeal) of DEA’s decision. This, of course, would add more delay, possibly pushing rescheduling into 2025, or beyond. To put the timing in perspective, the process to reschedule Hydrocodone from Schedule III to Schedule II stretched **10 years** from 2004 until 2014.[2]

That kind of delay seems implausible to me, but so did other things that have happened in our country over the last several years.

This got me thinking. Could President Biden, DEA’s boss, put pressure on DEA to “skip” the Public Comment Period to expedite the rescheduling of cannabis before the November 2024 election? Is there a basis for DEA to do so?

Yes, and yes. First, there is a strong argument that DEA does not even have authority to proceed in the way described above because the CSA explicitly says that the Attorney General **must** bypass the Public Comment Period:

“(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General ***shall*** issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, ***without regard to the findings … and … procedures …***” (emphasis added)[3]

Control *is* required by the United States as a participant in the UN Single Convention on Narcotics of 1961 (the “UN Single Convention”), so the Attorney General (AG) *shall* reschedule “without regard to findings…and…procedure,” meaning, without public comments and hearings. The problem is that

the UN Single Convention treats cannabis like a Schedule I drug currently, and while there is the possibility of "working around" this complication, the path forward is anything but clear.[4] Perhaps this is the reason the AG has not asserted authority over the rescheduling decision and has left it to DEA.

Second, DEA could shorten the process and avoid some litigation by exercising its authority under Section 553 of the Administrative Procedure Act (APA) to bypass the Public Comment Period, like it did when it rescheduled Epidiolex in 2018.[5] The APA provides exceptions to the notice and comment requirement when an agency finds "good cause" to bypass the procedure. This "good cause" exemption allows agencies to forego the notice and comment period if they determine that it is impracticable, unnecessary, or contrary to the public interest.[6]

In doing so, DEA would eliminate an entire group of potentially "aggrieved [interested] parties" who would otherwise have standing to seek judicial review of the rescheduling decision, although this would not completely avoid litigation (more on this below). Additionally, there is no doubt that bypassing the Public Comment Period would shorten the process dramatically and reduce delay-causing litigation. In fact, DEA could tell the world tomorrow that it accepts HHS's recommendation that cannabis be rescheduled, and rescheduling could occur 30-60 days later.[7]

If DEA were to choose this path, the decision to skip the Public Comment Period is itself appealable in federal court, albeit with a high bar that requires the aggrieved party to show that DEA's decision was "arbitrary and capricious," not in accordance with law, or an abuse of discretion.[8] One court described the standard as follows: "an agency action normally is arbitrary or capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983). While attorneys can argue over exactly what this means, given the amount of time, effort, and written documentation that has been gathered and reviewed in considering the rescheduling of cannabis, it's hard to imagine any court could find DEA's decision to skip the Public Comment Period rises to an "arbitrary and capricious level." As the Supreme Court explained, "the scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Veh. Mfrs. Ass'n*, 463 U.S. at 43.

With respect to justifying the decision on judicial review, DEA has a pretty simple argument - there is no need to have a Public Comment Period because we have enough information to make a decision. The purpose of the Public Comment Period is (i) to promote transparency by giving interested parties, such as stakeholders, experts, and the public, an opportunity to review and provide feedback on proposed regulatory changes; and (ii) to help DEA make more informed decisions by considering a wide range of perspectives, scientific evidence, and potential impacts on various stakeholders.[9]

With respect to transparency, HHS's 252-page report[10] was leaked,[11] so we have all had access to it for some time now. At this point, other than not knowing exactly when the rescheduling decision will happen, do interested parties (stakeholder, experts, the public) need more transparency? Do they need to provide or see *more*

feedback? Most officials and the public are on the same page that cannabis should not be in the same category as heroin and that it should be regulated and kept away from children.[12] For those who are not on that same page, we know all the reasons why. My guess is that most interested parties (even those opposing rescheduling) would say the process has been transparent enough; it's time for a decision (one way or the other). To be clear, interested parties would still have a Public Comment Period if DEA put forth draft regulations with respect to the rescheduling of cannabis, so they would have a say how rescheduling is handled and implemented.[13]

With respect to DEA's ability to make an informed decision to accept the recommendation, what information does DEA still need and will this Public Comment Period, inclusive of public hearings, provide this information? Remember, this is not the "first cannabis rodeo" for DEA. In 2016, DEA declined to reschedule cannabis,[14] but has been collecting data on the cannabis industry ever since (without enforcing federal law against state-licensed cannabis companies). Will any of the information gleaned during the Public Comment Period actually assist with DEA's decision? For example, is there an expert that DEA still wants to hear from that could legitimately impact its decision to accept HHS's recommendation? If there is no "need" to review and respond to public comments (and to be clear, by law, the agency must review and respond to every single comment [15]) or hold public hearings that could stretch out for years inclusive of judicial review and re-evaluation of the recommendation itself, then DEA should get on with it and exercise its authority to skip the Public Comment Period.

But it is never that easy. A few days ago, we heard grumblings that there is disagreement in DEA ranks over the rescheduling decision and that perhaps those disagreements are delaying a decision and public announcement.[16] While dissension within DEA about this decision is expected, it would weigh in favor of DEA choosing to hold a Public Comment Period to provide itself with both legal and political "cover" for the rescheduling decision. In doing so, however, DEA will actually spend excessive resources during the course of the Public Comment Period (instead of, say, working on combatting the opioid and fentanyl crisis) and create a whole group of "aggrieved parties" to challenge the rescheduling decision, as opposed to one challenge related to skipping the Public Comment Period (to which a very high standard of review - in favor of DEA - is applied).

Unless you work for HHS, FDA or DEA, you probably know as much as I do about what is happening behind the scenes with respect to this rescheduling decision. DEA is about to make a very consequential decision to the cannabis industry; and frankly, to the entire country; but it is important for DEA to be strategic about how to get to the decision. If rescheduling cannabis has bipartisan support and public (majority) support, DEA can avoid wasting taxpayer money on an unnecessary Public Comment Period and defer to HHS, who put together a comprehensive report recommending rescheduling. Rescheduling can then be quicker and just a little less painful for everyone.

For additional information, please reach out to:

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[1] the_rulemaking_process.pdf (federalregister.gov)

[2] Federal Register :: Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II

[3] 21 U.S. Code § 811 - Authority and criteria for classification of substances | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)

[4] The CSA prohibits rescheduling of drugs if doing so violates the Single Convention, and the Single Convention classifies cannabis as a Schedule I drug. So, even if DEA adopts HHS's recommendation to reschedule, the decision is vulnerable to judicial review. The same vulnerability applies if the AG (or DEA if designated by the AG) exercised authority to reschedule cannabis to Schedule III. That said, other signatories to the Single Convention, like Canada and Mexico, are also out of compliance with respect to cannabis; the US state legal frameworks arguably already violate the Single Convention; and there's an argument to be made that the Single Convention only applies to international movement of cannabis and not domestic movement inside a country. There are other arguments, but this is a topic that requires its own article.

[5] Federal Register :: Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements

[6] 5 U.S. Code § 553 - Rule making | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)

[7] It is worth noting also that this could all be upset by the Supreme Court's pending decision in Chevron v. NRDC, which provides the legal underpinning for the deference DEA is to give to HHS in the rescheduling decision. Chevron U.S.A., Inc. v. NRDC :: 467 U.S. 837 (1984) :: Justia US Supreme Court Center. If the Supreme Court overturns or partially overturns *Chevron* (as it is expected to do) before DEA announces the rescheduling decision, it is possible that DEA's decision on rescheduling could change. That would be a disaster for the industry and for President Biden's reelection. (This is yet another article).

[8]5 U.S. Code § 706 - Scope of review | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu); TOURUS RECORDS INC v. DRUG ENFORCEMENT ADMINISTRATION (2001) | FindLaw

[9] The Public Comment Period to also used to comply with the APA with respect to rule-making, and new and amended regulations; but unless DEA is going to surprise everyone with proposed regulations to go along with the rescheduling decision, this is inapplicable right now. the_rulemaking_process.pdf (federalregister.gov)

[10] IN12240.pdf (SECURED) (congress.gov)

[11] Report: Leaked HHS Letter Calls Upon DEA to Reschedule Cannabis - NORML

[12] Grassroots Support for Legalizing Marijuana Hits Record 70% (gallup.com)

[13] Administrative Procedure Act | Wex | US Law | LII / Legal Information Institute (cornell.edu)

[14] DEA Rejects Attempt To Loosen Federal Restrictions On Marijuana : NPR

[15] The Notice and Comment Process Legally Provided for Agency Rulemaking | Administrative Law Center | Justia

[16] DEA Officials Reportedly At Odds With Biden Admin Over Marijuana Rescheduling Push - Marijuana Moment