AMERICAN TRADE ASSOCIATION FOR CANNABIS AND HEMP

RESCHEDULING Q&A

1. If this change were to happen, what would happen to the state-regulated marijuana industry?

- ATACH does not anticipate a significant change to state-regulated marijuana markets from a rescheduling from Schedule I to Schedule III alone:
- FDA already has regulatory authority over marijuana, THC and CBD, and Schedule I to Schedule III does not increase or diminish FDA's current authority or discretion in regulating state-level marijuana markets.
- To the FDA, the entire marijuana market (including medical marijuana) is not federally legal, and for all intents and purposes, is only interested to the extent that it safeguards public health and safety. While it has statutory regulatory authority over cannabis, it has not intervened except in a narrow set of circumstances. The state-regulated market operates completely outside the pharmaceutical drug development administered by the FDA and DEA, and that is unlikely to change due to scheduling from I to III.
- FDA has limited resources for even its current responsibilities, and in order for FDA to be more involved, it would need additional funding from Congress or a significant change in federal law such as the passage of adult-use legalization.
- It is hoped that Schedule III would open the door to more research, and there may be more interest by pharmaceutical companies in drug formulations, but could have sought those formulations without a change in the scheduling and this FDA process for investigation of new drugs will not change due to scheduling.
- Perhaps most important to state-legal marijuana businesses, Schedule III would remove 280E taxation that the IRS is currently misapplying to the cannabis industry.

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2. How would this change FDA's regulatory authority over marijuana? Wouldn't descheduling be better?

- FDA has authority over cannabis when used in consumer products, and even if marijuana were removed from the list of controlled substances, FDA would retain substantial regulatory authority — not much less than it does now. This is why ATACH is recommending that marijuana be subject to regulation through TTB, similar to alcohol, rather than through FDA alone. ATACH's goal is to deschedule marijuana through comprehensive federal legalization and have marijuana treated like alcohol.

3. How might the rescheduling of marijuana affect the marijuana industry?

- The most direct impact is that it would remove the 280e tax burden for state-licensed businesses. The result of this tax for most businesses is that they pay an effective tax rate of 81% revenue, which is staggering. This would allow the regulated businesses to be taxed fairly for the first time since reform began.
- Most of the changes that will come from rescheduling will be positive for business, and do not support the idea that marijuana would exclusively be the purview of pharmaceutical companies. The reality is that marijuana is a widely used recreational substance that is easy to create, and is not of interest for that purpose to any established pharmaceutical businesses seeking unique drug formulations for medicine. Recreational marijuana products are not part of the pharmaceutical business model, which relies on unique formulations that can be exclusively marketed for medical purposes.

4. What is FDA's interest in regulating cannabis?

- There is a common misconception that rescheduling or descheduling impacts FDA's role and its authority over cannabis products. While scheduling does impact how the product can be used, the agency has shown little current interest in regulating recreational use of marijuana without more funding and a federal framework, despite its current authority to do so.

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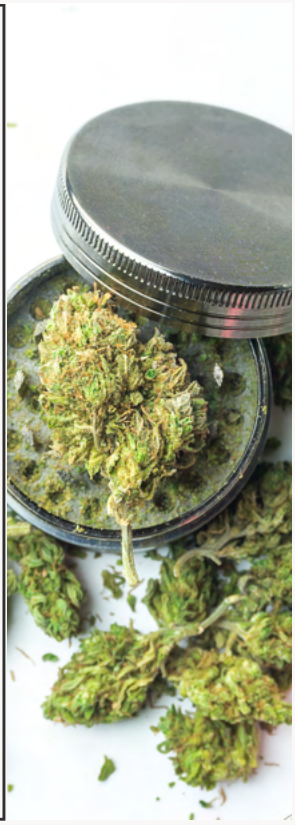
4. (Continued) What is FDA's interest in regulating cannabis?

- The FDA's current interest in regulating cannabis stems from its public health mission and authority in the Federal Food, Drug, and Cosmetic Act (FD&C Act). For cannabis, the FDA treats it like any other regulated product, regardless of whether it's classified as marijuana or hemp.
- As with all foods and supplements, the FDA must consider them safe — usually through standards such as good manufacturing practices. Because the FDA has not extended those standards to cannabinoids, the FDA considers them adulterants and illegal to use. That means that smokable or edible marijuana products are not approved. As mentioned, it has not sought enforcement action against state programs or individual businesses despite that determination.
- As it pertains to enforcement, FDA has said that it has and will continue to monitor the marketplace and take action to protect the public health against companies selling cannabis and cannabis-derived products that are being marketed for therapeutic uses for which they are not approved. So far, it is products that have associated drug claims that are of greatest interest and concern for the FDA.

5. What enforcement powers does the FDA have?

- The FDA currently enforces the FD&C Act by taking action against individuals or entities violating it and the sale of non-compliant products. Various FDA offices, including the Office of Regulatory Affairs, the Center for Food Safety and Applied Nutrition, and the Center for Drug Evaluation and Research, are involved in monitoring and enforcing compliance. Their efforts aim to protect consumers from unsafe drugs, misbranded products, and more. These offices have initiated actions such as issuing warning letters against those marketing CBD and Delta-8 THC products in violation of the FD&C Act. Past warning letters targeted companies selling CBD products with claims of preventing, diagnosing, treating, or curing diseases, often inappropriately. Some of these products violated the act further by being marketed as dietary supplements or by containing CBD in food. The FDA refrains from taking action against CBD products not making drug claims or targeting children.
- As mentioned, the FDA does not have the resources and has expressed no interest in trying to combat the expansive regulated cannabis market, now operating within regulatory systems in 3 out of 4 states.



RESCHEDULING Q&A

6. Following re-scheduling, will state-regulated cannabis companies face FDA regulation similar to pharmaceutical companies?

- Re-scheduling wouldn't alter FDA's authority over cannabis or state-regulated companies. Just as there are GMP rules for food, if a company sells a cannabis edible across state lines, it's bound by GMP rules, whether cannabis is scheduled or not. FDA generally hasn't enforced these rules on cannabis-containing products (except approved drugs).
- FDA maintains an FAQ regarding states allowing cannabis for medical use without FDA approval. It emphasizes the need for clinical trials to ensure cannabis product safety and efficacy. FDA offers support and information on federal and scientific standards for states considering medical research on cannabis and derivatives.

7. Would it be easier to get a research license from the FDA?

- Congress recently passed the Medical Marijuana and Cannabidiol Research Expansion Act, H.R. 8454, which may have an impact on the availability of cannabis for research purposes. This law aims to advance cannabis research by streamlining DEA's role and expanding sources of research-grade marijuana. The law mandates DEA to accept applications for registration if approved by applicable agencies FDA or NIH, or if DEA protocols are met. The law also aims to increase commercial production and manufacturers for research. Though it doesn't solve all access issues, it aims to significantly broaden DEA-registered research sources. That said, some have argued that it makes obtaining a research license harder, not easier, so it may not be clear until the the law in fully implemented.

8. Why is the Health and Human Services (HHS) recommendation to move marijuana to Schedule III significant?

- This is the first time an agency with regulatory authority over marijuana has recommended a different category. Since it was first put on the list of controlled substances back in 1971, marijuana has been categorized in the most severe category we have for drugs in the US, Schedule I. That has limited research, and treated it exclusively as a controlled substance, in which possession or use is punishable as a criminal offense. Convictions have broad impacts, affecting job prospects, housing, and educational opportunities long after any criminal sentence is over.

RESCHEDULING Q&A

9. What role does the Drug Enforcement Administration (DEA) play in this process?

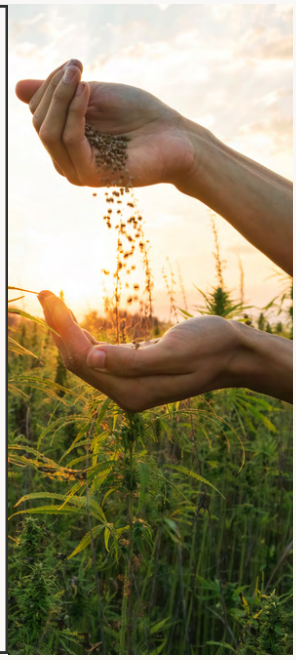
- Once HHS provides its findings and recommendations to the DEA, the DEA reviews this information and initiates its own evaluation process. The DEA's involvement includes reviewing the evidence, medical and scientific data, and public health considerations before making a final determination on whether to reschedule a drug.

10. How likely is it that the DEA will refuse to reschedule marijuana?

- It is unlikely that the DEA will not follow HHS's recommendations even though they have a separate evaluation process. DEA generally defers to FDA in a rescheduling process. In light of DEA's lack of aggressive law enforcement related to marijuana generally since passage of the Rohrabacher-Farr Amendment in 2015, the fact that both HHS and the DEA are part of the same Administration which called for the review, it is unlikely DEA would not support the recommendation.

11. Will the Single Convention on Narcotic Drugs (our treaty through the UN), prevent the US from making this change, or ultimately legalizing marijuana in the U.S.?

- No, for three reasons. First, the President's directive implies that treaty considerations shouldn't determine marijuana's scheduling, as he requested the reconsideration of its status. Second, the U.S. is already non-compliant and would remain non-compliant with the Single Convention due to state-regulated adult-use markets, even if marijuana stays in schedule I. Third, the Single Convention allows non-compliance if it conflicts with the signatory state's constitutional framework, which applies due to the need to destroy the regulated state-level industry for compliance. The federal government would need to do so in 3 out of 4 states, many of which adopted legalization through their own constitutional amendments.



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12. What has ATACH done in support of rescheduling?

- Shortly after President Biden's October 6th, 2022 announcement, ATACH launched a Special Committee on Scheduling, which brought together cannabis companies, advocacy organizations, and scientific and legal experts to make the case for scheduling reform. ATACH is playing the leading association role in the scheduling effort nationally and is a founder and the administrator of the Coalition for Cannabis Scheduling Reform. Additionally, ATACH helped publish the June 2023 report as part of the administration's evaluation process which can be read here.

13. Why not hold out for descheduling (removing marijuana from the Controlled Substances List)?

- Descheduling is our strong preference, but was not offered as an option by Health and Human Services, and it is not politically viable. Nonetheless, rescheduling offers clear benefits, particularly considering how severe the restrictions are for Schedule I controlled substances.

14. Will this mean that the final goal of legalization (descheduling) will be harder to achieve?

- Significant reform in Washington often takes incremental change. As mentioned through this Q&A, even with rescheduling, these issues will not be fully resolved until we can remove marijuana from the list of controlled substances and treat it like alcohol. But we believe this change is a significant and important step forward.

15. How can individuals and businesses stay updated on developments related to marijuana rescheduling?

- ATACH is taking new members, whether they are marijuana licensees, hemp companies, state trade associations, or support businesses. This is an exciting time for the marijuana community and we invite you to join ATACH today!