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U.S. Department of Health and Human Services Releases Unredacted Recommendation to Move Marijuana to Schedule III: Seven Key Takeaways

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In this article, the authors offer key takeaways, including the recommendation that marijuana should be rescheduled from a Schedule I to a Schedule III controlled substance, from newly unredacted U.S. Department of Health and Human Services documents.

The U.S. Department of Health and Human Services (HHS) recently released over 250 pages of documents in response to a Freedom of Information Act (FOIA) request, including the recommendation that marijuana should be rescheduled from a Schedule I to a Schedule III controlled substance, and the results of the HHS's analysis. While industry and advocates have seen heavily redacted copies, the release of the recommendation infused excitement and hope into an industry strained by tensions between federal law and the laws of 38 states that have legalized cannabis for medical or adult use.

In 2022, HHS was tasked by President Biden with reviewing the status of marijuana under the Controlled Substances Act, using an eight-factor test[1] to assess:

1. The abuse potential compared to other drugs,
2. Whether there is a currently accepted medical use, and
3. The relative safety or ability to produce physical dependence compared to other drugs.

This article offers key takeaways from the newly unredacted HHS documents.

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HHS Determined Marijuana Poses Less Risk Than Other Scheduled Substances

After decades of prohibition and stigma rooted in fear about the dangers of marijuana, HHS took the historic step of acknowledging the relative safety of marijuana compared to other substances. HHS concluded that the "risks to the public health posed by marijuana are low compared to other drugs of abuse (e.g., heroin, cocaine, benzodiazepines), based on an evaluation of various epidemiological databases for emergency department (ED) visits, hospitalizations, unintentional exposures, and most importantly, for overdose deaths." Marijuana also proved far less harmful than alcohol when measuring adverse health events, overdoses, and the prevalence of driving under the influence.

HHS Recognizes That Cannabis Has Accepted Medical Uses

Almost two decades after the passage of the first state medical cannabis law, the federal government has recognized the accepted medical uses of cannabis in the treatment and management of disease. Unlike HHS's 2015 review, the widespread medical use of cannabis through state medical programs provided the breadth and depth of evidence needed to satisfy this criterion. As more states legalize, the body of research on medical cannabis will continue to grow, giving medical professionals more information on how medicinal cannabis can impact diseases.

Moving to Schedule III Does Not Diminish the Food and Drug Administration's Authority to Regulate Cannabis

News of HHS's recommendation to reschedule cannabis was not met with universal excitement from industry and advocates. Many fear the move to Schedule III would facilitate a takeover by the pharmaceutical industry and mean the end of state cannabis programs. Rescheduling would not change existing Food and Drug Administration (FDA) authority to regulate cannabis, nor would it change current incentives or pathways for the development of

cannabis pharmaceuticals. Rescheduling does not make cannabis an approved drug. Like hemp products, the FDA would likely step in where a cannabis product is marketed as an FDA-regulated product, including drugs, dietary supplements, or pet medicines, and the product or marketing presents a risk to public health or safety.

Moving to Schedule III Wouldn't Fully Legalize Cannabis, But It Could Reduce Business Risk and Increase Market Stability

Rescheduling marijuana does not decriminalize cannabis. Cannabis decriminalization, even with de-scheduling, would require an act of Congress. However, the move would end the application of Internal Revenue Service code section 280(e) to the legal cannabis industry. Code Section 280(e) presently taxes legal cannabis businesses like cartels with effective tax rates commonly ranging between 70 and 90 percent. The Congressional Research Service has affirmed that if the Biden administration reschedules cannabis, then 280(e) would no longer apply. Ending 280(e) for legal cannabis businesses could significantly lower their tax burden. This would help stabilize the industry, especially small businesses, and infuse the industry with resources to reinvest in research, infrastructure, and workforce. Additionally, the recognition of medical value and the shift in legal status from an illicit substance will likely soften the risk environment that increases business costs from real estate to banking.

This Action by the Biden Administration Should Increase the Pressure on Congress to End Federal Prohibition

Despite a significant majority of American voters favoring federal cannabis legalization, Congress has remained unwilling to progress with legalization. With HHS now acknowledging the relative safety and the acceptance of cannabis as medicine, this could mean some members of Congress evolve on their legalization stance. With bipartisan proposals on the table including the STATES Act, PREPARE Act, and incremental reforms such as the SAFE Banking Act, advocates and the industry should be prepared

to help lawmakers move past old thinking and find solutions to end the disconnect between state and federal governments to update antiquated criminal penalties and promote a safe and sensibly regulated cannabis industry.

HHS Reminds Us That CBD Does Not Have Meaningful Abuse Potential

HHS cited the FDA's review of the new drug application for Epidiolex, as well as its own eight-factor analysis that found, "Based on the totality of the available scientific data, cannabidiol (CBD) does not have meaningful abuse potential." While HHS has asserted that CBD lacks meaningful abuse potential, it remains stuck in a federal regulatory gray area that has limited industry growth and viability and led to inconsistent regulation in the states. Hemp and CBD companies should examine shifts in the federal government's position on cannabis products to help inform strategies to change the policy necessary to create a federal regulatory pathway for hemp consumer products.

Industry Focus on Responsible Use Initiatives and Education Is Critical to Protecting the Public and Ending Federal Prohibition

The safety concerns cited in the documents primarily relate to cannabis abuse—not use. While marijuana fared better than other controlled substances in many of the measures of safety, HHS's findings underscore the fact that even substances with less risk must still be used responsibly. Investment in internal responsible use policies, the promotion of responsible industry marketing practices, and advocating for policies to educate patients, consumers, and the public on responsible use, including abstinence and the dangers of intoxicated driving, is necessary to create a safe and sustainable regulated industry.

Conclusion

HHS rescheduling recommendation represents a historic shift in the federal government's position on marijuana. With the ball

now in the Drug Enforcement Administration's court, we anticipate more forward movement on rescheduling before the election in November. With rescheduling would come the need for substantial legislative fixes and federal agency engagement to align law and policy with marijuana's new status. Rescheduling would represent a giant step toward federal legalization. Advocates from industry to social justice will need to increase government engagement, especially with lawmakers in Washington, D.C., to ensure a seat at the table.

Notes

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1. The factors are: Actual or relative potential for abuse; scientific evidence of pharmacological effect, if known; state of current scientific knowledge regarding the drug; history and pattern for abuse; scope, duration, and significance of abuse; public health risk, if any; psychic or physiological dependence liability; and whether the substance is an immediate precursor of a substance already controlled.