Department of Health and Human Services, Washington DC Recommend Rescheduling Marijuana to Schedule III

The following facts were taken from the FDA's medical marijuana research findings reviewed by the National Institute on Drug Abuse in a 252 page document prepared by FDA's Controlled Substance Staff.

FDA Document: https://www.dropbox.com/scl/fi/pw3rfs9gm6lg80ij9tja6/2023-01171-Supplemental-Release-1.pdf?rlkey=v5atj0tcnhxhnszyyzcwdcvvt&dl=0

Botanical Cannabis is currently Schedule I defined as Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

The Department of Health and Human Services has recommended marijuana (botanical cannabis) be moved to Schedule III drugs which is defined as, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. DEA will have final say in re-scheduling.

Background about rescheduling documents:	**Research findings:**
The rescheduling recommendation letter was written on August 29th 2023 to the FDA but was not made public in its entirety until Jan. 12, 2024.	• The letter to the FDA from the Health and Human Services in Washington DC recommending rescheduling was only released to the public after a lawsuit ensued under the freedom of information act brought by attorney Matt Zorn and Shane Pennington. • This and the other findings of the review are a major departure in how the federal government views cannabis.
Information presented in the past:	**Current research findings in FDA document:**
"Marijuana is much too dangerous for Kansans, and it is on Schedule I for a reason."	• The Department of Health and Human Services and FDA concluded that marijuana is less harmful than other dangerous drugs. • They also found evidence of its medical benefits. This led to the reschedule recommendation. • The review was based on 8 different scientific criteria including its potential for abuse, the state of current scientific knowledge and its likelihood for physiological and psychological dependence.
"Marijuana is not really medicine."	• Before prohibition and removal from the US Pharmacopeia cannabis was grown and sold by US pharmaceutical companies. • It was commonly prescribed by physicians for 100 common illnesses. So yes, cannabis is medicine and was used as such here in the US. Cannabis legalization has spread rapidly across the country over the last decade. • 38 states have established medical marijuana programs. • The FDA-published review unequivocally counters the long-held stance that "cannabis has no accepted medical use." • The FDA also determined that the public health risk and potential for abuse is lower than other scheduled drugs.

"Marijuana is not really medicine." cont.	• There are currently well-established lists of medical conditions treated with cannabis that are supported with scientific studies and data. • Federal health officials said in the recommendation that "none of the evidence from the systematic reviews included in our analysis identified any safety concerns that would preclude the use of marijuana in the indications for which there exists some credible scientific support for its therapeutic benefit." • The FDA review found that the "largest evidence base for effectiveness exists for marijuana use within the pain indication."
Marijuana is highly addictive.	• Studies and data continue to show this statement is untrue hence the reschedule recommendation. • The FDA also found that cannabis use disorder defined as *psychological dependence* ranges from 10-20% in people who regularly use cannabis. • **NOTE: this is lower than tobacco, opiates, and alcohol.** • According to the HHS, "evidence also exists showing that the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others."
ADDITIONAL INFORMATION: Opponent Statements	**Study and Factual Data:**
"Marijuana causes psychosis"- information presented often pertains to adult use (recreational), not medical use.	• 66 papers were analyzed, of which 23 were cohort trials and 43 were reviews***. The relationship between cannabis use and psychosis has not been fully elucidated.*** • Cannabis use doubles the risk of developing psychosis ***in vulnerable people***. • There even exists a relationship regarding the dose used and the age of first use. NOTE: Potentially vulnerable patients will be evaluated, monitored and educated on cannabis use risk. They can also be denied a license. This is much different than an adult use program where anyone can have access to cannabis. It is well known that overconsumption of THC can cause a temporary response of anxiety and paranoia. These symptoms are self-limiting and go away as the cannabis is metabolized.
"Legalizing medical marijuana will lead to increased crime, auto accidents, have negative effects on the workforce and increase teen use."	• A comprehensive study was done in Wisconsin and included ***data from states with medical marijuana programs only. They found the following:*** Research on states that have fully legalized recreational — that is, ***adult use*** — cannabis shows a tradeoff: An overwhelming finding of higher traffic fatalities and, by the weight of the evidence, either no increase and possibly a decrease in statewide crime rates. • ***When you focus solely on the research related to medical cannabis legalization, you do not see that same tradeoff.*** • Medical cannabis legalization in other states has had either no impact or a positive impact on **property and violent crime** statewide.

Legalizing medical marijuana cont.	• Establishing a medical cannabis market will likely reduce **traffic fatalities** but will – at worst – have no impact on road safety. • Legalizing *medical* use of cannabis in a state increases the **labor force participation** of certain groups of individuals. • Medical cannabis legalization has caused a small reduction in **workers' compensation costs.** • Unlike adult-use legalization, the limited nature of existing research does *not* give us the ability to understand how medical use access will impact unemployment or disability claims at this time. The available research shows that a move to legalize medical cannabis will likely not disrupt the downward trend in youth use but will accelerate the trend we see in adult use. • Allowing the medical use of cannabis in a state will increase **adult medical use** of the substance. • A policy that only allows medical sales and use of cannabis appears to either have no impact or reduce **teen use**. ***NOTE: Since legal dispensaries have opened a federal study from the CDC shows teen use has been declining.***
"All people want to do is smoke and get high, and they're using a medical condition to do that."	• The percentage of people calculated to be using cannabis medically across the US in March 2023 is approximately 8.3 million people. Although smoking and vaping are popular ways to use marijuana recreationally, edibles, topicals, or tinctures are more commonly used for medical management. • Smoking and vaping offer fast effective symptom relief for acute problems and must not be discounted as an option for patients. • Non healthcare people as well as licensed healthcare workers must take care to not discriminate against any cannabis patient based on their own personal beliefs and bias.
Advocates just want to pass a medical marijuana program that will allow for "marijuana lite."	• The term "marijuana lite" has been used for several years during discussion and its definition is unclear and left open to personal interpretation causing confusion. Research shows this term often refers to Delta 8 THC. Delta 8 a mostly synthesized hemp-based product has been added to CBD products. It is claimed to produce a lesser intoxicating feeling than Delta 9. • **Public use of unregulated products containing delta-8-THC is greater in states where cannabis is criminalized, according to data published in the *Journal of the American Medical Association* (JAMA).** • Investigators affiliated with the University of Michigan, the University of Buffalo, and the Legacy Research Institute in Portland, Oregon analyzed survey results from over 1,100 respondents. Overall, 12 percent of respondents acknowledged having consumed delta-8-THC products in the past year**.** • ***Respondents who resided in states without either medical cannabis or adult-use access were more likely to report delta-8-THC consumption*.**

Advocates continued:	• *Concise, accurate terminology is important to avoid confusion during any cannabis discussion. Advocates would appreciate a definition of the term "marijuana lite" and how it applies to a Kansas medical cannabis program.*
"Dosage of medical marijuana are not standardized. People using medical marijuana should have a specific dose that they take for a specific illnesses and symptoms just like regular pharmaceuticals."	• Cannabis (Cannabis sativa) is a herbal plant, NOT a pharmaceutical product. It contains over 500 identified plant constituents in 3 groups called cannabinoids, terpenes, and flavonoids. (7) The cannabinoids in cannabis work by binding to specific sites in the brain and on the nerves. (Webb MD) Cannabis and other herbal preparations use all plant constituents to work synergistically within the body. *Pharmaceutical preparations work differently and can be standardized*. • Herbal drugs are not subject to the same testing, manufacturing, and labeling standards and regulations as pharmaceutical drugs. Many prescription drugs and over-the-counter medicines are also made from plant products, but these products contain only purified ingredients and are regulated by the FDA. • Herbal supplements may contain entire plants or plant parts. Herbal supplements come in all forms: dried, chopped, powdered, capsule, or liquid, and can be used in various ways, including: • Swallowed as pills, powders, and tinctures • Brewed as tea • Applied to the skin as gels, lotions, or creams • Inhaled vapor • Suppositories • Sublingual • ***The dosage of cannabis each patient uses is denoted by the patient and their response to using cannabis. Some patients require more or less than others to get symptom relief.*** • Doses can also be dependent on patient response to a specific cultivar (plant type). Patients often change plant types to find the specific product with the combination of cannabinoids and terpenes that help them best. • Patients will be guided by trained healthcare professionals to monitor dosage and effectiveness. • Many cannabis products come in specific THC/CBD dosages. 2.5, 5 and 10 mg. are commonly seen. Some products are 1:1,1:2 etc. (for example 5 mg THC/ 5 mg CBD is a 1:1 product) • Patients must have access to whole plant cannabis products. They need different cultivar (plant types), different administration options, and lab testing results that include terpene profiles. • There are well known use guidelines that have been developed including tolerance break information available to healthcare workers and patients.

References:	

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Office of the Assistant Secretary for Health
Washington, D.C. 20201

August 29, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Anne Milgram:

Pursuant to the Controlled Substances Act (CSA), 21 U.S.C. 811(b) and (c), I, the Assistant Secretary for Health, am recommending that marijuana, referring to botanical cannabis (*Cannabis sativa L.*) that is within the definition "marihuana" or "marijuana" in the CSA, be controlled in Schedule III of the CSA.

Upon consideration of the eight factors determinative of control of a substance under 21 U.S.C. 811(c), the Food and Drug Administration (FDA) recommends that marijuana be placed in Schedule III of the CSA. The National Institute on Drug Abuse has reviewed the enclosed documents (which were prepared by FDA's Controlled Substance Staff and are the basis for FDA's recommendation) and concurs with FDA's recommendation. Marijuana meets the findings for control in Schedule III set forth in 21 U.S.C. 812(b)(3).

Based on my review of the evidence and FDA's recommendation, it is my recommendation as the Assistant Secretary for Health that marijuana should be placed in Schedule III of the CSA.

Should you have any questions regarding this recommendation, please contact FDA's Center for Drug Evaluation and Research, Office of Executive Programs (cderexsec@cder.fda.gov), at (301) 796-3200.

Sincerely,

Rachel L. Levine, M.D.
ADM, USPHS
Assistant Secretary for Health

Enclosure