Drug Scheduling

SAM Smart Approaches to Marijuana
preventing another big tobacco

The Scheduling of Marijuana

Marijuana advocates have a long history of challenging the schedule of marijuana

The CSA allows for 2 ways a drug can be scheduled:

- **Through an act of Congress**
- **Through a bureaucratic process led by the DEA with help from HHS (FDA)**

Drug scheduling is typically reevaluated every 10 years unless there is a challenge or a directive

Marijuana was last evaluated in 2016 when President Obama's DEA chose to keep it in Schedule I

In October of 2022, President Biden initiated this process and in late summer of 2023, HHS publicly stated their recommendation that marijuana move to Schedule III

SAM Smart Approaches to Marijuana
preventing another big tobacco

Drug Scheduling: NOT a harm index, a legal categorization

DEA: classified into five (5) distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential

Schedule I substances have no accepted medical use and a high rate of abuse. Examples: heroin, marijuana, LSD, ecstasy

Schedule II substances have a high potential for abuse but some accepted medical use. Examples: oxycotin, adderall, methadone, fentanyl.

Schedule III substances are drugs with a moderate to low potential for physical and psychological dependence. Examples: products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone

SAM Smart Approaches to Marijuana
preventing another big tobacco

Drug Scheduling: NOT a harm index, a legal categorization

Schedule IV substances are drugs with a low potential for abuse and low risk of dependence. Examples: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

Schedule V substances are drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.

Why Schedule III?

On August 30th, 2023, HHS announced it recommended the reclassification of marijuana to Schedule III to the Drug Enforcement Administration (DEA). Four months later, HHS released an unredacted version of its recommendation to reclassify the drug. The 252-page review had been hidden from the public and was only released after legal action was threatened against HHS.

This HHS recommendation is based on cherry-picked data and represents a weak and intellectually dishonest argument to reschedule marijuana.

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

Moving marijuana to Schedule III would not legalize the drug, nor allow its prescription

The industry does NOT want marijuana to be treated like or regulated like a prescription drug

Schedule III substances are not subject to IRS Section 280E, meaning they can deduct business expenses, drastically increasing their profit margins. This means more advertising, commercialization, and normalization.

SAM Smart Approaches to Marijuana
preventing another big tobacco

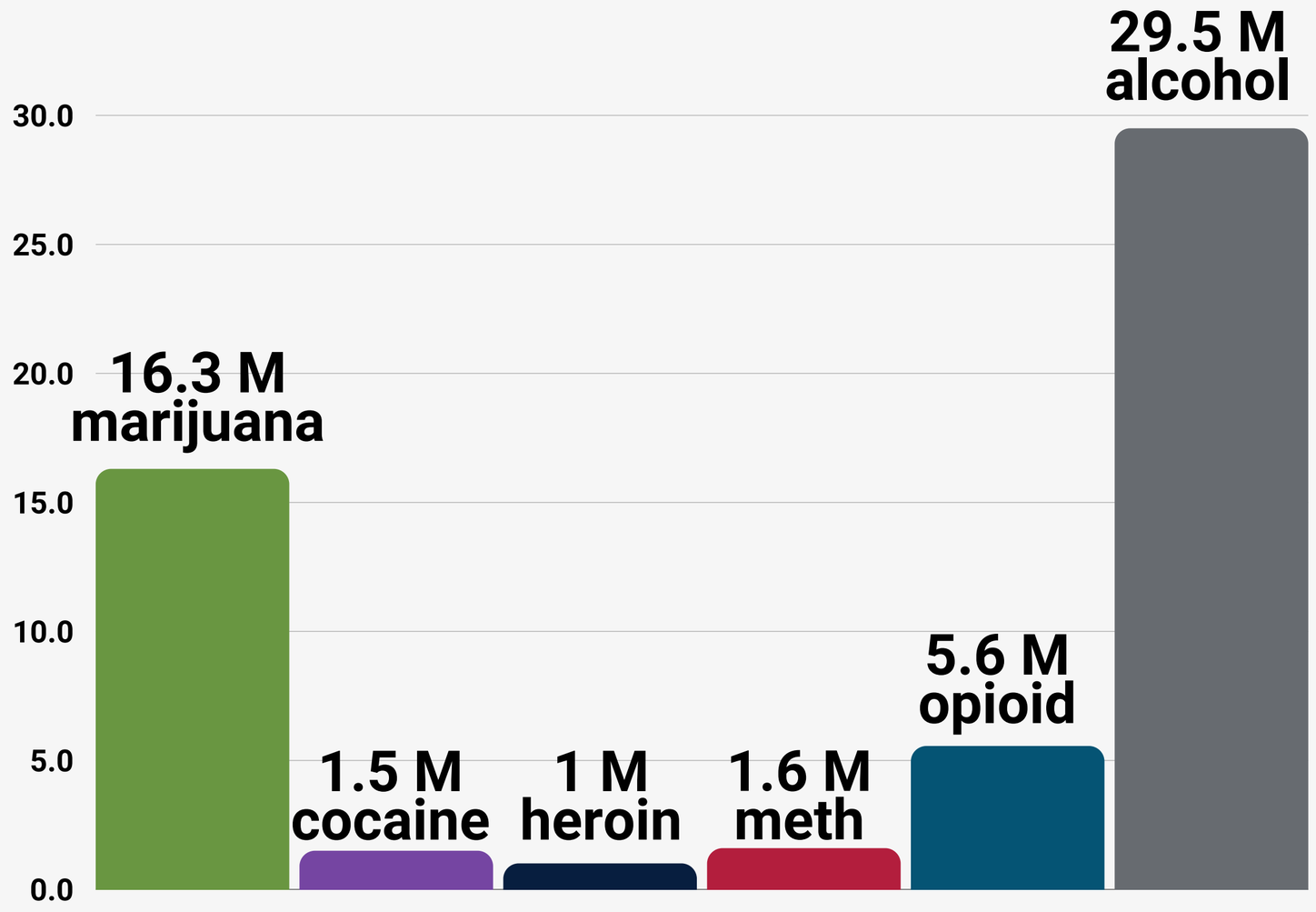

Among 12–17-year-olds, marijuana was the most common substance (including alcohol) associated with a substance use disorder.
https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases
SAM
Smart Approaches to Marijuana
preventing another big tobacco

National Institute on Drug Abuse, 2021

SAM Smart Approaches to Marijuana
preventing another big tobacco

Rates of Substance Use Disorder

Rates of substance use disorder in the US across all age groups



https://www.samhsa.gov/data/release/2021-national-survey-drug-use-and-health-nsduh-releases

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

In years past, the FDA, an agency of the HHS in charge of approving medicinal drugs, used an established five-factor analysis in determining whether Schedule I drugs have "currently accepted medical use." This test was established by the Attorney General in response to the DC Circuit Court's directive in *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration* (1994).

In this case, the court analyzed whether the existing 8 factor scheduling analysis, which looks at factors like availability, was a sufficient test for Schedule I drugs which are not widely available. The Court directed the AG (at the time) to determine a sufficient test specific to Schedule I drugs and the AG produced a 5 factor analysis that has been used ever since.

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

It is not clear why the FDA moved away from the five-factor test, unless the agency approached the rescheduling review with a pre-determined conclusion.

The five-factor test has been used for decades by Republican and Democratic Administrations. Additionally, the United States Court of Appeals for the District of Columbia Circuit examined and validated the test in *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration*.

The marijuana industry petitioners in that case even conceded that the five-factor test had no flaws, as explained in the opinion for the court.

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

In the current report supporting the recommendation to reschedule marijuana, the FDA changed these criteria to get its desired answer.

If marijuana had been held to the same standards as other drugs, it would not be deemed to have "currently accepted medical use," due to the infeasibility of measuring all strains and the insufficient amount of existing research into its safety and efficacy.

The FDA's new two-factor test explicitly states that studies used to support marijuana's accepted medical use do not need to be controlled, a standard that was required in the five-factor test (save an evaluation done by a consensus of experts).

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

The FDA now considers the existence of state medical marijuana programs as evidence that marijuana has currently accepted medical use.

A drug's popularity among the public has never been used as a standard to determine medicine.

The FDA's novel standard in recommending marijuana's rescheduling is rooted in a logical fallacy: some people say that marijuana is medicine, so marijuana must be medicine.

The FDA is delegating its authority to determine that medications are safe and effective to popular opinion, a practice that not only exceeds the statutory authority of the agency but makes a mockery of the congressional intent of the Food, Drug, and Cosmetic Act to protect the public health.

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

The FDA compares marijuana to a limited, hand-picked list of other controlled and noncontrolled substances (e.g., heroin, alcohol, cocaine), not all Schedule I drugs.

In the recommendation, the FDA measured marijuana's potential for abuse by comparing it to a hand-picked selection of Schedule I, II, and III drugs.

Comparing marijuana's abuse potential against all Schedule I drugs would have allowed for a more rigorous analysis, but it would not have allowed the FDA to conclude that marijuana belongs in Schedule III.

To qualify for Schedule III, a drug or other substance must have "potential for abuse less than the drugs or other substances in Schedules I and II" (21 USC 812(b)). Fifty years of data published by HHS show that marijuana does not meet this standard.

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

None of the studies used by the FDA to justify its claim that marijuana is medicine support that conclusion.

The FDA determined that marijuana is acceptable for medical use for pain, nausea and vomiting, and anorexia. Only three studies were used to justify this claim.

The first concluded that results were “inconclusive or mixed.” The second relied primarily on a study for which the results were not statistically significant. In the third, the FDA concluded that the positive effects of marijuana in the study were small and that “the increased risk of dizziness, nausea, and sedation [from marijuana use] may limit the benefit”.

Furthermore, some of these studies were with inhalable marijuana; prior FDA evaluations have excluded inhalable marijuana studies due to their unreliability and questionable practices.

SAM Smart Approaches to Marijuana
preventing another big tobacco

Why Schedule III?

Full SAM analysis of HHS rationale

SAM Smart Approaches to Marijuana
preventing another big tobacco

Potential Legal Challenges

Treaty requirements: The United States is a signatory to the United Nation's 1961 Single Convention on Narcotic Drugs, which requires that marijuana and other drugs be scheduled. In 2016, when they rejected the rescheduling of marijuana, the DEA said, "schedules I and II are the only possible schedules in which marijuana may be placed," so as to maintain compliance with the treaty.

The weak rationale of HHS: The 5 part test was developed by DEA as directed by the DC Circuit court, it could be argued that HHS has to follow those factors when recommending as HHS lacks the statutory authority to change the criteria

Rulemaking Challenges

SAM Smart Approaches to Marijuana
preventing another big tobacco

What's Next?

The DEA's Decision

Notice of Proposed Rulemaking

Public Comment Period

Final Rule

(Potential) Congressional Review Act

SAM Smart Approaches to Marijuana
preventing another big tobacco