

Executive Summary

On August 30th, 2023, the Department of Health and Human Services (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 <u>252-page review</u> 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. This summary describes just a few of the many flaws in the HHS methodology and conclusions. SAM's full report provides an indepth analysis of what the HHS got wrong and how the process could have been strengthened.

1. 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." In the current report supporting the recommendation to reschedule marijuana, the FDA <u>changed</u> 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. In fact, 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).

2. 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 <u>Alliance for Cannabis Therapeutics v. Drug Enforcement</u> <u>Administration</u>. The marijuana industry petitioners in that case even conceded that the fivefactor test had no flaws, as explained in the opinion for the court.

3. 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. Supreme Court Justice Steven Breyer in <u>Gonzalez v Raich (545 U.S. 1 (2005)</u>, a case involving a medical necessity for the use of marijuana, <u>opined</u> during oral arguments that "medicine by regulation is better than medicine by referendum." The Court's 6-3 decision, which Justice Breyer joined, upheld the prohibition of marijuana for medical use under the Controlled Substances Act (CSA). 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. Following the FDA's logic, psychedelic drugs, which are seeing a popular push for medical legalization, could also be considered medicine and be rescheduled due to shifting public opinion.

4. 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. For example, the FDA compared marijuana to heroin, another Schedule I drug. The recommendation claims that because marijuana has a lower abuse potential than heroin, it shouldn't be in the same category. Yet the FDA failed to compare marijuana to other Schedule I drugs, such as LSD. 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.

5. 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 (University of Florida), concluded that results were "inconclusive or mixed." The second (National Academies of Sciences & Medicine) relied primarily on a study for which the results were not statistically significant. For the third (Agency for Healthcare Research and Quality), 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" (page 27 of 252). Furthermore, some of these studies were with inhalable marijuana; prior FDA evaluations have excluded inhalable marijuana studies due to their unreliability and questionable practices.

Full Analysis

Does Marijuana Have "Currently Accepted Medical Use"?

When the FDA and DEA determine whether a drug has "currently accepted medical use"—as they did for <u>marijuana in 2016</u>, <u>five synthetic benzodiazepine substances</u> in July 2023, and <u>nine</u> <u>fentanyl-related substances</u> in December 2023, among others—they rely on the use of an established <u>five-part test</u>. The five parts are:

- 1. The drug's chemistry must be known and reproducible.
 - a. ""The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, <u>21 U.S.C. 321(j)</u>, is sufficient to meet this requirement."
- 2. There must be adequate safety studies.
 - a. "There must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder."
- 3. There must be adequate and well-controlled studies proving efficacy.
 - a. "There must be adequate, well-controlled, well-designed, well-conducted, and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could be fairly and responsibly concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder."
- 4. The drug must be accepted by qualified experts.
 - a. "The drug has a New Drug Application (NDA) approved by the Food and Drug Administration, pursuant to the Food, Drug and Cosmetic Act, <u>21 U.S.C. 355</u>. Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus."
- 5. The scientific evidence must be widely available.
 - a. "In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and

effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder."

The 2016 scheduling review of marijuana concluded: "Marijuana does not meet any of the five elements necessary for a drug to have a 'currently accepted medical use.'"

However, likely knowing marijuana would again fail to pass this established five-part test, which was previously used to assess marijuana and continues to be used to assess other drugs, the FDA developed a new "two-part test" (page 3 of 252). This new test "takes into account the current widespread medical use of marijuana under the supervision of licensed health care practitioners (HCPs) under state-authorized programs."

Part 1 "considered whether there is widespread current experience with medical use of marijuana in the United States by licensed HCPs operating in accordance with implemented state-authorized programs, where such medical use is recognized by entities that regulate the practice of medicine under these state jurisdictions."

Part 2 "evaluated whether there exists some credible scientific support for at least one of the medical conditions for which the Part 1 test is satisfied."

In effect, the latest review from the FDA asserted that marijuana has "currently accepted medical use" because it is prescribed by health care practitioners through medical marijuana programs—often following the passage of industry-funded ballot measures to create said medical marijuana markets.

The FDA changed the established test used to determine whether a drug has "currently accepted medical use" in order to get the answer it wanted. If marijuana had been held to the same standards as other drugs, it would not have been deemed to have "currently accepted medical use," due to the unfeasibility of measuring all strains and the insufficient amount of existing research into its safety and efficacy.

Though the FDA made its determination based on marijuana's prescription by health care practitioners, the DEA in 2016 specifically <u>noted</u> that "medical practitioners are not qualified by scientific training and experience to evaluate the safety and effectiveness of drugs." Moreover, DEA <u>explained</u>, "based on the above definition of a 'qualified expert', who is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug, state-level medical marijuana laws do not provide evidence of a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder."

If we analyze some of the FDA's conclusions in this recommendation through the lens of the five-factor test, it's clear that marijuana would fail. To pass the test, all five factors must be met.

According to the evidence outlined by the FDA, marijuana would not meet *any* of the factors. Below, find the descriptions of each factor and a quote from the FDA recommendation showing that marijuana does not fulfill the respective factor.

- 1. The drug's chemistry must be known and reproducible.
 - a. "Marijuana samples derived from various cultivated chemovars may vary with respect to their composition and concentration of various chemical constituents, including whether they contain significant amounts of Δ9-THC or other cannabinoids (Appendino et al., 2011; Smith et al., 2022). As a consequence, marijuana products from different strains will have differing biological and pharmacological profiles" (page 11 of 252).
- 2. There must be adequate safety studies.
 - a. FDA's evaluation in Part 2 is not meant to be, nor is it, a determination of safety and efficacy under the Federal Food, Drug, and Cosmetic Act's (FD& C Act's) drug approval standard for new human or animal drugs" (page 25 of 252).
 - b. The clinical safety data identified in the literature from controlled trials were generally consistent between sources but limited in the rigor of safety reporting" (page 27 of 252).
- 3. There must be adequate and well-controlled studies proving efficacy.
 - a. "In evaluating whether there exists some credible scientific support under Part 2 of the CAMU test for a particular use, factors considered in favor of a positive finding included whether: 1) favorable clinical studies of the medical use of marijuana, although not necessarily adequate and well-controlled clinical studies that would support approval of a NDA, have been published in peer-reviewed journals" (page 26 of 252).
- 4. The drug must be accepted by qualified experts.
 - a. "It is important to note that, to date, FDA has not approved an NDA for a drug product containing botanical marijuana" (page 4 of 252).
 - b. "The American Psychiatric Association (APA)... stated that marijuana is known to worsen certain psychiatric conditions" (page 116 of 252).
- 5. The scientific evidence must be widely available.
 - a. "Our review of the available information identified mixed findings of effectiveness across indications" (page 26 of 252).

Two-Factor Test Analysis: Part 1

Part 1 of the FDA's new, made-up test about whether marijuana has "currently accepted medical use" looked at "whether there is widespread current experience with medical use of marijuana in the United States by licensed HCPs operating in accordance with implemented

state-authorized programs, where such medical use is recognized by entities that regulate the practice of medicine under these state jurisdictions." The review said, "Currently, more than 30,000 HCPs are authorized to recommend the use of marijuana for more than six million patients with medical conditions that are enrolled in authorized marijuana for medical use programs" (page 81 of 252).

However, this does not mean that 30,000 health care practitioners actively recommend the use of marijuana to their patients, even if they are authorized to do so. An April 2023 <u>study</u> found only 10% of physicians "had ever signed a medical cannabis authorization form for their patients."

What's more, cross referencing the number of practitioners who are authorized to prescribe medical marijuana, according to Table 4 of the report (page 96 of 252), by the number of physicians in a state, reported by the <u>Kaiser Family Foundation</u>, reveals that only a small minority of doctors even bother to become authorized to prescribe medical marijuana. In states with medical marijuana—but not recreational marijuana, where individuals would not need to seek a prescription—few doctors prescribe it:

- 989 out of 8,169 physicians in Arkansas
- 35 out of 4,557 physicians in Hawaii
- 1,821 out of 9,595 physicians in Iowa
- 122 out of 7,274 physicians in Mississippi
- 1,273 out of 4,519 physicians in New Hampshire
- 340 out of 2,271 physicians in North Dakota
- 1,812 out of 56,658 physicians in Pennsylvania
- 208 out of 2,254 physicians in South Dakota
- 473 out of 7,421 physicians in Utah
- 131 out of 5,882 physicians in West Virginia

In states where medical marijuana is legal, there is not "currently accepted medical use" among physicians. In no state is there a 50.1% majority of physicians—which would indicate most accept its medical use—that utilize medical marijuana.

Two-Factor Test Analysis: Part 2

Part 2 of the made-up test "evaluated whether there exists some credible scientific support for at least one of the medical conditions for which the Part 1 test is satisfied." To measure this, the "factors considered in favor of a positive finding included whether: 1) favorable clinical studies of the medical use of marijuana, although not necessarily adequate and well-controlled clinical

studies that would support approval of a new drug application (NDA), have been published in peer-reviewed journals and/or 2) qualified expert organizations (e.g., academic or professional societies, government agencies) have opined in favor of the medical use or provided guidance to HCPs on the medical use" (page 113 of 256).

The first aspect lowers the bar for marijuana and does not require the same rigor or degree of evidence that is required for new drugs. These studies, or lack thereof, would not have led to marijuana's approval if marijuana had been reviewed like other drugs.

The FDA concludes that marijuana has a currently accepted medical use for three conditions: "anorexia related to a medical condition; nausea and vomiting (e.g., chemotherapy-induced); and pain" (page 29 of 252). Yet, by the FDA's own admission, the research supporting these claims are mixed at best.

Pain

The recommendation explained that "the largest evidence base for effectiveness exists for marijuana use within the pain indication." The first piece of evidence the FDA uses to support the medical use of marijuana for pain is "a systematic review of scientific and medical literature" conducted by the University of Florida (UF) under contract with the FDA. The FDA touts the study, writing, "UF epidemiologists identified some data supporting effectiveness of marijuana." In the same paragraph, though, the FDA undermines the UF study entirely, stating, "however, they [UF] ultimately concluded the results are inconclusive or mixed" (pages 26-27 of 252).

The strongest evidence the FDA cites suggesting that marijuana assists with pain is the National Academies of Sciences & Medicine (NASEM) report from 2017, which concluded that there is "substantial evidence" that marijuana helps with pain (page 27 of 252). The NASEM report itself states that the most comprehensive study supporting this notion was <u>Whiting et al. (2015)</u>. In the "Results" section of Whiting et al., the authors write, "Most trials showed improvement in symptoms associated with cannabinoids but these associations did not reach statistical significance in all trials." The odds ratio (OR) interval for the "reduction in pain" category was 0.99-2.00, indicating that Whiting et al. did not find that marijuana reduced pain at a statistically significant value. Further, Whiting et al. had to issue four corrections to their paper after publishing incorrect values and graphs.

The only other source the FDA used to justify its assessment that marijuana is effective for pain management was the Agency for Healthcare Research and Quality's (AHRQ) living systematic review. The FDA admits, though, that the AHRQ review "concluded that there is some support for the use of marijuana-related products in the treatment of pain, but overall concluded these effects were small and the increased risk of dizziness, nausea, and sedation may limit the benefit" (page 27 of 252).

Anorexia, Nausea, and Vomiting

The FDA only used one study (the UF review) to justify its claim the marijuana is accepted as medicine for anorexia and nausea and vomiting. The UF review noted that there is only "low- to moderate-quality evidence supporting the use of marijuana as medical treatment" for these conditions. Further, the FDA acknowledges that its own "review of systematic reviews showed mixed results for these indications" (page 27 of 252).

The second aspect, about whether expert organizations support the medical use of marijuana, concluded, "The vast majority of professional organizations did not recommend the medical use of marijuana in their respective specialty however, none specifically recommended against it, with the exception of the American Psychiatric Association (APA), which stated that marijuana is known to worsen certain psychiatric conditions" (page 201 of 252). Given that "the vast majority of professional organizations did not recommend the medical use of marijuana," this should have been interpreted to mean that there is no "currently accepted medical use" for marijuana. Additionally, many leading medical associations oppose medical marijuana, particularly when it is not the result of an NDA. For example:

- The <u>American Psychiatric Association</u> said, "There is currently no scientific evidence to support the use of cannabis as an effective treatment for any psychiatric illness," noting that "much of the evidence supporting cannabis use for non-psychiatric medical diagnoses remains anecdotal and based on small, limited studies."
- The <u>American Academy of Pediatrics</u> "opposes 'medical marijuana' outside the regulatory process of the US Food and Drug Administration," adding that the organization "opposes legalization of marijuana because of the potential harms to children and adolescents."
- The <u>American Medical Association</u>, in 2023, took the position that "scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use."

Abuse Potential: Hand-Picked Selection of Comparator Drugs

Though the designation of marijuana as having "currently accepted medical use" is the most notable point of the HHS report, the FDA also reviewed data about its abuse potential and impacts for public health and safety. Many of the FDA's arguments were misleading, halftruths, or omitted contradictory information. A few of the most glaring examples are outlined below. The review said, "FDA evaluated safety outcomes related to marijuana use in the setting of nonmedical use, use of uncertain intent, and unintentional exposure through a variety of epidemiological data sources and in relation to several comparator substances controlled under the CSA" (page 28 of 252).

Other than ketamine, a Schedule III drug, the FDA did not compare the abuse of marijuana to any hallucinogens, many of which are in Schedules I and II. <u>Psilocybin</u> (mushrooms), <u>LSD</u>, <u>peyote</u>, <u>mescaline</u>, <u>MDMA</u> (ectsasy), and <u>DMT</u> are Schedule I substances; <u>PCP</u> is Schedule II—all of these drugs are <u>included in the annual National Survey on Drug Use and Health</u> (NSDUH), which would have allowed for their inclusion in the HHS' review. Additionally, all hallucinogens but DMT have higher rates of past-year use than ketamine, making ketamine an odd choice for inclusion as the only hallucinogen, the NSDUH found. In 2022, the NSDUH reported there were more past-year marijuana users than past-year users of any hallucinogen, combined. While approximately 31 in 100 marijuana <u>users</u> developed a <u>cannabis use disorder</u>, only 1.2 in 100 hallucinogen users developed a hallucinogen use disorder—yet many of these substances remain placed in Schedules I or II. The NSDUH reported past-year marijuana users. If other or additional hallucinogens had been included as comparators, marijuana would have had a much greater perceived potential for abuse.

The review said, "Out of 1.4 million admissions documented in the 2020 TEDS dataset, the most frequently reported primary drug of admission was alcohol (31%, n= 442,014 admissions), followed by heroin (21%, n=292,126 admissions), marijuana (10%, n=139,481 admissions), and cocaine (5%, n=71,725 admissions). Other comparator drugs, including oxycodone, benzodiazepines, hydrocodone, ketamine, or tramadol, were each reported as the primary drug less than 2% of admissions." Though omitted from the FDA's review, <u>TEDS</u> also reported that "hallucinogens" were the primary substance for only 1,899 admissions, or 0.13% of all admissions—there were 73 times more admissions for marijuana.

Moreover, the <u>CDC's WONDER database</u> indicated there were 25 overdose deaths that listed either LSD (ICD-10 code: T40.8) or "Other and unspecified psychodysleptics [hallucinogens]" (T40.9) as a contributing cause of death in 2021. In comparison, "cannabis derivatives" (T40.7) were listed alongside 1,159 overdose deaths.

The lack of inclusion of hallucinogens other than ketamine led the FDA to conclude 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 ED visits, hospitalizations, unintentional exposures, and most importantly, for overdose deaths" and "These evaluations demonstrate that there is consistency across databases, across substances, and over time and that although abuse of marijuana produces clear evidence of a risk to public health, that risk is relatively lower than that posed by most other comparator

drugs" (page 58 of 252). Compared to hallucinogens, of which many are in Schedule I, marijuana would be perceived as much more harmful; with the selective inclusion of comparators like heroin, also in Schedule I, marijuana would be perceived as much less harmful.

The review noted, "Typically, substances that are not controlled under the CSA are not utilized as comparator drugs for scheduling placement considerations because they may not have been formally evaluated for abuse potential in standard preclinical and clinical abuse-related studies. However, alcohol is included in the analyses because of its extensive availability and use in the United States, which is also observed for nonmedical use of marijuana (also known as recreational use of marijuana)" (page 6 of 252).

Given that alcohol was explicitly exempted from the CSA, it should not have been used as a comparator substance. The inclusion of alcohol skews the presentation of the data, downplaying the relative risks of marijuana, for example with: "These data demonstrate that alcohol has the highest prevalence of past-year only use, followed by nonmedical use of marijuana. The prevalence of the other comparators is far below that of alcohol and marijuana" (page 34 of 252). Alcohol is not used to determine the scheduling of fentanyl and other narcotics; it should not have been used to review marijuana.

FDA Ignored Impacts on Pregnant Woman and Children

Factor 6, "what, if any, risk there is to public health," did not consider or include the unique risks that marijuana poses to pregnant women (page 45 of 252).

The Substance Abuse and Mental Health Services Administration (SAMHSA) warned, "Marijuana use during pregnancy can be harmful to a baby's health and cause many serious problems, including stillbirth, preterm birth, and growth and development issues," adding that "THC and other chemicals in marijuana can be passed to a baby through breast milk, increasing the baby's risk for problems with brain development." The CDC noted, "studies suggest that marijuana use by persons during pregnancy could be <u>linked to problems</u> with attention, memory, problem-solving skills, and behavior in their children later in life." And the FDA "<u>strongly advises against</u> the use of cannabidiol (CBD), tetrahydrocannabinol (THC), and marijuana in any form during pregnancy or while breastfeeding." A new <u>study</u> conducted by Duke Health found that marijuana use during pregnancy is linked to increases in childhood cancers. Of note, the effects of marijuana on pregnant women were referenced in the 2016 scheduling review of marijuana.

According to the <u>NSDUH</u>, the percentage of pregnant women between the ages of 15 and 44 that used marijuana in the past month increased from 7.1% in 2021 to 7.9% in 2022. In

comparison, it reported cocaine at 0.0%, heroin at 0.0%, LSD at 0.0% (any hallucinogen at 0.4%), opioids at 0.8%, and alcohol at 11.0%—again highlighting how the inclusion of alcohol changes the frame of reference. Of particular concern, the NSDUH also found that 15.3% of pregnant women between the ages of 18 and 25 used marijuana in the past month.

FDA Downplayed Impact of Daily Marijuana Use

The review said, "In NSDUH, among people with past-year marijuana nonmedical use, approximately half of individuals reported nonmedical marijuana use an average of less than 5 days/month while another 30% reported nonmedical marijuana use for an average of more than 20 days/month" (page 8 of 252).

While the FDA compared marijuana to alcohol, cocaine, and heroin for other measures, it did not for this one. Marijuana is misused much more frequently than many other drugs. According to the <u>2022 NSDUH</u>, past-month marijuana users used marijuana on an average of 16.2 days. In comparison, the average for alcohol was 8.1 days, hallucinogens was 2.8, cocaine was 6.4, and heroin was 20.3. Moreover, the average number of days of use among past-year users was 142.1 for marijuana, 15.3 for hallucinogens, 41.5 for cocaine, 89.1 for alcohol, and 173.8 for heroin.

While past-month use is indicative of heavier use, compared to past-year use, the FDA omitted the NSDUH's estimates of the prevalence of daily use (page 35 of 252). In 2022, according to the NSDUH, there were <u>15.07 million daily marijuana users</u>, compared to 116,000 daily cocaine users, 272,000 daily heroin users, 37,000 daily hallucinogen users, and 11.75 million daily alcohol users. Moreover, they found 24.4% of <u>past-year marijuana users</u> were <u>daily users</u>, compared to 2.2% of cocaine users, 0.4% of hallucinogen users, 26.0% of heroin users, and 6.6% of alcohol users. Among past-month users, 48.4% of marijuana users were <u>daily users</u>, compared to 9.8% of cocaine users, 2.4% of hallucinogen users, and 15.1% of alcohol users (heroin was omitted from SAMHSA's results due to "low precision").

The review said, "there was a 30% prevalence of meeting the criteria for marijuana SUD among individuals who used marijuana for nonmedical reasons only, with 17% of individuals with past-year nonmedical only use having a mild SUD, 8% having a moderate SUD, and 5% having a severe SUD" (page 41 of 252).

Yet FDA did not track increases over time. There were 15.07 million <u>daily marijuana users</u> in 2022, up from 13.30 million in 2021. Beyond the 13.89% increase in cannabis use disorder between 2021 and 2022 estimated by the NSDUH, there was an 8.51% increase in mild cases, a

20.32% increase in moderate cases, and a 22.88% increase in severe cases, indicating that the severity of cannabis use disorder has been increasing.

Misleading Statistics on Driving Under the Influence

The review stated, "The prevalence of driving under the influence of a drug when all individuals over the age of 16 are combined was 4% for marijuana and 5% for alcohol, with less than 1% for cocaine and for heroin" (page 51 of 252).

This statistic is misleading because it did not adjust for usage rates. The FDA should have reported the percentage of past-year users who drove under the influence of the substance, rather than the share of the entire population—which raises the relative share of alcohol because it is has a higher rate of use. For example, in 2022, 20.4% of <u>past-year marijuana users</u> over the age of 16 <u>drove under the influence of marijuana</u>, compared to 8.9% of past-year alcohol users over the age of 16 who drove under the influence of alcohol, according to the NSDUH.

Likewise, the review failed to consider traffic fatalities due to drivers under the influence of marijuana as a harm to public health—the 2016 scheduling review of marijuana referenced the possibility for an increase in traffic accidents and deaths associated with marijuana. Multiple analyses have reported that the presence of THC, the psychoactive component in marijuana, <u>doubles</u> the likelihood of a driver being involved in a crash. A 2022 <u>report</u> from the NTSB noted that marijuana is the second most commonly detected substance after alcohol in arrests for impairment and crashes—it is more often detected than stimulants, sedatives, and prescription drugs. Moreover, since recreational marijuana was legalized in Colorado 2013, <u>traffic deaths</u> where drivers tested positive for marijuana increased 138% while all Colorado traffic deaths increased 29%.

For questions and inquiries, please contact <u>info@learnaboutsam.org</u> Website: <u>www.learnaboutsam.org</u>