

Cannabis

HHS acknowledges some medical benefits of marijuana

Government Regulations

Additional details from HHS filing

Last Friday, Health and Human Services (HHS) released a 252-page document in response to a Freedom of Information Act filing by an individual. Last year, the HHS undertook a review of marijuana and came to the conclusion to recommend that marijuana be rescheduled from Schedule I (most restrictive) to Schedule III (restrictive, but notably improved access) of the CSA (Controlled Substances Act) based on its finding that that marijuana meets the three criteria for placing the substance in Schedule III of the CSA. The HHS/FDA report found that 1) marijuana has a potential for abuse less than other drugs or substances in Schedules I or II; 2) marijuana has a currently accepted medical use in treatment in the US for such ailments as anorexia, anxiety, epilepsy, inflammatory bowel disease, nausea and vomiting (chemotherapy-induced), pain and post traumatic stress disorder (PTSD), and 3) abuse of marijuana may lead to moderate or low physical dependence or higher psychological dependence. Data suggests that withdrawal symptoms typically peak within 2-6 days and decline over 1-2 weeks as the drug is eliminated from the body. The report clearly noted that while their analysis suggested some medical benefit, marijuana was not FDA approved.

DEA expected to make its recommendation by mid-year

Having received this full document in August from HHS, the Attorney General and the DEA (Drug Enforcement Agency) are currently holding their own review. Press commentary by current and former government officials suggest that topical DEA findings are typically announced by mid-year of an election year. If the DEA report indicates its concurrence with the HHS evaluation to reclassify, then press reports suggest a public commentary period will be required. We would note that in 2016, the DEA rejected a petition to reschedule marijuana, citing that that health officials believed at the time that marijuana had a “high potential for abuse, no accepted medical use in the US and lacks an acceptable level of safety for use even under medical supervision”. While the HHS filing appears to change its stance on many of the reasons for the DEA’s last denial, it remains to be seen if the DEA’s comments will follow those of the HHS. We would note that government data suggests that some 70% of Americans support marijuana legalization. We see a scheduling change in US federal laws regarding marijuana as key to expanding revenue opportunities for cannabis stocks and institutional investor interest in the sector.

Background

In October 2022, President Biden asked the Secretary of the Dept. of Health and Human Services (HHS) and the Attorney General “to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law.” The eight questions that the HHS looked at are discussed on page 2. See [What are the differences btwn cannabis scheduling reform options?](#) for additional color on cannabis reform options.

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12646736

Timestamp: 16 January 2024 04:07PM EST

16 January 2024

Equity
United States
Cannabis

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FDA = Food & Drug Administration

DEA = Drug Enforcement Agency

NIDA= National Institute on Drug Abuse

Brief overview of HHS review

In October 2022, President Biden asked the Secretary of the Dept. of Health and Human Services (HHS) and the Attorney General “to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law.” In considering the scheduling of marijuana, the Secretary of HHS is required to consider in a scientific and medical evaluation 8 factors under the Controlled Substances Act (CSA), including

- 1) **Its actual or relative potential for abuse.** The HHS found that evidence shows that some individuals are taking marijuana in amounts sufficient to create a hazard to their health and safety to others in the community. It also found evidence that the vast majority of individuals are doing so in a manner that does not lead to danger outcomes to themselves or others.

Data from 2015 to 2019 indicates that prevalence of past-year use of alcohol was 5-6x greater than that of past-year nonmedical use of marijuana. Additionally, the prevalence of past-year nonmedical use of heroin, cocaine, oxycodone, hydrocodone, tramadol, benzodiazepines, and zolpidem was 4-5x less than that for marijuana.”

The HHS also found that a lower risk to public health compared to other drugs of abuse (heroin, oxycodone, cocaine), based on emergency dept. visits, hospitalization, unintentional exposures and overdose deaths.

- 2) **Scientific evidence of its pharmacological effect, if known.** Cannabis is a plant that contains many natural constituents, including cannabinoids that vary in concentration and composition. As a result, marijuana products from different strains have different biological and pharmacological profiles. Common responses include sedative responses (drowsiness, relaxation), positive responses (euphoria, merriment, exhilaration, pleasure), negative responses (anxiety, restlessness, agitation), perception changes (hallucinations, sexual/spiritual enhancement), social/cognitive changes (illusions, delusions, impairment judgment) and physiological responses (nausea, facial flushing, dry mouth) among other responses.
- 3) **The state of current scientific knowledge regarding the drug or other substances.** In this section the HHS discusses the chemistry and human pharmacokinetics of marijuana. There was a discussion on the high variability of marijuana and marijuana derived products, given product composition, product types and other factors. It also noted that each state program “has a set of standards for manufacturing, testing, labeling and packaging but each state’s controls are different, leading to a wide variety of products across state-authorized programs. Additionally, the illicit market is not subject to any standards or oversight”, making for a large degree of variation in forms for consumption.
- 4) **Its history and current pattern of abuse.** This section reviews the history of cannabis control and legislation from the 1906 passage of the Pure Food and Drug Act to present. It reviews its current position as a Schedule I drug on the CSA along with passage of medical/adult use laws in many states.
- 5) **The scope, duration, and significance of abuse.** This section reviews data over time from several federal sources, such as the CDC, Youth Behavior and many other reports/surveys. The HHS’ conclusion from an evaluation of various epidemiological databases related to the medical outcomes from abuse of selected drugs “is that for all measures that were evaluated from 2015 to 2020, the rank order of the comparators in terms of greatest adverse consequence typically places alcohol, heroin, and/ or cocaine in the first or

immediately subsequent positions, with marijuana in a lower place in the ranking.”

- 6) **What, if any, risk there is to the public health.** This section reviewed the data on overdoses and healthcare data regarding poisoning from marijuana. For overdose deaths, marijuana is consistently in the lowest rankings among competitor drugs.
- 7) **Its psychic or physiological dependence liability.** Data indicates that chronic, but not acute use of marijuana can produce both psychic and physical dependence in humans, but are relatively mild for most individuals.
- 8) **Whether the substance is an immediate precursor of a substance already controlled.** The HHS does not consider marijuana to be an immediate precursor to another controlled substance.

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