

Biden Administration Recommendation for Marijuana to Move to Schedule III

Talking points

1. Marijuana would still be considered an illegal drug under Schedule III. All state legalization laws would still be out of compliance with the federal law. Marijuana would only be able to be legally administered by FDA-approved prescription.
2. This development is a “NPRM”, or notice of proposed rulemaking, which means there will be opportunity for public comment. Given the contentious nature of this proposed rule, there will likely be an administrative hearing. At the conclusion of this public comment period, a final rule will be published at which point the decision will be implemented.
3. If marijuana is reclassified to Schedule III, FDA would be required to enforce the law against all of the industry and state marijuana programs, as a Schedule III drug.
4. The Obama Administration recommended marijuana remain a Schedule I drug. There is no justification for removing marijuana from Schedule I. Since the last review, marijuana has only become more potent and dangerous to mental and physical health.
 1. New studies show that 20-30% of marijuana users develop an addiction. This certainly meets the classification of high potential for abuse. Schedule III drugs are considered substances without a high potential for abuse.
5. Marijuana is not FDA approved to treat or cure any disease or condition and there is a difference between marijuana as a whole and drugs that contain one or two of the over one hundred cannabinoids that make up marijuana’s chemical composition. Marinol and other FDA-approved medicines that contain one or two cannabinoids derived from marijuana are available now. Drugs approved by the FDA can be placed in different Schedules without rescheduling marijuana entirely. (This is the case with GHB, a Schedule I drug, and a GHB-containing pharmaceutical product, Xyrem®, which is a Schedule III drug.)

FAQs

1. What happens now?
 - a. The DEA will initiate a Notice of Proposed Rulemaking (NPRM) which means the public now has a chance to comment for a period of days. The comments submitted are considered part of the official record and DEA is supposed to take public comments into account before issuing a final rule. After the NPRM public comment period is over, DEA will examine the comments and issue a final rule.
2. What’s the difference between Schedule I and Schedule III?

- a. Schedule I substances are defined as having no accepted medical use and a high potential for abuse; Schedule III substances are defined as drugs with accepted medical use, meaning they may be prescribed, dispensed or administered; and have a moderate to low potential for physical and psychological dependence.
3. What other drugs are in Schedule III?
 - a. Some depressants (the ones people with a drug use disorder do not usually seek), Anabolic steroids, Buprenorphine, Ketamine, and Codeine, for examples. However, all of these drugs have an FDA accepted medical use/indication for use, marijuana does not.
4. If marijuana is moved to Schedule III, does this mean marijuana is legal?
 - a. No. Marijuana is still federally illegal. Schedule III drugs are still controlled drugs and improper sale or transfer of these drugs carries criminal penalties for trafficking, sale, etc.
5. What will happen in legal states if marijuana is moved to Schedule III?
 - a. Nothing; these states are still out of compliance with federal law, the activities surrounding marijuana, including banking, are also still federally illegal.
6. Has marijuana or the science around marijuana changed since the last time the DEA looked at scheduling?
 - a. No, if anything, we have more evidence pointing to the potentially addictive nature of marijuana. The DEA's [denial of rescheduling](#) petition from 2016 is still completely accurate.

Information on Drug Scheduling

The Controlled Substances Act (CSA) places all substances which were in some manner regulated under existing federal law into one of five Schedules based upon the substance's medical use, potential for abuse, and safety or dependence liability.

In determining into which Schedule a drug or other substance should be placed, or whether a substance should be decontrolled or rescheduled, certain factors are required to be considered:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

HHS (FDA) is directed by the Attorney General to consider the following factors when determining a drug's Schedule:

- scientific evidence of pharmacological effect of the drug or substance,
- state of current scientific knowledge regarding the drug/substance,
- what, if any, risk to public health it might pose
- psychic and psychological dependence liability,
- whether the substance is an immediate precursor of a substance already controlled
- and any medical and scientific considerations involved in:
 - the substance's actual or relative potential for abuse,
 - its history or current pattern of abuse,
 - the scope, duration, and significance of abuse.