

Legal Sidebar

The Legal Process to Reschedule Marijuana

11/02/2015

Amid the flurry of state legislative activity on marijuana in recent years, congressional action has, by comparison, remained relatively modest. [Proposals](#) have been introduced at the federal level to remove legal restrictions on the burgeoning marijuana industry, encourage marijuana research, or even to revise the drug's legal status, but Congress has not enacted any substantive amendments to the [Controlled Substances Act](#) (CSA)—the primary federal law prohibiting the possession, cultivation, or distribution of marijuana. Instead, Congress has chosen to influence marijuana policy through a handful of funding [restrictions](#). For example, Congress has approved language that would [prohibit](#) the Department of Justice from using funds to “prevent” medical marijuana states from “implementing” their laws.

The focus of most proposed federal legislation has generally been on “rescheduling” marijuana from its current position in the CSA as a heavily restricted “[Schedule I](#)” controlled substance with “no accepted medical use”, to a lower, less restrictive schedule that potentially reflects what a majority of states view as the drug's currently accepted medical use. Once removed from Schedule I, it is [argued](#) that marijuana could then be more easily researched and eventually prescribed and dispensed.

There are two general methods by which marijuana may be rescheduled:

1. **Congress** may choose to enact legislation amending the CSA. Congress placed marijuana in Schedule I when it enacted the CSA in 1970 and retains the authority to move the drug to a less restrictive schedule or to remove the drug from the CSA framework entirely.
2. The **Drug Enforcement Agency (DEA)** may administratively move marijuana to a lower schedule or remove it entirely. The CSA [authorizes](#) the DEA (by delegation from the Attorney General) to “transfer between [] schedules” any drug that meets the criteria for inclusion in the “schedule in which such drug is to be placed,” or to “remove any drug...from the schedules” if it “does not meet the requirements for inclusion in any schedule.” In addition to these basic scheduling criteria, the CSA lays out [eight factors](#) that must be considered in any scheduling determination.

An administrative rescheduling decision is not made by the DEA alone. In fact, before rescheduling a drug, the DEA is [required](#) to request from the Secretary of Health and Human Services (HHS) a binding “scientific and medical evaluation” along with a recommendation for appropriate scheduling. The Secretary has delegated the authority to conduct these evaluations to the Food and Drug Administration (FDA).

The DEA, in conjunction with the FDA, has consistently denied petitions to reschedule marijuana. The last formal [denial](#) occurred in 2011 after the FDA concluded that marijuana continues to meet the criteria for inclusion in Schedule I, i.e. a high potential for abuse, no currently accepted medical use, and a lack of an accepted level of safety for use under medical supervision. The DEA concurred, noting that marijuana lacked an accepted medical use because “[t]he drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.” In concluding that the drug also lacked “accepted safety for use,” the DEA looked to the FDA drug approval process, noting that there are no FDA-approved marijuana products, “nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication.”

The evaluation process was [restarted](#) last year, when DEA, after receiving additional public petitions to reschedule marijuana, again asked the FDA to evaluate the scientific and medical justification for marijuana's placement on Schedule I. The new FDA review is ongoing.

International law also plays a role in DEA's rescheduling decisions. The CSA [provides](#) that "[i]f control is required by United States obligations under international treaties...the [DEA] shall issue an order controlling such drug under the schedule [it] deems most appropriate to carry out such obligations...." The United States is party to various [treaties](#) that require signatory nations to impose certain controls on marijuana. The [Single Convention on Narcotic Drugs](#), for instance, requires parties to enact various restrictions on access, while generally limiting marijuana to authorized medical and scientific purposes. The executive branch has consistently taken the [position](#) that in order to comply with these international obligations, marijuana must be categorized as a Schedule I or Schedule II drug.

The mere act of rescheduling marijuana, however, would not immediately alter access to the drug. For example, the legal restrictions on marijuana research under the CSA—even as a Schedule II controlled substance—would remain significant. In addition, the Federal Food, Drug, and Cosmetic Act requires that a drug be shown to be [safe and effective](#) before it can be marketed. Therefore, it would appear unlikely that marijuana, or a marijuana-derived drug, would be widely and legally (under federal law) available to patients until [approved](#) by the FDA. As some commentators have [noted](#), the prospect of FDA approving and ultimately regulating marijuana raises a significant number of additional legal and policy issues.

Posted at 11/02/2015 10:35 AM