

Green Marimba Technologies

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Cannabis legalization: what has to happen?

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The legalization process and its implications

The foundation of cannabis's illegal status is its classification as a Schedule I prohibited substance under the U.S. Controlled Substances Act of 1970. Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.¹ The first step towards any legalization would likely be the rescheduling of cannabis as a Schedule II or III drug, with the resulting regulatory changes.

If cannabis were down-scheduled to Schedule II-V, it would still be illegal under federal law because no controlled substances can be purchased without a prescription, which requires FDA approval of the drug. The FDA is very unlikely to approve marijuana as a plant,² although cannabis derivatives could be approved. For example, the FDA-approved drug Marinol is made from synthetic THC. The FDA website states that, "the FDA has not approved any product containing or derived from botanical marijuana for any indication. This means that the FDA has not found any such product to be safe or effective for the treatment of any disease or condition. Study of marijuana in clinical trial settings is needed to assess the safety and effectiveness of marijuana for medical use." Therefore, FDA approval of cannabis products is likely to be slow.

In order for cannabis products to be legally sold without a prescription, either cannabis would have to be removed from the list of controlled substances, or a specific law would have to be enacted by Congress to allow it to be sold without a prescription under Title 21 Code of Regulations §1306.26 f), which states that "a prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law"³.

The Act theoretically establishes that the attorney general has the power to "remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule."⁴ During Senate confirmation, Jeff Sessions stated that in regard to rescheduling, he would "defer to the American Medical Association and researchers at the National Institutes of Health"⁵, which suggests that he is likely to take a passive approach. (His comments outside the Senate also suggest disinclination to changing the law.)

Officially, the authority to change the classification of controlled substances is delegated by the President to the attorney general, who in turn delegates the power to the DEA, and to the Department of Health and Human Services, who in turn delegates clinical testing to the FDA.⁶ The process for rescheduling or removing a controlled substance is established by the Act, and can be initiated internally by the DEA or attorney general or externally via a petition to the DEA from an advocacy group, company, or other thirdparty.⁷ It gives the attorney general the authority to control the process, but includes limitations on his power. Here is the text from the Act:

¹ DEA website: <https://www.dea.gov/druginfo/ds.shtml>

² <http://www.inc.com/will-yakowicz/can-the-next-us-president-reschedule-marijuana.html>

³ https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_26.htm

⁴ <https://www.deadiversion.usdoj.gov/21cfr/21usc/811.htm>

⁵ <https://www.marijuana.com/blog/news/2017/02/jeff-sessions-confirmed-as-u-s-attorney-general/>

⁶ <http://www.inc.com/will-yakowicz/can-the-next-us-president-reschedule-marijuana.html>

⁷ https://en.wikipedia.org/wiki/Removal_of_cannabis_from_Schedule_I_of_the_Controlled_Substances_Act#cite_note-3

*“The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, **and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.** If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.”⁸ [emphasis mine]*

Thus, if the Secretary’s scientific and medical evaluation concludes that cannabis should not be considered a controlled substance, and the Secretary issues a recommendation along those lines, the Attorney General cannot oppose it. However it also means that the HHS, through the FDA, has to approve its medical use and safe consumption. The FDA has stated that “the scientific evidence to date is not sufficient for the marijuana plant to gain FDA approval.”⁹ It also notes that marijuana can be addictive and clinical testing on the benefits of marijuana are not conclusive.¹⁰ Despite the fact that a WebMD/Medscape survey in 2014 found that a majority of doctors support cannabis legalization,¹¹ government health organizations are more conservative.

Note that the DEA is under no obligation to act quickly. The last petition was filed in 2002 and was ultimately denied in 2011¹², meaning that the review took 9 years. Denials can also be challenged in court, as the advocacy group Americans for Safe Access tried unsuccessfully in 2012¹³, but legal actions can also be time consuming.

President Trump could take initiative on the issue to try to accelerate rescheduling or legalization. However, a president cannot reschedule drugs via an executive order,¹⁴ does not have the authority to change the law, and cannot order the attorney general to interpret the law in a certain way. Ultimately the attorney general could legally oppose the president if the HHS review did not find grounds for cannabis rescheduling. In any case, Trump would likely not try to promote rescheduling if the attorney general

⁸<https://www.deadiversion.usdoj.gov/21cfr/21usc/811.htm>

⁹<http://www.politifact.com/truth-o-meter/statements/2014/feb/04/barack-obama/barack-obama-says-its-congress-change-how-feds-cla/>

¹⁰ Ibid.

¹¹<http://www.webmd.com/pain-management/news/20140225/webmd-marijuana-survey-web#1>

¹² Ibid.

¹³<http://openjurist.org/15/f3d/1131/alliance-for-cannabis-therapeutics-v-drug-enforcement-administration-aids-drug-policy-foundation>

¹⁴<http://www.inc.com/will-yakowicz/can-the-next-us-president-reschedule-marijuana.html>

made his opposition clear, and there is little evidence at this time to suggest that Trump is willing to champion cannabis legalization given his many other priorities.

The Controlled Substances Act was created by the Congress, and of course the Congress has the authority to amend it or decide that a substance should no longer be considered a controlled substance¹⁵, as it has done with tobacco and alcohol. However, while bills for legalizing marijuana have been introduced in the past and as recently as 2015, none of them have been considered for a hearing¹⁶. Given that as of September 2016 only 20 US representatives and 2 senators have publicly expressed support for legalization¹⁷, congressional action on legalization seems unlikely at present time, and would probably require substantial presidential support.

In conclusion, while there are many players involved and multiple potential paths to cannabis legalization, there is little evidence to suggest that a change could come soon.

¹⁵<http://www.politifact.com/truth-o-meter/statements/2014/feb/04/barack-obama/barack-obama-says-its-congress-change-how-feds-cla/>

¹⁶<https://www.congress.gov/search?q={%22congress%22:%22114%22,%22source%22:%22legislation%22,%22search%22:%22marijuana%22}>

¹⁷https://www.washingtonpost.com/news/wonk/wp/2016/09/29/meet-the-senators-and-congressmen-who-support-marijuana-legalization/?utm_term=.11d017da44c0