

Non-FDA-Approved Marijuana for Therapeutic Purposes: Premised Upon Politics, Not Science

The Food and Drug Administration (FDA) has not approved the sale of marijuana for the treatment of any disease or condition.ⁱ Nevertheless, 37 states and the District of Columbia have used political processes to legalize marijuana for certain therapeutic uses.ⁱⁱ This fact sheet explains how politics, not science, drives state-level legalization of marijuana for therapeutic purposes.

Marijuana is illegal under federal law and has no currently accepted medical use

Marijuana is a Schedule I controlled substance under the federal Controlled Substances Act (CSA).ⁱⁱⁱ Schedule I substances have a high potential for misuse and no currently accepted medical use for treatment in the United States.^{iv} It is illegal under federal law to manufacture, distribute, dispense, or possess marijuana.^v

FDA-approved drugs require extensive research and substantial evidence of safety and efficacy

Drugs are substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.^{vi} The FDA has federal authority to approve drugs for medicinal use in the U.S. Federal law only allows manufacturers of FDA-approved drugs to make therapeutic claims about their products.^{vii}

Companies seeking to develop and sell a drug in the U.S. must first conduct extensive scientific testing (e.g., pre-clinical and clinical trials) to ensure that the drug being developed is safe and effective for its intended use.^{viii} The FDA reviews this data to ensure that the drug meets the agency's standards for safety and efficacy. Drugs must also satisfy FDA standards for quality, purity, and dosage. If the FDA determines that the drug's benefits outweigh its known risks, it will approve the drug for sale in the U.S. The drug approval process can take years, and not every drug completes the process or is approved.^{ix} No drugmaker has completed this process for marijuana.

Marijuana is not an FDA-approved drug

The FDA has not approved the sale of marijuana for the treatment of any disease or condition.^x As of July 2022, the FDA has approved one medication that contains a purified substance derived from marijuana (Epidiolex for the treatment of seizures associated with three rare health conditions).^{xi} The FDA has approved three synthetic marijuana-related medications, nabilone and two forms of dronabinol. These FDA-approved medications are only available with a prescription from a licensed health care provider (HCP).^{xii}

States use political processes to allow non-FDA-approved marijuana to be used for therapeutic purposes

Despite marijuana's status as a Schedule I controlled substance under federal law with no approved medical use, 37 states and the District of Columbia have used political processes to allow marijuana to be used for therapeutic purposes by qualified individuals.^{xiii} These processes may entail ballot initiatives or legislation, or both.^{xiv} After voters or legislators authorize the use of marijuana for therapeutic purposes, a state agency is typically tasked with developing specific rules to implement those laws. States have varying laws and regulations surrounding the use of marijuana for therapeutic purposes, resulting in a patchwork of differing state governance regimes.

The state-level political processes for approving the use of marijuana for therapeutic purposes are much different from the uniform, scientific, data-driven drug approval process required by federal law. Marijuana has not met the federal standards for safety and efficacy required for approval as a treatment for any disease or condition.

To review a sample of state laws and regulations governing marijuana use for therapeutic purposes, see Community Impact NC's [publication](#), *Marijuana: Laws and Lessons to Inform North Carolina Policy*, or [CINC laws lessons summary](#).

States allow varying forms of marijuana to be used for therapeutic purposes, all of which are illegal under federal law

Unlike the FDA-approved medications described above that have uniform active ingredients, marijuana itself is a botanical (and intoxicating) product with hundreds of different chemical compounds that can vary among plants.^{xv} Individuals can smoke or vaporize the dried flowers or use various other THC-containing products that are derived from marijuana.

States differ in which forms of marijuana may be used for therapeutic purposes. For example, Washington permits qualifying patients to possess limited quantities of whole plants and dried flowers, which can be smoked, as well as various products that contain marijuana and its extracts.^{xvi} Pennsylvania permits use by vaporization, excluding dried leaf and plant forms. Pennsylvania also allows the use of pills, sprays, oils, topical products, tinctures, and liquids.^{xvii} All such marijuana-containing products are illegal under federal law.

For information on the health risks of using non-FDA-approved marijuana for therapeutic purposes, please see our fact sheet, [CINC Risk of MJ for Therapeutic Purposes](#).

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<https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process>

<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>

21 U.S.C. § 801 et seq.

Id.

21 U.S.C. § 841

21 U.S.C. § 823

<https://scholarship.shu.edu/cgi/viewcontent.cgi?article=1187&context=shlj>

<https://www.fda.gov/drugs/development-approval-process-drugs>

Id.; <https://scholarship.shu.edu/cgi/viewcontent.cgi?article=1187&context=shlj>

<https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process>

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>

<https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process#main-content>

<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>

<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>

https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf

See RCW 69.51A.010

<https://www.legis.state.pa.us/cfdocs/legis/LI/uconsCheck.cfm?>

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