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Regulation and legality of CBD in the U.S., explained

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Since passage of the 2018 farm bill, which removed hemp from the list of federally banned drugs, the Food and Drug Administration has been working on how to regulate the manufacturing, marketing and sale of products containing hemp-derived cannabidiol, or CBD.

All products containing CBD that comes from marijuana are illegal under federal law and some products containing hemp-derived CBD are still illegal, despite the farm bill.

The FDA is working on its regulatory policies in this area and could take action that would make it legal.

Federal law differentiates cannabis as marijuana or hemp

CANNABIS

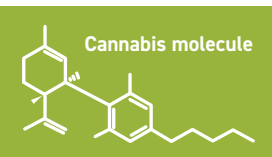
Marijuana > 0.3% THC ≥ Hemp

Cannabis plants contain chemical compounds called cannabinoids. The two main cannabinoids are tetrahydrocannabinol, or **THC**, which produces a psychoactive “high,”

and **CBD**, which is not psychoactive but may have significant medical value.

Federal law defines plants with more than 0.3 percent of THC by dry weight as **marijuana** and plants containing equal to or less than that percentage as **hemp**.

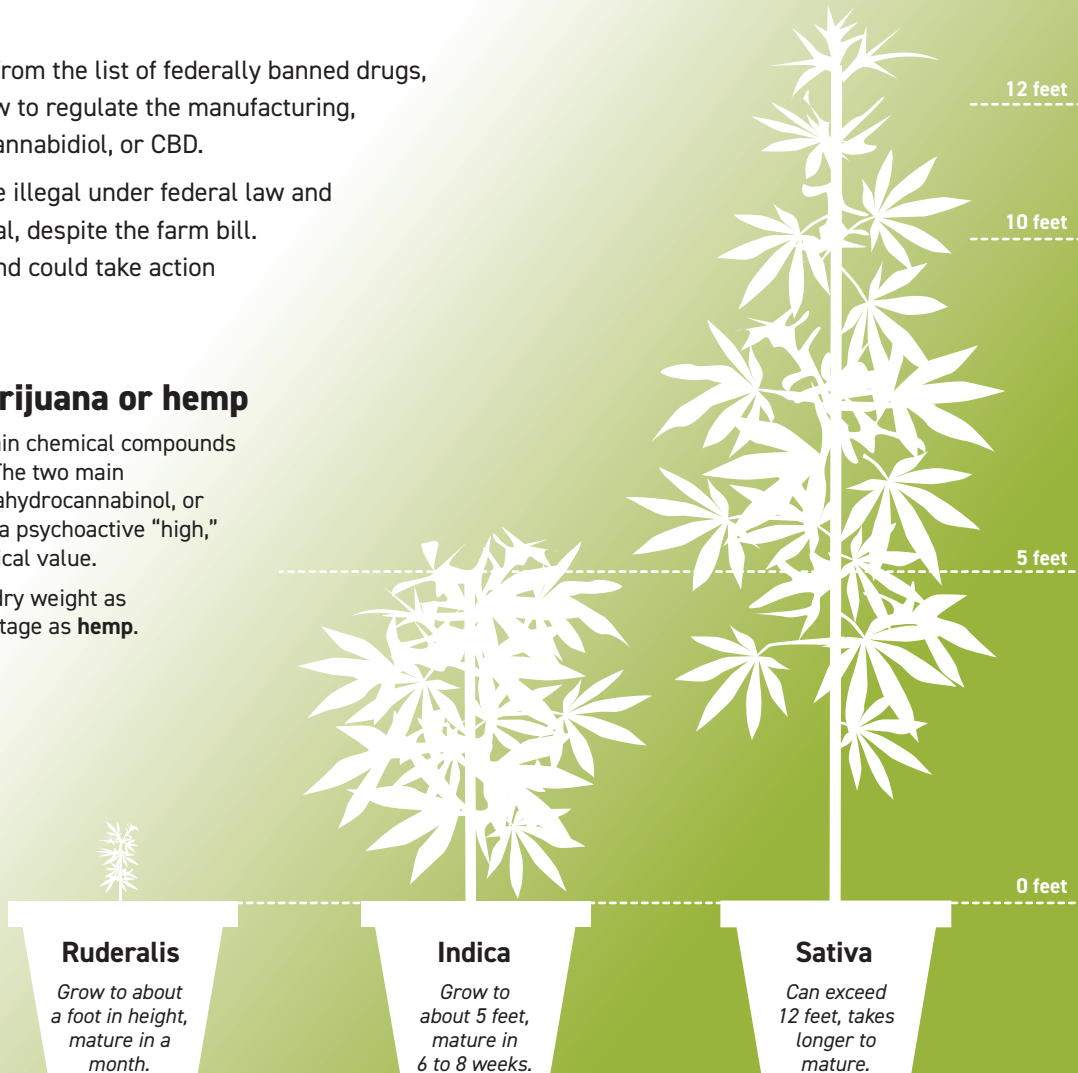
CBD in cannabis



The CBD molecule in cannabis has been found to be safe and effective in the treatment of some seizures. Animal studies suggest it has a wide range of

potential medical uses. Although there are many studies on people ongoing, CBD has not been found to be safe and effective in anything other than certain seizure disorders.

CBD side effects include fatigue and diarrhea.



Federal law applies to cannabis products but FDA needs to figure out how to specifically address CBD

Federal and state laws relating to cannabis have been in tension for several years. Many states have passed laws allowing the sale of cannabis for medical use or other use in recent years, however, and the 2018 farm bill legalized hemp at the federal level.

Regardless of state law, food, beverages, and dietary supplements containing CBD are illegal at the federal level, whether the CBD derives from marijuana or hemp. Products containing hemp-derived CBD that are not meant to be ingested and are not intended for medical use are not illegal under federal law, but they may be regulated by FDA.

Several federal laws apply to the production, marketing and use of cannabis:

CONTROLLED SUBSTANCES ACT

Since 1971, the Controlled Substance Act regulates cannabis and determines which drugs or substances should be federally controlled based on evaluation of actual or relative potential for abuse, scientific evidence of pharmacological effect, if known, and psychic or physiological dependence liability.

Schedule I drugs

Heroin
LSD
Ecstasy
Methaqualone
Peyote
Cannabis

Hemp

The law originally categorized all substances containing THC as Schedule I controlled substances.

Moving forward, the farm bill explicitly maintained FDA's authority to regulate cannabis products, including hemp-derived CBD.

AGRICULTURAL IMPROVEMENT ACT

The 2018 farm bill redefined hemp as any part of the cannabis plant, including seeds and derivatives, containing no more than 0.3 percent of THC on a dry weight basis.



The definition change declassified hemp as a controlled substance and removed it from CSA control, allowing hemp-derived CBD to be a marketable product subject to FDA regulation.

FOOD, DRUG AND COSMETICS ACT

This law gives FDA authority to regulate any and all products containing CBD, whether derived from marijuana, which is a controlled substance, or hemp, which is not.



- Cleansing, beauty and appearance-altering products may contain hemp or its constituent cannabinoids (including CBD) and are regulated by FDA as cosmetics.
- Certain food products containing hemp seed or derived from hemp may be legal to sell even if they contain a trace amount of CBD.
- FDA views food, beverages and dietary supplements with added CBD as federally illegal but a formal, final rule or regulation is not in place.

Many cannabis-derived products are marketed today, but only a few are legal under federal law

The FD&C Act defines drugs as products intended for therapeutic or medical use and products (other than food) intended to affect bodily functions. New drugs must be approved by the FDA before being distributed and sold.

To date, the FDA has approved four prescription-only cannabis drug products and only one of the drugs — Epidiolex — contains CBD.

FDA-approved drug containing CBD



CANNABIS-DERIVED

Epidiolex

(For treatment of epilepsy)

Contains a purified form of CBD obtained directly from the cannabis plant.

FDA-approved drugs containing THC



CANNABIS-RELATED

Marinol, Syndros and Cesamet

(For treatment of weight loss in patients with AIDS)

Marinol and Syndros contain synthetic THC; Cesamet contains the synthetic active ingredient nabilone similar to THC.

Even though states may permit manufacturing and sale of medical products containing CBD or THC, they are still federally illegal because they are drugs and are subject to FDA approval. Non-medical products derived from the cannabis plant may be federally legal depending on a product's ingredients.

FDA is reevaluating how it regulates products containing cannabis and cannabis-derived compounds. For now, the agency is not ordering products off the market but is warning companies about making unproven medical claims.

Federally legal



COSMETICS

Under the FD&C Act, cosmetics with cannabis or cannabis-derived ingredients are not subject to FDA approval before being marketed.

Not federally legal



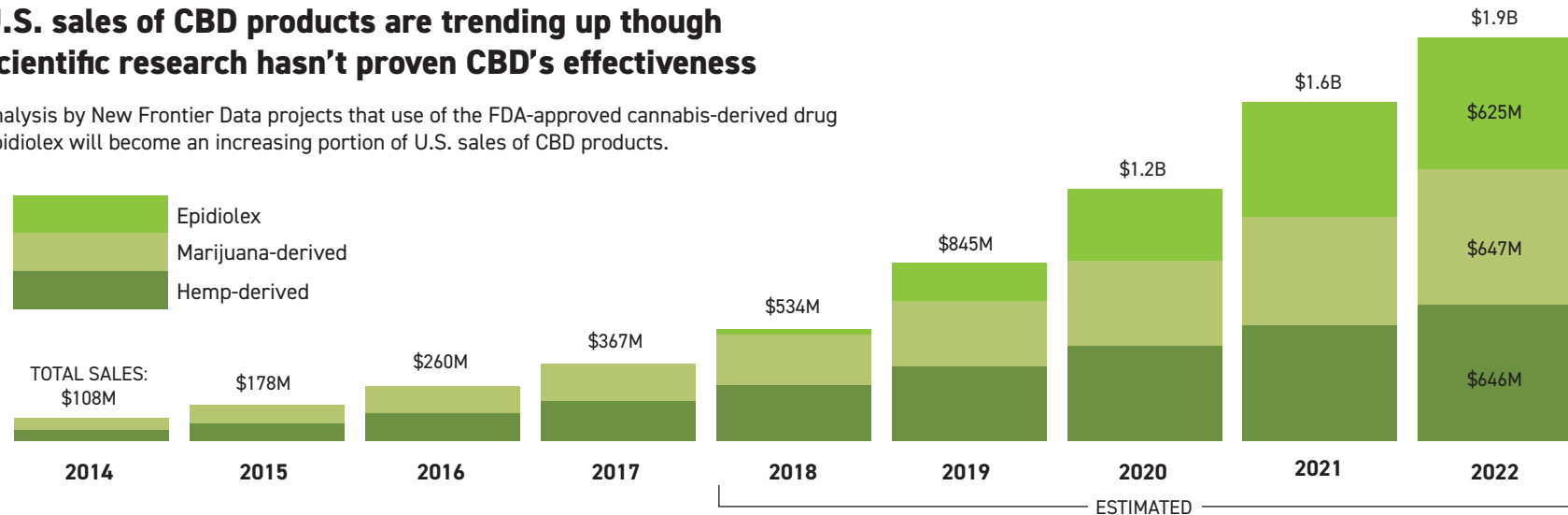
DIETARY SUPPLEMENTS AND FOOD PRODUCTS

Hemp and dietary supplement industries oppose FDA's view, and because no formal rule or regulation exists regarding the legality of CBD additives, products are being sold nationwide.

Food with hulled hemp seed, hemp protein powder or oil can be legally marketed if compliant with human food laws.

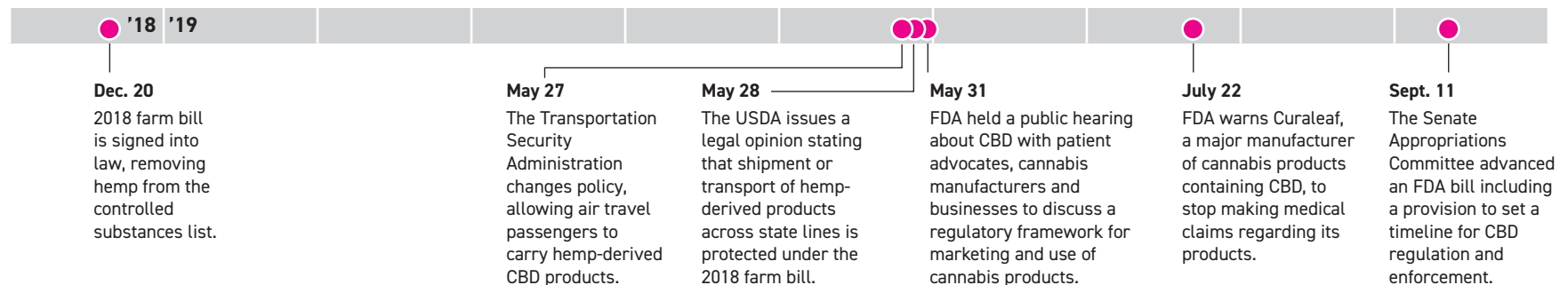
U.S. sales of CBD products are trending up though scientific research hasn't proven CBD's effectiveness

Analysis by New Frontier Data projects that use of the FDA-approved cannabis-derived drug Epidiolex will become an increasing portion of U.S. sales of CBD products.



Federal government regulation has been trying to catch up with the increasing trend of CBD use

Major federal actions regarding CBD use since passage of the 2018 farm bill:



Sources: FDA; healthline.com; cnbs.org; Harvard Health blog article "Cannabidiol (CBD) – what we know and what we don't;" United States Code Title 21: FOOD AND DRUGS. Part B: Authority To Control, Standards and Schedules, Section 811: Authority and criteria for classification of substances; Congressional Research Service June 12, 2019 report "FDA Regulation of Cannabidiol (CBD) Products;" Brightfield Group 2019 report "From Farm to Aisle: U.S. CBD Market;" DEA; New Frontier Data; Erika Lietzan, Associate Professor, University of Missouri School of Law; Jonathan Miller, General Counsel of the U.S. Hemp Roundtable; POLITICO staff reports