CBD Regulation in the U.S.

Cannabis Forum, Manufactures Association of Israel

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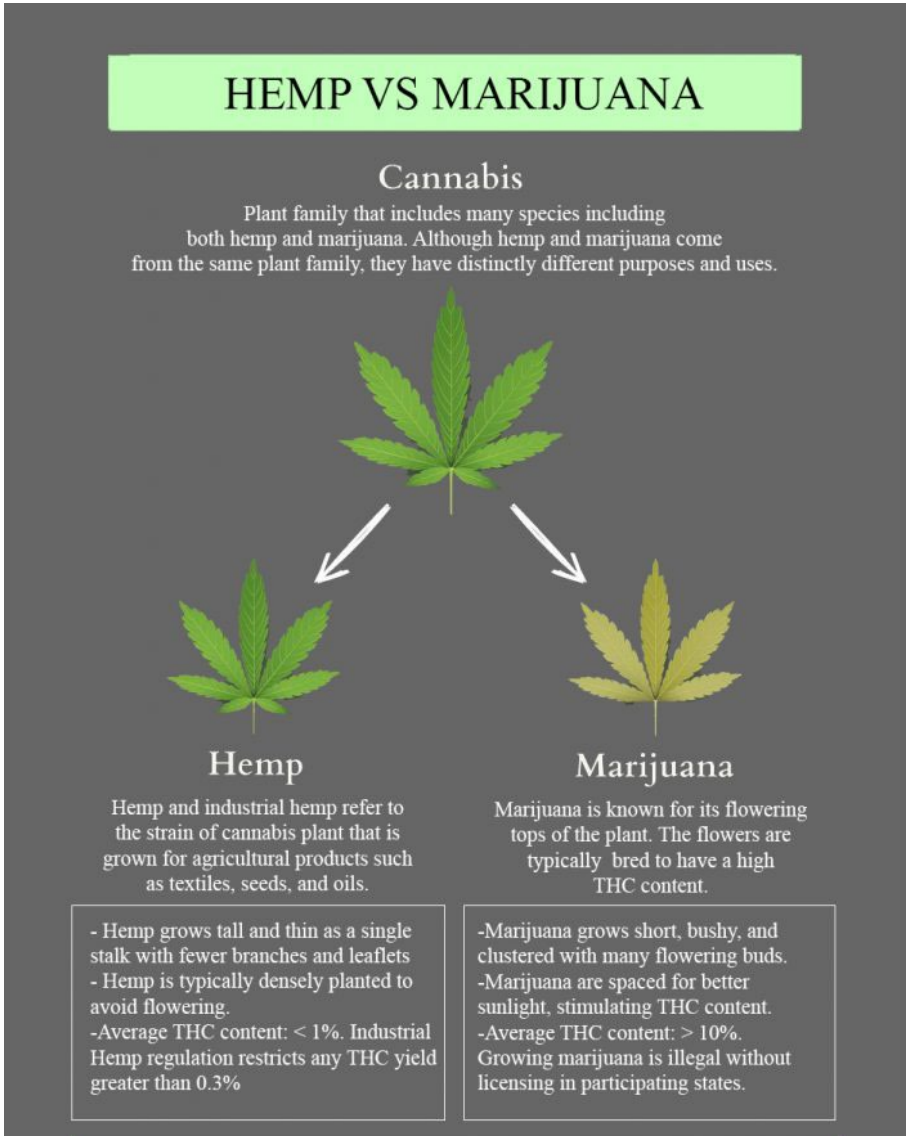
Holland & Knight

Disclaimer

This is a highly complex and fluid regulatory environment

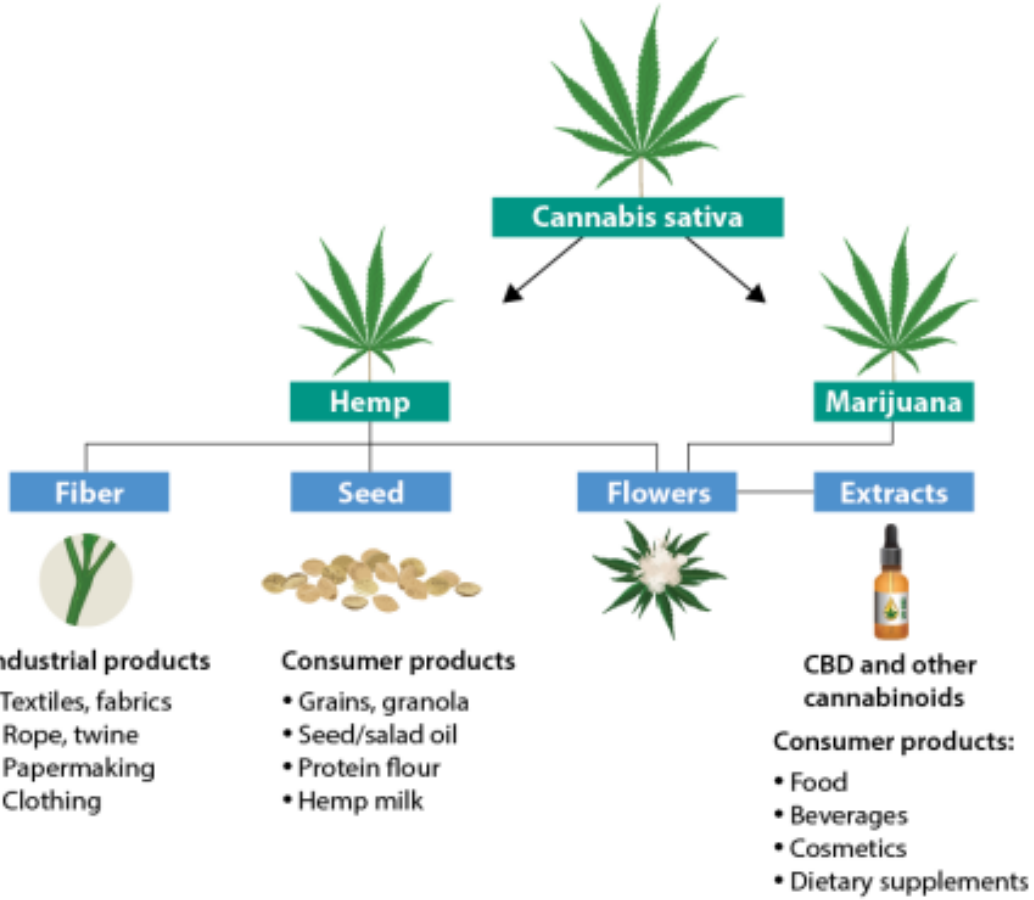
- Federal regulations being written as we speak
- How federal rules interact with existing state laws remains largely TBD
- Competing mandates among federal agencies could mean lingering uncertainty in some areas
- Federal Legislative “fixes” may be forthcoming

Hemp in the 2018 Farm Bill



» Source: gocureco.com

Cannabis Sativa



» **Source:** Created by CRS (Congressional Research Service).

The 2018 Farm Bill

The 2018 Farm Bill changed federal law so that hemp, defined as cannabis and cannabis derivatives with very low levels of the psychoactive intoxicating component of cannabis, delta-9 tetrahydrocannabinol (THC) are no longer controlled substances ("Schedule I")

Provisions in 2018 Farm Bill designed to greatly expand industrial hemp production

- "Industrial Hemp" defined broadly
- Includes seeds, derivatives, cannabinoids, extracts, and other parts of the Cannabis sativa L. plant
- Any hemp-derived product will be legal as long as it contains no more than 0.3% THC on a dry weight basis

How to calculate THC levels for finished products?

- On July 21, FDA published the "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research, Draft Guidance for Industry,"
- The Draft Guidelines covers sources for clinical research, information on quality considerations and other recommendations for those pursuing investigational new drug (IND) applications and new drug applications (NDAs) for both cannabis and hemp-derived compounds.

- FDA recommends that developers base the calculation of THC percentage "on the composition of the formulation with the amount of water removed, including any water that may be contained in excipients." This new method of testing, while targeted at drug development, could provide insight into how the Agency may calculate the THC content of consumer CBD products in the future, although that remains to be seen.

U.S. CBD Market

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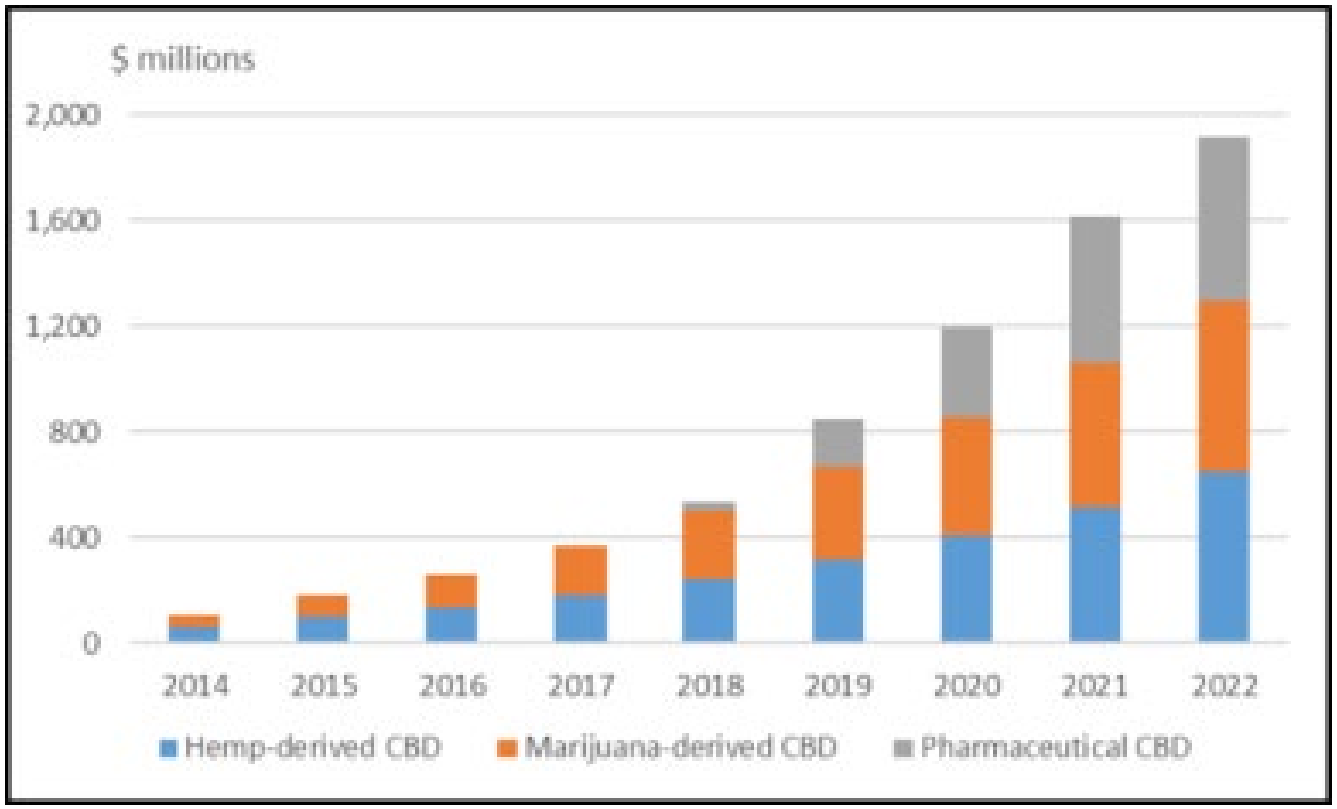

Source: Hemp Business Journal, *The CBD Report: 2018 Industry Outlook*, 2019 (New Frontier Data). All pharmaceutical channel sales are represented by the drug Epidiolex.

FDA Regulatory Landscape

US Food and Drug Administration (FDA) regulates cosmetics, foods, dietary supplements, and drugs

- FDA regulating CBD the same as other products
- FDA regulates products based on their intended use as evidenced by claims and labeling.
- FDA takes enforcement against companies who are in violation of the Food, Drug, and Cosmetic Act (FDCA).

Currently:

- CBD cannot legally be sold in a *food or dietary supplement* per the Food, Drug, and Cosmetic Act because CBD is already in an approved drug – Epidiolex
- The CBD as dietary supplement prohibition applies for both humans and animals
- The same statutory prohibition does not exist for *cosmetics*. However, FDA has also never said it IS legal
- CBD-infused fabric: under FDA jurisdiction if there is a health-related intended use.

FDA Enforcement Discretion

- FDA has taken enforcement discretion against companies making misleading claims regarding CBD for the diagnosis, cure, mitigation, treatment, or prevention of any disease.
  - E.g.: “Fights against cancer,” “decreased chronic inflammatory and neuropathic pain”
- This year, FDA issued a number of warning letters to companies that sold “Unapproved and Misbranded” products related to COVID-19: CBD products for sale in the U.S. claiming these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19

FDA Report to U.S. Congress on CBD Marketplace

- On July 8, 2020 FDA issued a report to the U.S. Congress on "Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated":
  - Of nearly 150 CBD products tested for cannabinoid content, the FDA found **less than half contain the amount of CBD on the label**.
  - Report underscores a trend of mislabeled products and a growing need for FDA to regulate CBD as a dietary supplement and food additive
  - FDA developed a long-term sampling plan to continue taking "a representative, random sample of the current CBD product marketplace" in 2020, putting an emphasis on products with a higher market share.
  - Long term sampled products include: Tinctures, oils, and extracts; Capsules and powders; Gummies; Water and other beverages; Other conventional foods; Leave-on cosmetic products, like face and body lotions; Device and combination products, like personal lubricants, tampons, and suppositories; Vape cartridges; Products sold for consumption by pets

Cannabidiol Enforcement Policy

- In light of the proliferation of CBD products marketed in violation of federal law, U.S. Congress has called on FDA to provide guidance on lawful pathways for marketing hemp-derived CBD in food and dietary supplements. In absence of a regulatory framework for hemp-derived CBD, in the explanatory statement accompanying the FY2020 enacted appropriation, Congress directed FDA to issue a policy of enforcement discretion with respect to CBD products that meet the statutory definition of hemp.
- On July 22, 2020, FDA sent to the White House Office of Management and Budget (OMB) for review a draft guidance, “Cannabidiol Enforcement Policy.” The draft guidance has not yet been released to the public.
- The expectation is that the draft policy will clarify what FDA considers legal use in supplements or consumer products and may be the launching point for regulations that the CBD industry has been asking for.

Interstate and International Trade in CBD Consumer Goods

- **Transporting CBD consumer goods across U.S. state borders:**
  - Food and dietary supplements: FDA concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which CBD has been added.
  - **CBD cosmetics and textile**
  - Risky because DEA has seized CBD products saying they were not derived from industrial hemp. And, if the product makes a health claim, FDA will say it's illegal

Importing CBD consumer goods to the U.S.: generally, prohibited

- **Exporting CBD consumer goods manufactured in the U.S.:** generally, prohibited

Banking Services for CBD Consumer Goods Companies

- In December 2019 financial services barriers for **hemp related businesses** were lifted. Banks are no longer required to file suspicious activity reports (SAR) for customers solely because they are engaged in the growth or cultivation of hemp in accordance with applicable laws and regulations.
- Banks are only expected to follow standard SAR procedures, and file a SAR if indiciation of suspicious activity warrants.
- For the **cannabis marijuana related business**: The proposed Secure and Safe Enforcement (SAFE) Banking Act
- The cannabis trade associations continue to push for SAFE Banking in the next COVID relief package. The general message from leadership is that SAFE is still in play and democrats remain committed to seeing it in the final package.
- Following the release of a bipartisan sign on letter from State Treasurers in support of the SAFE Banking Act, the Democratic Treasurers Association is becoming more engaged on cannabis issues, with the intention to support the industry beyond just access to banking and other financial services.

What's Next?

- There are several efforts by the U.S. Congress to carve CBD out as a dietary supplement legislatively, expressly permitting CBD that meets the definition of hemp to be used as a food additive or dietary supplement, etc.
- Week of September 21, the House will likely vote on descheduling cannabis entirely.
- U.S. Congress could also take further legislative action in the future, such as requiring FDA to issue a regulation.
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- In determining whether a legislative approach is appropriate, Congress may consider the potential for adverse health effects and other unintended consequences

Case Study: What might go wrong…

Louisiana: Cajun Cannabis Owner Arrested

- CBD retail shop and cafe owner was arrested and had his product seized by local Sherriff's Office.
- He was initially arrested after a traffic stop, had a search warrant executed on his storefront, and the Sherriff's Office seized CBD-oil, CBD-infused gummies, and other edible products.
- Charged with 17 counts, including distribution or possession of marijuana.
- Louisiana Office of Alcohol and Tobacco Control said that products containing even zero percent THC are illegal.
- In Louisiana, the state Board of Pharmacy and the Louisiana Office of Alcohol and Tobacco Control have taken the stance that any CBD is illegal in the state.

Summary: Dos and Don'ts

- **To reduce (though, not eliminate) risk:**
  - Use CBD dervied from industrial hemp
  - Have your product manufactured in the U.S., in the state that is your main market and local state laws don't prohibit CBD.
  - Follow local state laws relating to CBD and labeling
  - Avoid making any health claims in labeling, marketing materials, CBD website, etc.

Useful Resources

- FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD): https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd
  - Consumer Information
  - FDA Communications
  - Regulatory Resources
  - Questions and Answers

Thank you!

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