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Hemp-Derived CBD: Current Regulatory Landscape

IFT: Food Policy Impact
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The Agricultural Improvement Act of 2018 (2018 Farm Bill)

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- Legalized "hemp" and its derivatives, including CBD, provided THC concentration is not more than 0.3% on a dry-weight basis.
- Previously, only **exempted parts** of the Cannabis plant were excluded from the Controlled Substances Act (i.e., mature stalks, stems, sterilized seed).
  - CBD considered "marijuana extract" by DEA.
- Domestic hemp **must** be grown under a plan approved by USDA.

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2018 Farm Bill

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- Two important caveats:
  1) Does **not** affect or modify FDA's authority over hemp and CBD products under its jurisdiction.
  2) Expressly allows states to regulate hemp/CBD products in a more restrictive manner, however:
     - *"Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp…or hemp products."*
     - *"No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G…"*

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USDA Hemp Rule

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- On October 31, 2019, USDA issued an **Interim Final Rule for Domestic Hemp Production**
  - Outlines provisions for USDA to approve hemp plans submitted by states and Indian tribes, and a federal plan for states/territories that do not have their own plan.
  - Minimal sampling and testing requirements for hemp plants.
- Clarifies that **interstate transportation** of hemp is allowed, even if a state or tribe prohibits its production.
- ***However, the rule does not address*:**
  - Imported hemp and exportation of hemp
  - Finished hemp goods (ingredients, products)

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What does this all mean?

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- Hemp may be sourced from growers and processors licensed *and tested* in accordance with the USDA rules.
  - Several states have submitted plans to USDA for approval.
- Still some risks associated with interstate transport of hemp until 2018 Farm Bill is fully implemented.
- Supply chain documentation (testing + sourcing) is – and will continue to be – key to demonstrating compliance.

FDA, FTC, and States are the key regulators of hemp foods, supplements, and cosmetics

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FDA Considerations

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- FD&C Act excludes **an article** [**?**] approved or authorized for investigation as a new drug from the definition of "dietary supplement"; also prohibits the use of such of articles in conventional food.
  - Referred to as the "IND Preclusion."
- Exception if the substance was [**legally**] **marketed** as a supplement or food before the drug was approved or new drug investigations were authorized; based on available evidence, FDA has concluded this is not the case for CBD.
- FDA may issue a regulation that otherwise allows the "article" to be used in food and dietary supplements.

FDA U.S. FOOD & DRUG ADMINISTRATION

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FDA Considerations

- However, the IND preclusion does not apply to:
  - **Cosmetic (topical) products** that contain CBD.
  - Hemp seed derivatives with trace amounts of THC and CBD.
    - No questions from FDA following "Generally Recognized as Safe" (GRAS) conclusions for hulled hemp seed, hemp seed protein powder, and hemp seed oil.
- To date, FDA enforcement has focused on disease claims.
  - Since 2015, numerous Warning Letters issued to CBD product marketers; 22 issued in 2019.
  - Nearly all cited disease claims, which caused the products to be unapproved drugs, or CBD products observed during inspection where adulterated products also cited.

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FDA Considerations

- **Lack of safety data** is a primary concern.
  - Cumulative exposure to CBD (and THC), impact on vulnerable populations, liver and reproductive toxicity.
  - Contaminants, e.g., heavy metals, microbials.
- Congress pressuring FDA to act quickly.
  - Possible federal legislation to allow CBD in food/supplements.
  - Report language in FY2020 Appropriations bill.
- Other key issues:
  - **What is the "article"?**
  - Impact on drug development.
  - Compliance with cGMPs.

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FDA Considerations

"At FDA, we don't have one set of rules for cannabis-derived substances, and another set of rules for other substances. We don't approach CBD or other cannabis-derived substances with any sort of animus or impose unique burdens."

1. CBD has the potential to harm you, and harm can happen even before you become aware of it.
   - CBD can cause liver injury.
   - CBD can affect the metabolism of other drugs, causing serious side effects.
   - Use of CBD with alcohol or other Central Nervous System depressants increases the risk of sedation and drowsiness, which can lead to injuries.

3. There are many important aspects about CBD that we just don't know, such as:
   - What happens if you take CBD daily for sustained periods of time?
   - What is the effect of CBD on the developing brain (such as children who take CBD)?
   - What are the effects of CBD on the developing fetus or breastfed newborn?
   - How does CBD interact with herbs and botanicals?
   - Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?

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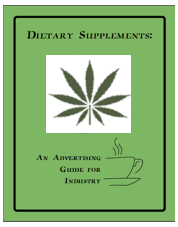
FTC Considerations

- FTC has primary jurisdiction over the advertising for food, supplements, and cosmetics.
  - Advertising must be truthful, not misleading, and substantiated.
- In general, the evidence should be **relevant** to the specific product and claim, be **scientifically sound**, and be adequate in the context of the **surrounding body of evidence**.
- FTC takes a flexible approach to substantiation, however...



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Substantiation Challenges

- Different dosage, formula or ingredient
  - For botanicals, level of *active constituent* matters, not just the total amount of extract.
  - Isolate studies vs. extract studies (full vs. broad spectrum).
  - Different hemp strains?
- Different endpoints vs. claimed effect
- Different study population, or conditions of use
- Studies only on the ingredient vs. product
- Level of science is overstated

"Claims that do not match the science, no matter how sound that science is, are likely to be unsubstantiated."

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FTC Enforcement

- Like FDA, enforcement has focused on serious disease claims.

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatments for Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis

FOR RELEASE
September 10, 2019

FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions

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State Considerations

- Wide variation in approaches to hemp and CBD
  - Concerns regarding contaminants, labeled content of CBD/THC, and lack of guidance/enforcement from FDA.
- Some states restrict hemp generally and the sale of hemp/CBD products, others have adopted FDA's position on CBD.
- Several states expressly allow hemp/CBD products with conditions:
  - Unique labeling and testing requirements.
  - Registration of products; manufacturer, retailer, and distributor registration.

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Other Considerations

- State Attorneys General:
  - A powerful group of regulators with broad jurisdiction to target potentially deceptive and fraudulent claims or products.
  - Joint comments to FDA from 37 AGs regarding CBD; asks the agency to preserve their consumer protection role.
- Class action risks:
  - "THC-free" or "zero THC" product claims.
  - Labeled CBD/hemp extract content vs. actual content.
  - False advertising as dietary supplement, food, or animal food.
- Other potential class action targets:
  - "Full spectrum" or "broad spectrum" claims.
  - Bioavailability, efficacy claims, "borderline" disease claims.

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Thank You!

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