Hemp and CBD Regulation

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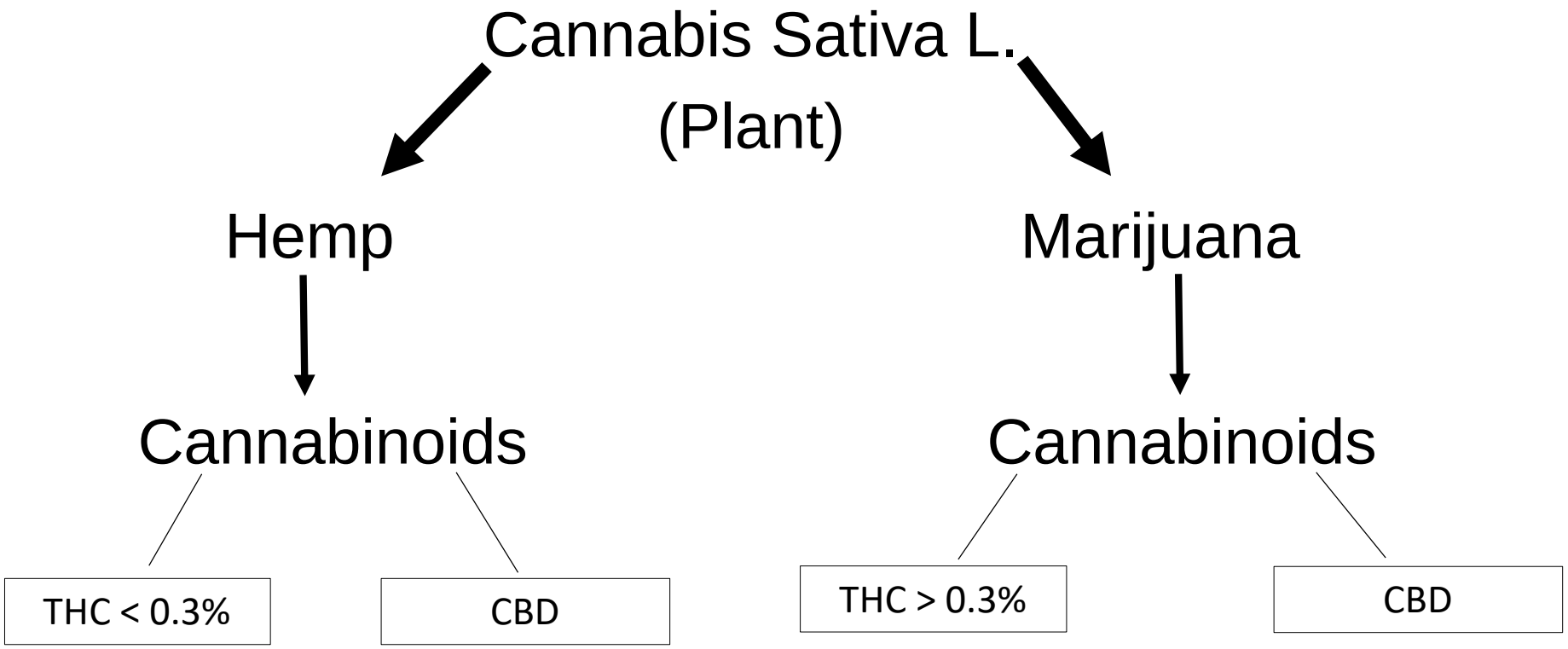
The Controlled Substance Act ("CSA")

- The CSA establishes a comprehensive federal scheme to regulate controlled substances.
- The CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance . . . ."
- Restrictions on the manufacture, distribution, and possession of a controlled substance depend on the "schedule" in which Congress has placed the drug.

The CSA and "Marijuana"

- From its inception, the CSA classified both "marijuana" and THC as Schedule I controlled substances.
- Definition of "marijuana" (pre-2018 Farm Bill):
  - ***"[A]ll parts of the plant <u>Cannabis sativa L.,</u> whether growing or not***; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin."
    - Excludes: "the mature stalk of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination."

Hemp v. Marijuana



Cannabidiol (CBD) Generally

- Unlike THC, which gives users the “high” feeling, CBD is non-psychoactive
- Although the data is mixed, CBD may have potential clinical effects on anxiety disorders, movement disorders, cognition, and pain
- CBD can be ingested/applied in multiple different ways, including:
  - Tinctures (essentially droplets of CBD infused alcohol placed under tongue)
  - Capsules
  - Oil
  - Inhalation of smoke or vapor
  - Infused food/drink
  - Cream
- At least one report suggests that the hemp-CBD market alone is poised to hit $22 billion by 2022

2014 Farm Bill

- 2014 Farm Bill
  - Notwithstanding the Controlled Substances Act . . . or any other Federal law, an institution of higher education (as defined in section 1001 of title 20) or a State department of agriculture may grow or cultivate industrial hemp if—
    - (1) the industrial hemp is grown or cultivated for purposes of research conducted under an **agricultural pilot program** or other agricultural or academic research . . .
- The 2014 Farm Bill defines "agricultural pilot program" as "a pilot program to study the growth, cultivation, or **marketing of industrial hemp** . . ."
- The 2014 Farm Bill defines "industrial hemp" as the "plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

2018 Farm Bill

- 2018 Farm Bill
  1. Removed “hemp” from CSA definition of “marijuana”
     - Defines “hemp” as “the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, whether growing or not, ***with a [THC] concentration of not more than 0.3 percent on a dry weight basis***.”
  2. Gave primary regulatory authority to states
     - If a state does not regulate, then federal regulations govern
  3. Forbids states from interfering with interstate shipment of hemp
  4. Does not affect the Food Drug & Cosmetic Act, among other things, as well as the authority of the FDA to promulgate regulations and guidelines under the FD&C Act.

2018 Farm Bill: Interstate Transportation

- “No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products **produced in accordance with [the 2018 Farm Bill]** through the State or the territory of the Indian Tribe, as applicable”

FDA Implications

- Federal Food, Drug, and Cosmetic Act (the "FD&C Act")
  - 2018 Farm Bill preserved the FDA's current authority to regulate products containing hemp-CBD under the FD&C Act
  - FDA issued a statement on hemp-CBD products that reiterated treatment of CBD as a "drug" and not a "dietary supplement" under FD&C Act, but suggested that this may change in the near future
    - Epidiolex
    - Sale of a "drug", including food containing the "drug", requires FDA regulatory approval

FDA Implications (cont'd)

- Federal Food, Drug, and Cosmetic Act (the "FD&C Act")
  - The FDA statement recognized "growing public interest in [CBD]", as well as "the potential opportunities that cannabis or cannabis-derived compounds could offer..."
  - The FDA statement committed to making the pathways for marketing CBD products more efficient
- FDA Enforcement
  - FDA enforcement priorities appear to focus on vendors that are making serious health claims about their CBD products
    - For example, "CBDs are effective against MRSA"
  - In those cases, the FDA issued warning letters:
    - 2015 – 6 Letters
    - 2016 – 8 Letters
    - 2017 – 4 Letters
    - 2018 – 1 Letter
  - FDA warning letters typically allow for post-warning compliance without penalty or fine