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CBD - New Gold Rush or Regulatory Minefield?

Presented by: Emily Gant, Garvey Schubert Barer

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Hemp or Marijuana?



Terminology



Hemp: the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.



Cannabinoid (“CBD”): compound of cannabis.

Purported benefits include relief from pain and anxiety relief. Does not make users feel “high” or “stoned.”



Tetrahydrocannabinol (“THC”): compound that is the main physiologically active ingredient of cannabis.

Makes users feel “high” or “stoned.”

Basics of the Farm Bill

- **Removes hemp from definition of “marihuana” in the Controlled Substances Act (“CSA”)**
- **Means that hemp is not a Schedule I controlled substance under the CSA**
- **No effect on state-legalized marijuana programs, whether medical or recreational**



Basics of the Farm Bill Cont'd

- **State and Tribal governments have primary regulatory authority over production of hemp, if they so choose**
- **Must submit plan to the US Department of Agriculture (“Dept of Ag”)**
- **Dept of Ag plan applies in States/Tribal jurisdictions in which no State/tribal plan**
- **Dept of Ag is drafting regulations**



Response From the FDA

**Expressly does not affect FDA's jurisdiction
under the Food, Drug, and Cosmetics Act
("FDCA")**

Response From the FDA Cont'd

December 20, 2018 Statement from FDA:

- Treats cannabis products like all other FDA-regulated products
- Therapeutic benefit claim → FDA approval needed before introduction into interstate commerce
- Intended for use in diagnosis, cure, mitigation, treatment or prevention of diseases → New drug; FDA approval needed before marketed in US



Response From the FDA Cont'd

December 20, 2018 Statement from FDA, cont'd:

- **CBD and THC are active ingredients in FDA-approved drug**
- **Food containing CBD/THC introduced in interstate commerce → Illegal**
- **Foods containing hemp, but not CBD/THC → Generally legal**
- **Marketing CBD/THC as dietary supplements → Illegal**



High Level Issues

State license required?	Source of hemp-based CBD product?
Import/export issues	Insurance
Impact on liquor license? Labeling requirements?	Employment issues
Compliant marketing programs	Liability considerations

Thank you!



CONTACT

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