

Pennsylvania's Industrial Hemp Program

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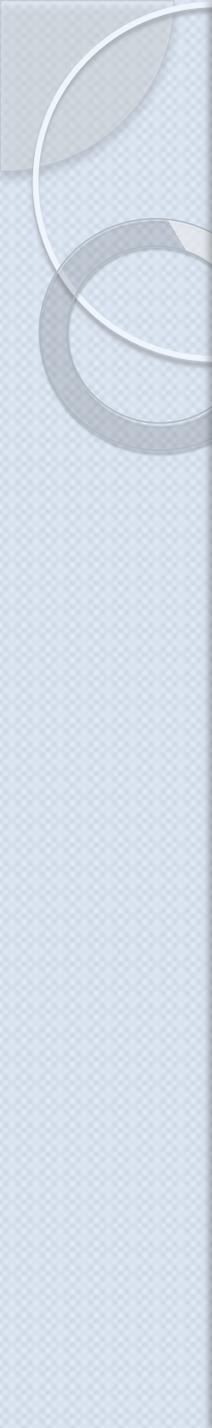
The Next 50 Minutes...

- Hemp vs. Marijuana
- Legislative History of Hemp
- Specific Issues in PA
- Product Development and Marketing
- Comparison with Other States/National Perspective

“Guess I get the gist of it”

Hemp vs. Marijuana

- Terminology
 - Cannabis
 - Marijuana
 - Hemp
 - Defined as cannabis that contains less than 0.3-percent THC
- Applicable Laws
 - Marijuana: CSA, Pa MMJA
 - Hemp: Farm Bill, Pa Ind. Hemp Pilot Program, FDCA (?)
- Governing State Agencies
 - Marijuana: Pa. Department of Health
 - Hemp: Pa. Department of Agriculture



“Well the first days are the hardest days”
Legislative History of Hemp

- **2014 Farm Bill**
 - Signed into law by President Obama on 2/7/14
- **Section 7606**
 - Authorizes institutions of higher education or state department's of agriculture in states that legalized hemp cultivation to regulate and conduct research and pilot programs.
 - Defines industrial hemp as distinct from marijuana.

“You better watch your speed”

Pennsylvania’s Response

- July 20, 2016 Gov. Wolf creates PA’s Industrial Hemp Pilot Research Program
 - An Act Amending Title 3 (Agriculture) of the Pennsylvania Consolidated Statutes, providing for industrial hemp research; imposing powers and duties on the Department of Agriculture and the Legislative Reference Bureau; imposing criminal and civil penalties; abrogating a regulation; and making a related repeal.
- Focus on research
- Empowers PDA to implement regulations and rules
 - “Program Parameters”

“Wildflower seed on the sand and stone”

Early Grow Seasons

- 2017 Program Parameters and limits
 - Size of grow
 - Number of permits
 - Application Process/Info Needed
 - Uses of Hemp

- Expansion of Program for 2018
 - Size increase
 - Production and research of CBD

“And the seeds that were silent all burst into bloom, and decay”

Preparing for the 2019 Grow Season

- **2019 Program Parameters**
 - Massive expansion of applicants and interest
 - Allowance of marketing research
 - CBD research still allowed
- **Applications due December, 2018**
 - Difference between PDA application and PaDOH application
- **Accepted applications notified on January 4, 2019**

“Did you hear what I just heard?”

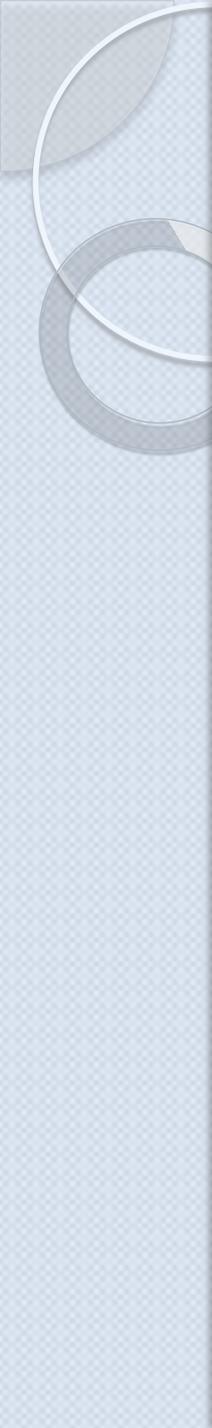
2018 Farm Bill

- Signed into law by President Trump on December 20, 2018
 - Government was shut down
 - Lacked immediate rule making capabilities
- Removes Hemp, as defined by the act, from the Schedule I of the CSA
- Allows States to regulate the growth and cultivation of Hemp, eliminating the “research” requirement
- States to submit their plan to USDA for approval
 - If State fails to submit, then USDA plan applies

“There is a road, no simple highway”

Applying the 2018 Farm Bill

- Immediate impact on PA’s 2019 grow season
 - Unlimited grows and more applications
- Courts’ response to the change:
 - *United States v. Mallory, S.D. West Virginia*
 - *No. 3:18-1289 (Jan. 17, 2019)*
 - *Dissolving an injunction and allowing hemp processors to “immediately transport the product to Pennsylvania for processing and sale of the CBD Isolate.”*
 - *“The Court cautions Defendants, however,....”*



“For this is all a dream we dreamed”
Uses of Hemp: CBD

- Hemp is legalized now, but what about CBD?
- 2018 Farm Bill explicitly references and defers to the FDCA
- FDA’s approval of GW Pharmaceutical’s drug: Epidiolex
 - *Marijuana* derived CBDs

“There are times you must live in doubt”

The FDA’s position on CBD

- [I]t’s unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.”
- “This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it’s illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.”
 - - Scott Gottlieb, December 20, 2018

“Could be an illusion, but I might as well try”
FDA Enforcement Actions

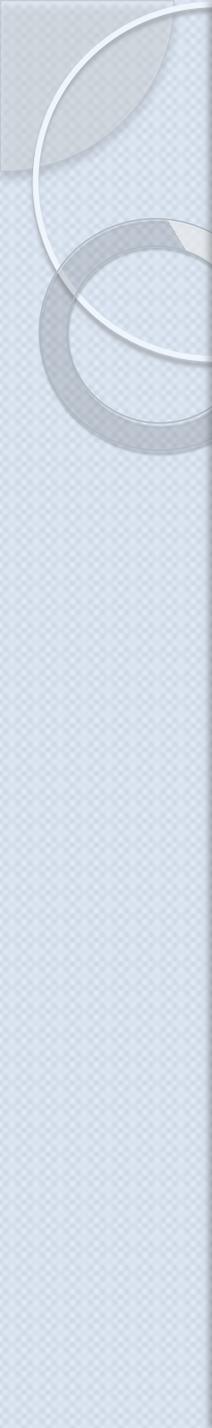
- FDA says guidance and regulations will be forthcoming. Until then, FDA maintains its position on CBD sales is clear.
- *“FDA Officials Confiscated CBD Edibles, Yuma Shop Owner Says”*
 - – Phoenix Times, Jan. 4, 2019
- *“Health Department banning CBD from all NYC restaurants”* –
 - - NY Post, Feb. 5, 2019

“Almost ablaze, still you don’t feel the heat”
Where does this leave us?

- Adding CBDs to food/drink products, or advertising that CBD or CBD infused products have health benefits violates the FDCA.
 - Defenses? Hemp/Marijuana CBD?
- For sale everywhere, but enforcement actions increasing, through State health Departments and asset seizure efforts.
- FDA in no apparent rush to promulgate regulations
 - Absent new guidance, expect continued enforcement actions

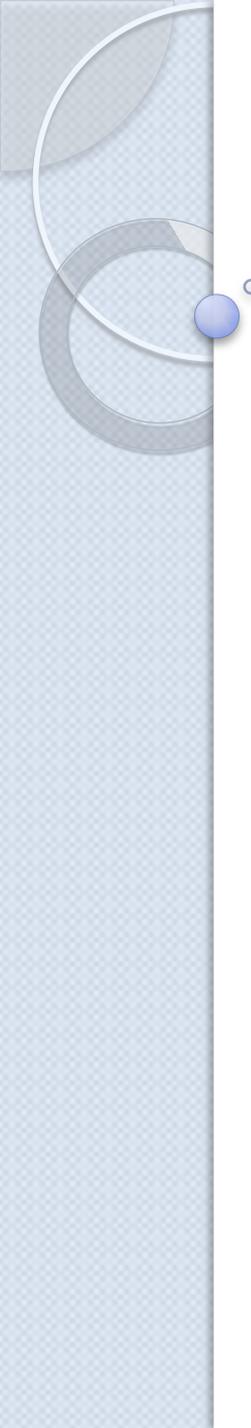
“Together, more or less in line, just keep truckin' on.”
US v. Mallory, revisited

- So where is the line between growing and processing hemp, which is lawful, and the sale of CBDs, which may run afoul of the FDCA?
 - “The mere potential of a downstream use that may violate certain federal regulations does not entitle the Government to an injunction on producing and selling the CBD isolate here.”
 - *US v. Mallory*, pg. 6
 - “The Court cautions...if Defendants intend to tout the health benefits of CBD or add it to food or health products without approval it risks running afoul of the FDCA and FDA regulations.”
 - *Id.*, pg. 7.



“Just one thing I ask of you”

- Questions?



Thank you.

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