

*AANP 2020 Webinar Series*

# **Hemp/CBD and the Integrative Practitioner: Lawful But Not Legal**

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February 20, 2020



# Housekeeping

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- Media rules apply. Please contact Frank Lampe ([frank@unpa.com](mailto:frank@unpa.com)) prior to publication of any webinar content.

# How all this started...

- The Agricultural Improvement Act of 2018 (the farm bill) removed hemp containing less than 0.3% THC from controlled substance status. That's the good news.
- The bad news is Congress did not clarify the lawful status of hemp-derived cannabinoids (CBD as the best example).

- FDA states CBD is not a lawful ingredient.
- And yet the market exploded, and FDA's actions have been limited to warning letters against extreme claims for CBD.
- This has created a mess.

- This PowerPoint was recently given to UNPA members, and we are happy to share this same presentation with AANP through the UNPA/AANP MOU partnership.

# Developments since December 20, 2019

Please recall Congress directed FDA to do the following:

- A 60-day report to obtain and analyze data to determine a policy of enforcement discretion and the process by which CBD meeting the definition of hemp will be evaluated for use in products.

- 180-day report to perform a sampling study of the current CBD marketplace to determine the extent to which products are mislabeled or adulterated.
- \$2 million was allocated for research, policy evaluation, market surveillance, issuance of an enforcement discretion policy and appropriate regulatory activities with respect to products under the jurisdiction of FDA, which contain CBD.

# UNPA shadow sampling study underway

- We will be working with member labs (Alkemist, NSF, Eurofins, Dyad) and MOU partner NCNPR to conduct a shadow sampling study to assess the market, evaluate results and investigate causes of mislabeling or adulteration (inadequate GMPs, poor source material, improper lab techniques).



The objective is the same as the New York AG shadow study – to provide us direct insight and understanding of the market conditions, thus allowing us to brief up Congressional staff members, prepare media responses and a corrective plan to address and resolve problems found.

UNPA and other TAs had proposed language that was pulled, and a new language (as noted above) was inserted as replacement text. This bought six months of time, and the reports will likely cause concern in Congress, very possibly chilling their efforts to support our “open the 321ff” pathway.

# New players

Since late December, there are many new players jumping into the CBD/hemp discussion. Examples:

- CBD Association (John Venardos)
- The Collaborative for CBD Safety and Science (sponsor of the CBD Summit)
- Coalition of Synthetic Cannabinoid Producers (co-sponsors of the CBD Summit)

This is creating new confusion, conflicting objectives, dilution of resources and blurring of the core ask.

# DSTA efforts

UNPA and its peer trade associations (AHPA, CRN, CHPA), along with the Hemp Roundtable and Hemp Industries Association, are conducting frequent calls and meetings to exchange information and discuss efforts to align interests, key objectives and strategies.

# CBD Summit

## January 15, 2020

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Summary of who was there, what was said and what this means.

# UNPA speaking schedule

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We are aggressively getting into the market to communicate our views, work toward building common understanding of the issues, alignment of efforts and coordination of resources.

## Events include:

- Expo West CBD Summit, March 3 – LDI to keynote
- Prevention Magazine media event, Feb. 27 in New York City – Larisa Pavlick invited to speak
- Dietary Supplements Regulatory Summit in Washington, D.C., on May 27 (CBD/Hemp Extracts Session)
- NBJ Summit, July 27-30 – LDI to co-develop CBD/hemp session and two speaking slots
- Webinar for AANP, Feb. 20
- ICSB (Ole Miss), April 3
- Holistic Primary Care Practitioner Forum, April 23, NYC

Other events are now in planning.

# Market conditions

- Price of dried hemp has sharply fallen
- Hemp farmers are in trouble
- Prices of CBD isolate and hemp extracts have fallen sharply
- Extractors and brand holders are increasingly distressed
- Venture capital and other financing is now scarce due to high levels of regulatory uncertainty



# Other issues

- Class action lawsuits – appear to be growing
- Amazon – no sell, but easy to buy. Investigative reporting now going on
- USDA rule-making – not helpful. We are bringing in USDA expertise to help advise members.

- White House 2021 budget review – with regard to dietary supplements and CBD
- CRS reports (2)

# Summary

- We need prompt resolution on a regulatory pathway.
- A collective effort on safety and evaluation of CBD and preparation to file NDIs is crucial.

- Congressional staff must be coached to support a “DS only” CBD regulatory pathway with NDI as a required step.
- Aggressive efforts must be made to align the DS industry around these objectives.

- Opponents will include food, beverage and synthetic cannabinoids. The unknown is whether GW will negotiate a dosage level and label claims that FDA will also support.
- Legislative vehicles are few.
- The political dynamics in D.C. are not favorable at this time.

- So, this is where we are. UNPA staff, Peter & Trish, are spending 60%+ time on CBD/hemp issues.
- We cannot continue at this work rate without further member support and new CBD/hemp member companies. We believe we have the right strategy, the right team, and a good chance of success if adequate resources are available.

- It's now up to the members to decide what level of UNPA staff activity they will support.
- We will circulate an updated 2020 revised work budget to the HE/C Committee and seek your individual response. We will then make a decision on what level of activity is possible.



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**Thank you!**

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