Looking at the future of the Hemp-CBD market

Presentation prepared for ILSI North America

Danny Rubenstein & Erik Janus – Steptoe and Johnson LLP

July 10, 2020

Steptoe

Topics for discussion

- Why Hemp-Derived CBD?
- Breaking Down US Market Trends
- Barriers to CBD Market Growth
- FDA Regulatory Position
- Looking Ahead

Steptoe

Why Hemp-Derived CBD?

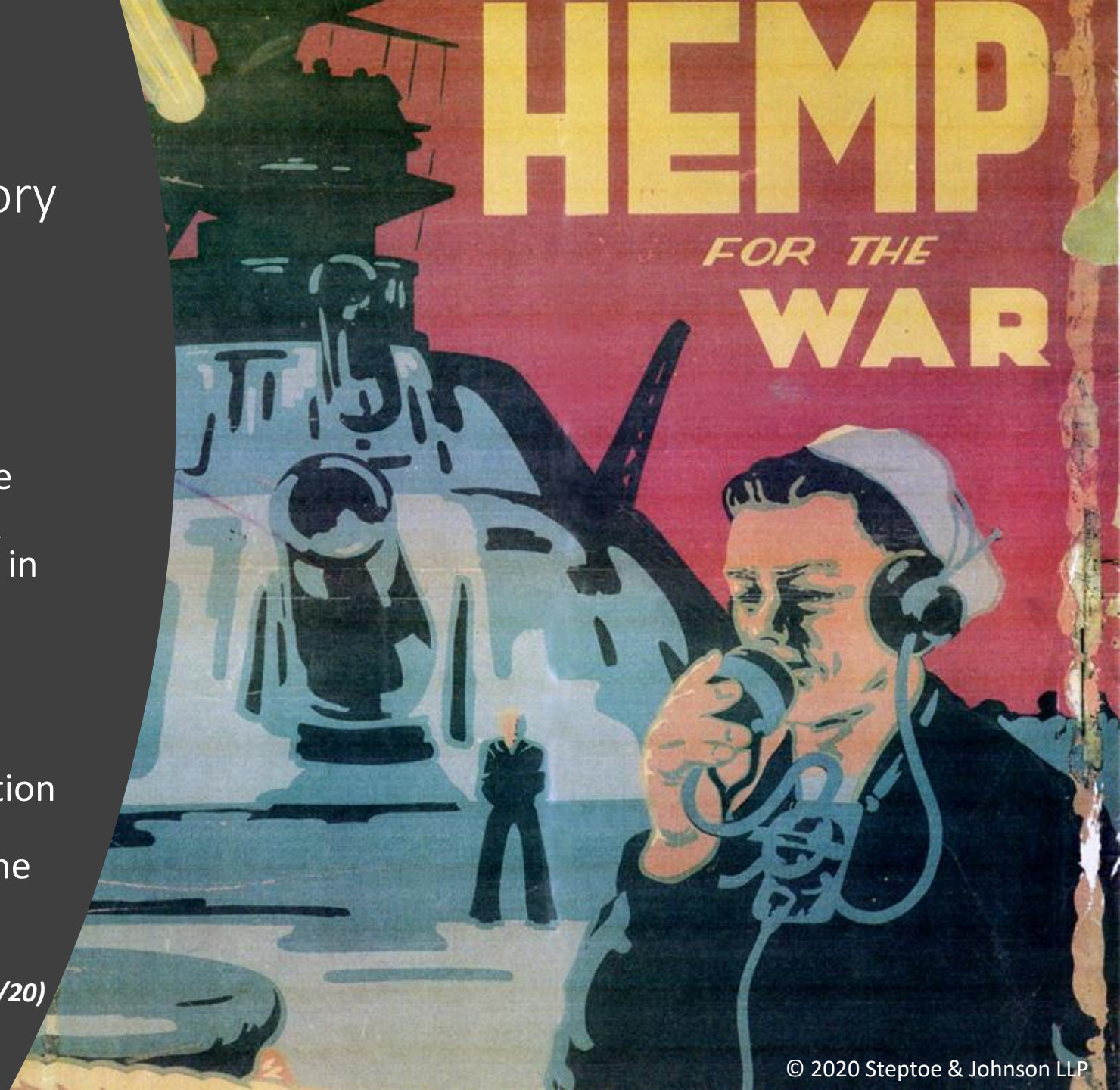
- *Cannabis sativa* is a versatile plant ("hemp" v. "marijuana") that is used for medical, recreational and industrial purposes – dependent on genetics of individual strains and agronomic conditions
- Cannabidiolic acid (CBDA) is one of 100+ cannabinoid acids produced by *Cannabis sativa* spp., predominantly by hemp-type cultivars
  - Cannabidiol (CBD) is produced upon extraction and heating ("decarboxylation")
  - CBD is non-psychoactive and potentially associated with pain control and health & wellness outcomes (i.e. sleep and stress management), though evidence is limited.
- 2018 Farm Bill removed hemp-derived CBD containing <0.3% THC from Schedule I of the Controlled Substances Act

Steptoe

US is Setting New Production Records with Broader Regulatory Approach and Cooperation

- As a result of the 2018 Farm Bill (and previous state-based hemp pilot production programs), the US is now producing more hemp than ever before
  - Previously, peak acreage was 146k acres (1943) - VoteHemp reported in excess of 500k in 2019
  - As of December 2019, only ID, MS and SD currently lack hemp production legislation
- Hemp added to USDA organic certification program in 2016; DEA restrictions on imported seed lifted with changes to the CSA under the 2018 Farm Bill

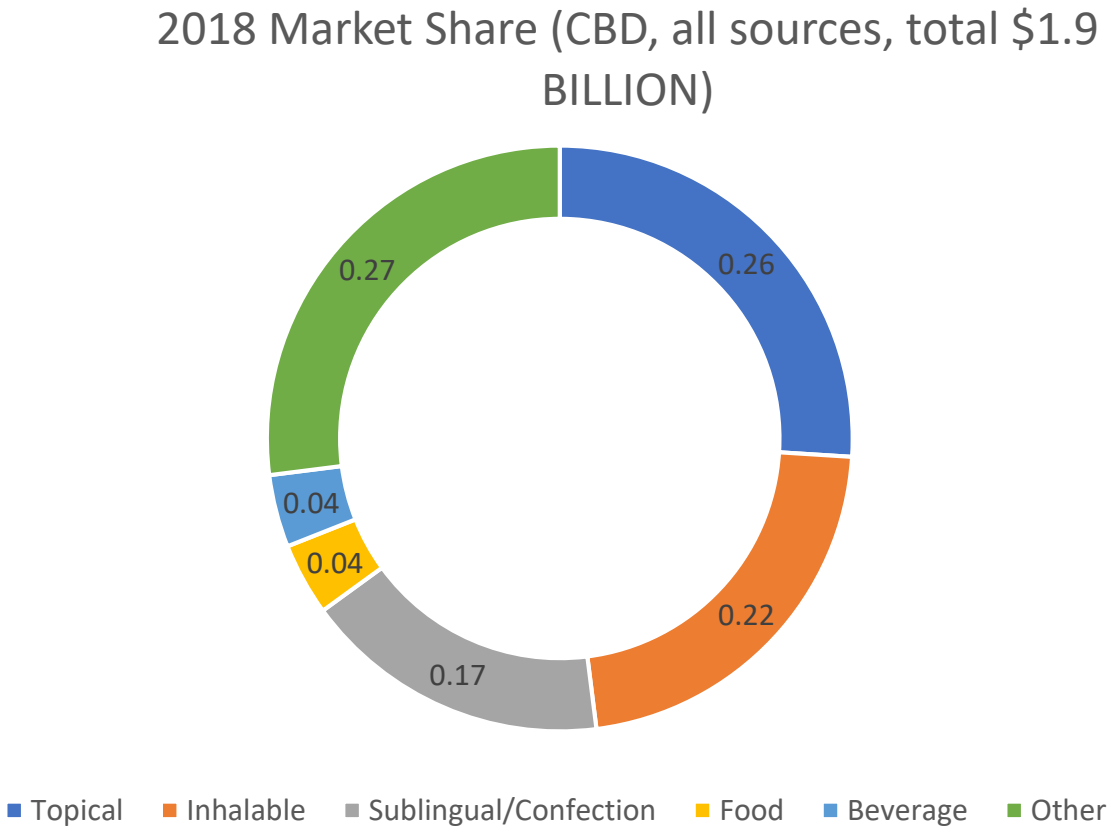
Source: Hemp-Derived CBD Economic Viability Report (USDA ERS 2/20)



Steptoe

CBD Consumer Demand

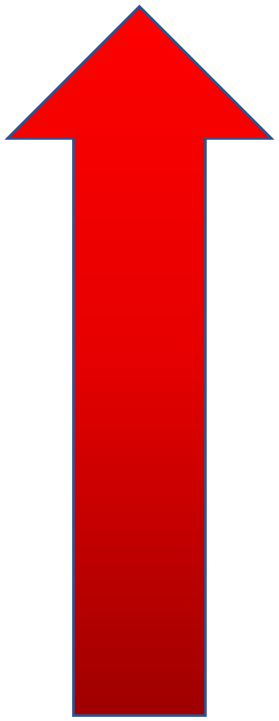
- CBD has been used in a variety of applications – including as a component of foods, dietary supplements, drugs and cosmetics.
- Importantly, however, many of these uses are not yet authorized in the US by FDA.
- Current authorizations in US effectively limited to one drug (Epidiolex®) and cosmetics.



hCBD market valued at $90 Million in 2015 and predicted to be $450 Million in 2020 (Brightfield Group, Hemp Business Journal)

Steptoe

Continued growth is anticipated in the near- to medium-term in all markets



- Total US CBD market value predictions for 2024-2025 range from $18-24 billion with CAGRs of ~45-50% (Brightfield, BDS Analytics, Canaccord)
  - Edibles: $6.9 billion (BDS)
  - Food & Beverages expected to be ~ 10% (~ $2.5 billion) by 2023 (Brightfield)
- Retail sales expected to drive future growth
- These mirror international forecasts: total CBD sales in Europe estimated to be €1.5 billion in 2023; UK total CBD market valued at $1.3 billion by 2025 (Brightfield, Ashbury)

Breaking Down US Sales Trends

- "Brick and Mortar" sales have surpassed online sales of CBD products, due to the entrance of retail, grocery and pharmacy chains
  - 57% of sales through retail and 22% online in 2019 (Brightfield Group)
  - Expect additional entrants: pet stores, gyms, other big box stores in the near future
- CBD-infused beverages as a subset of F&B may grow more quickly:
  - US sales expected to grow from $86 million (2019) to >$1.4 billion by 2023 (Zenith Global's Beverage Digest)
  - $2.8 billion market for CBD beverages by 2025 (Grand View Research)
  - Estimated 63% CAGR through 2023 (Brightfield)
- But regulatory obstacles remain…

Dispensary Sales of CBD are Predictive

- Dispensary channel (i.e. medical and recreational market products) distribution still dominates total CBD product sales (65% of an estimated $1.9 bill market in 2018) (BDS, Canaccord)
  - Sales of “CBD dominant” strains and associated products have grown ~4x in the last 5 years
- Non-dispensary hemp-CBD product sales tracks with dispensary-mediated products (BDS, Canaccord)
  - 53% edibles, 24% topicals, 11% inhalable Sublingual/topical formulations more popular at dispensaries than edibles and concentrates

Steptoe

USDA Review of hCBD Economic Viability

- USDA Economic Research Service (February 2020) reported that economic viability of the US hemp-derived CBD market is still uncertain and the markets are not expected to be viable in every state
  - Viability expected to be concentrated in regions near contracting and processing companies and where revenue is competitive with other crops
- States with early (non-commercial, research) pilot programs have not yet turned out to be major producers as of today
- Viability impacted by:
  - competition from other domestic crops for acreage,
  - well-established foreign competitors in hemp and hemp products,
  - Changes to production and pricing as a result of more market information and transparency, and
  - the evolving regulatory environment.

Steptoe

Looking at obstacles to market expansion

- Consumer demand is driving market through expansion of brand awareness and digital sales, but global consumer product use still only ~ 10% in 2020 (NaturalProducts Insider, BDS)
- Greater US market penetration is dependent on a number of obstacles (many discussed by USDA ERS):
  - Scientific & Technical: unclear terminology, lack of data
  - Legal & Liability: interstate commerce subject to FDA authority, USDA testing limitations, regulatory guidance needed, IP/trademark protection
  - State-Specific regulations: Oregon, South Carolina, etc.

Steptoe

FDA Regulation of Hemp-Derived CBD

- Federal Food, Drug and Cosmetic Act treats hemp-derived CBD as it would “any other compound” under federal regulation.
- Depending on the application(s) of interest, requirements range from a general safety status to premarket approval.
- FDA is taking a contemplated approach to the regulation of hemp-derived CBD.
- Agency is aware that the market is ahead of current regulatory landscape, but enforcement resources are limited.
- Current focus is on “low-hanging fruit” – drug claims, marketing and advertising focused on sensitive subpopulations.
- Future activities will likely focus on a balance of compliance and enforcement.
- Marijuana regulation is “de-coupled” from CBD, but still influences policy.

FDA Regulation of Hemp-Derived CBD

Types of Regulated Products

- **Food:** Three Generally Recognized as Safe (GRAS) ingredients – that's it!
- **Dietary Supplements:** None currently authorized by FDA
- **Drugs:** One specific authorization (Epidiolex®)
  - Clinical studies and approval foreclosed self-determined GRAS option for food
- **Cosmetics:**
  - Generally not subject to premarket approval by FDA…
  - Except for the use of color additives in the manufacture of a finished cosmetic.
  - Instead, cosmetics are simply "regulated" by FDA and ingredients must be safe.
  - Safe = not *adulterated* or *misbranded*, as those terms are defined under the FD&C Act

Steptoe

FDA Regulation of Hemp-Derived CBD

Claims Matter!

Adulterated:
If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling.

Misbranded:
False or misleading labeling. But claims matter not only because of misbranding, but also because of product positioning:

- Structure/Function claims ("CBD improves ____") = dietary supplement
- Diagnose/treat/cure/prevent a disease ("CBD cures ____") = drug

Products intended as cosmetics could *become* dietary supplements or drugs by virtue of product labeling – FDA will enforce as such.

Steptoe

FDA Regulation of Hemp-Derived CBD

Enforcement Activities

- Warning letters used as primary enforcement activity (quick, simple, effective, and very visible from a public standpoint)

- Agency focus on claims:
  - Products that purport to function as dietary supplements or drugs not permitted
  - FDA will state affirmatively that products "appear to be unapproved _____"
  - Remedial action usually involves amending product labels and claims; occasional withdrawal

- Agency focus on sensitive subpopulations:
  - Advertising that targets vulnerable –sick, elderly, children
  - Coordination with Federal Trade Commission and state agencies

Steptoe

Regulation of CBD at the State Level

- 2018 Farm Bill expanded state pilot programs originally authorized under 2014 Farm Bill
- Elimination of hemp-derived CBD from Schedule I opened the door to state regulation without directly conflicting with federal law
- Some states have taken a cautious approach (limited agricultural programs, often in conjunction with academic or institutional facilities with state funding or oversight)
- Other states have taken a more progressive approach (authorizing uses that go above and beyond FDA regulated uses, “when FDA catches up”)
- State enforcement also varies widely – certain products on the market with implicit state sanction; despite federal restrictions. Other states enforce federal restrictions aggressively. Some inconsistencies in understanding of FDA regulation at the state level.

Steptoe

Looking Ahead

- The demand for CBD products will continue to climb - despite offsets in supply (such as the poor 2019 hemp production season and COVID-related disruption this year)
- High-profile food and beverage applications will continue – including a recent application as a “novel food” in OECD (CBD classified as such in January 2019)
- Impacts of FDA leadership and class action lawsuits
- Future FDA guidance(s) on CBD in supplements and F&B [and associated timelines for roll-out]

Looking Ahead

- Hemp seed-derived products (dehulled hemp seeds, hemp seed protein, and hemp seed oil), which contain *de minimis* levels of CBD, are considered GRAS currently can be lawfully marketed in human food without the need for any further FDA approval
- Some companies have considered alternative formulations (i.e., topical products) as a way to enter the market while waiting for F&B obstacles to be reduced/eliminated
- Some companies are beginning to market alternative non-psychoactive cannabinoids with similar properties to CBD (i.e., CBG, CBC)
- Research into alternative sourcing for phytocannabinoid production has started

Japanese Company Says It Can Make CBD Out Of Orange Peels (May 29, 2020)

Innovations in Food Packaging

- Increased packaging needed for increased demand in the retail sector
- Bio-based packaging has increased in popularity and some large companies have produced plant-based plastic packaging for F&B
- Sources of plant-based plastics include leftover hemp biomass

Steptoe

Thanks for your attention! Questions?

Steptoe

Erik Janus
202.828.3617
ejanus@steptoe.com

Danny Rubenstein
202.429.1309
drubenstein@steptoe.com