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Business Information in a Global Context

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California – Land of the Regulated:

Prop 65, Slack Fill, and Other Significant California Regulations for the Dietary Supplement Industry

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Tweeting about this conference?

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Agenda

- Proposition 65
- Slack Fill
- Probiotic Labeling Legislation
- Subscription Disclosures
- Hemp / CBD

Prop 65: Litigation Wins

- **Preemption**

- In *Sowinski v. Post*, the Court of Appeal ruled that Prop 65 warnings for acrylamide in breakfast are preempted because they conflict with the FDA's longstanding policy encouraging consumption of whole grains and breakfast cereal
- Decision cannot be cited as precedent thanks to concerted effort by activists and the California AG to have it depublished
- Decision was very much based on facts and FDA statements over the years
- Nevertheless a recognition of FDA's power should it choose to exert itself

- **First Amendment**

- In *Wheat Growers v. Becerra*, the District Court (E.D. Cal.) enjoined the California AG from enforcing Proposition 65's warning requirement as to glyphosate, the active ingredient in Round Up
- The Court applied developing standards for compelled false speech that require the government to prove that the required statement is factual and non-controversial
- Re-reverses the Prop 65 burden of proof
- Case is stayed pending one more 9th Circuit decision on similar issues (*CTIA*)

Prop 65: Enforcement Trends

- **Tea settlement on lead**

- 60-day notices issued mid- to late-2016 to 58 companies
- Chemicals identified: lead (in 53) and naphthalene (in 7 (2 listed both))
- Several early independent settlements; average = \$23,000
- Joint settlement in November 2017 @ \$20k / \$40k / \$60k
- Most significant: Allow for calculation in brewed tea rather than tea bag

- **Spices**

- Dozens of 60-day notices in last 5 years over lead, arsenic, and cadmium
 - Turmeric
 - Ginger
 - Cumin
 - Cinnamon
 - Sage
- Primarily by Consumer Advocacy Group (Reuben Yeroushalmi)
- Proliferation of warnings

Prop 65: Regulations

- **Coffee Regulation**

- On June 3, OEHHA adopted a regulation declaring that carcinogens created in roasting or brewing coffee pose no significant risk of cancer
- Effective October 1, 2019
- Litigation continues over validity of regulation and pending enforcement action

- **Lead MADL**

- OEHHA has dropped its effort to lower the lead MADL; still at 0.5 mcg/day

- **Averaging Over Time**

- OEHHA has dropped its effort to restrict reproductive toxicants to a one-day period
- But OEHHA has still stated that its lead MADL uses a one-day period

- **Lot Averaging**

- OEHHA may proceed with effort to restrict averaging of concentrations across lots (foods)
- Likely to be reworked significantly from earlier proposals

- **Arithmetic Mean**

- OEHHA has proposed to “clarify” that “average” means arithmetic and not geometric mean
- Results in much lower warning thresholds for foods
- OEHHA may proceed with this effort

Prop 65: Listings

- **Addition of “nickel (soluble compounds)” as a reproductive toxin**
 - Defined as “compounds of nickel with solubility in water of greater than 0.1 moles per liter (mol/L) at 20 degrees Celsius”
 - Certainly includes nickel sulfate and nickel chloride; other compounds?
 - Analytical methods not readily available
 - Listing effective October 26, 2019
- **Cannabis and reproductive toxicity**
 - On March 15, 2019, OEHHA requested information on reproductive toxicity of four chemicals:
 - Cannabis (marijuana)
 - Marijuana (cannabis) smoke – already listed for cancer
 - Cannabis extracts
 - Δ -9-Tetrahydrocannabinol (THC)
 - Submission period closed April 29, 2019
 - OEHHA will develop the Hazard Identification Materials for submission to the DART-IC at a later date

Slack Fill

- **Approximately 80 class actions alleging slack fill were filed in 2017-18.**
- **Countless more settled upon receipt of demand letters.**
- **Leading jurisdictions:**
 - **California** (Bus. & Prof. Code §§ 12606; 12606.2; 17200 (UCL); 17500 (FAL))
 - **New York** (NY Gen. Bus. Law §§ 349, 350)
 - **Missouri** (Mo. Merchandising Practice Act, MRS 407.020 *et seq.*)
- **California District Attorneys are also very active**
 - **Bars**
 - **Protein and other powders**

Slack Fill

- **Cal. Assembly Bill 2632 (Santiago) added new safe harbors for both food (B&P § 12606.2) and non-food commodities (B&P § 12606)**
 - Prompted by business community concerns about application of slack fill laws to common forms of packaging and communication as well as the rise of internet commerce
- **Exempts from the slack fill prohibition packages where the mode of commerce (e.g., online) does not allow the consumer to view or handle the physical container or product**
- **Exempts packages where one or more of the following applies:**
 - (A) visible product content;
 - (B) actual size disclosures and number of units; or
 - (C) fill line.

Probiotic Labeling

- **AB 1178**
 - **Would add Section 110422.1 to the CA Health and Safety Code.**
 - **As introduced by Assemblyman Bill Quirk:**
 - (a) **Commencing January 1, 2022, a manufacturer or distributor of dietary supplements, as defined in Section 321(ff) of Title 21 of the United States Code, sold in the state that contain live microorganisms shall include both of the following on the label of the dietary supplement:**
 - (1) **The genus, species, and strain of each live microorganism in the dietary supplement.**
 - (2) **The total estimated quantity of all live microorganisms in the dietary supplement at the end of its shelf life, as measured by colony forming units (CFU).**
 - (b) **This section does not in any way limit or restrict any rights, remedies, or duties otherwise applicable by law.**
 - (c) **This section shall be implemented to the extent permitted by federal law.**
 - **Opposed by AHPA and CRN; supported by California Medical Association and International Scientific Association for Probiotics and Prebiotics.**

Probiotic Labeling

- **CRN / IPA Best Practices Guidelines for Probiotics (since January 2017); Labeling Recommendations:**
 - A. The quantitative amount(s) of probiotics in a product should be expressed in Colony Forming Units (CFUs).***
 - B. The labeled quantity of probiotics should reflect the quantity of live microorganisms at the end of the stated shelf life, not at the time of manufacture.**
 - C. The label should identify the genus, species, and strain for each microorganism in the product.**
 - D. Quantities should be declared as specified below.**
 - **i. Product containing only one strain: Declare the quantity of the strain in CFUs.**
 - **ii. Product containing multiple strains: Declare the total count of the blend in CFUs.****

* 21 CFR 101.36(b)(3)(ii)(A) requires that the quantity of probiotic dietary ingredients be declared in metric units.

** When technically feasible, also declare the quantity of each genus or species in the blend.

Probiotic Labeling

- **AB 1178**
 - Would add Section 110422.1 to the CA Health and Safety Code.
 - As amended:
 - (a) Commencing January 1, 2022, a manufacturer or distributor of dietary supplements, as defined in Section 321(ff) of Title 21 of the United States Code, sold in the state that contain live microorganisms shall include **both of the following** the genus, species, and strain of each live microorganism in the dietary supplement on the label of the dietary supplement. **The total estimated count of all live microorganisms in the dietary supplement at the end of its shelf life.**
 - (b) This section does not apply to dietary supplements containing live microorganisms manufactured before July 1, 2021, that are sold prior to January 1, 2023.
 - (c) This section does not in any way limit or restrict any rights, remedies, or duties otherwise applicable by law.
 - (d) This section shall be implemented to the extent permitted by federal law.
- Passed CA Assembly; sent to CA Senate Committee on Health (6-3-2019).

Subscription Disclosures

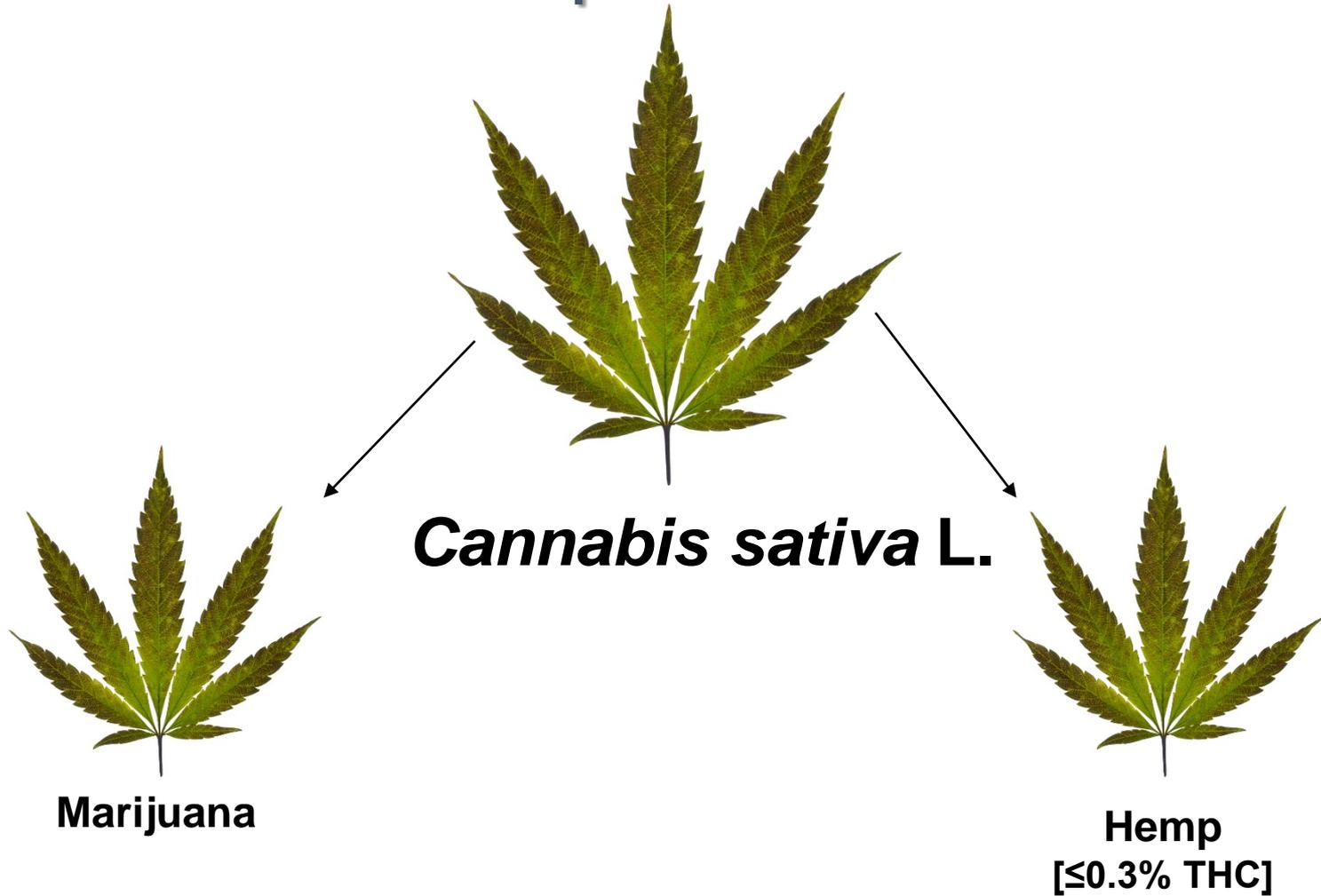
- **Federal law: Restore Online Shoppers' Confidence Act (ROSCA)**
 - General requirements for disclosures and consent
 - Enforced by FTC
- **California law: B&P 17600 *et seq.***
 - Clear and conspicuous
 - Visual proximity
 - Separate check-box (required in settlements)
 - Summary of renewal terms
 - Permit online cancellation
- **Private class-action settlements in CA**
 - Apple: \$16.5M (July 2018)
 - Code42 Software: \$400,000 (July 2017)
 - LifeLock: \$2.5M (July 2015)
- **Increased scrutiny from CA District and City Attorneys**

Subscription Disclosures

Company	Civil Penalties	Restitution	Costs	Total
Just Fabulous (July 2014)	\$980,000	n/a	\$895,000	\$1,875,000
MyLife (Feb 2015)	\$800,000	\$250,000	n/a	\$1,050,000
Stamps.com (Sept 2015)	\$2,475,000	\$1,500,000	\$25,000	\$4,000,000
Active Network (June 2016)	\$2,700,000	\$1,000,000	\$150,000	\$3,850,000
Beachbody (Aug 2017)	\$2,579,000 (includes cost)	\$1,000,000 (cy pres)	n/a	\$3,579,000
Savvier (Dec 2017)	\$848,113	\$100,000 (cy pres)	\$120,000	\$1,068,000
eHarmony (Jan 2018)	\$1,205,000	\$1,000,000 (fund)	\$75,000	\$2,280,000
Dropbox (May 2018)	\$1,600,000	\$500,000 (\$450,000 fund +\$50,000 cy pres)	\$100,000	\$2,200,000
Skype (Aug 2018)	\$650,000	\$50,000 (cy pres)	\$20,000	\$720,000
AdoreMe (Aug 2018)	\$600,000	\$200,000 + merchandise of \$250,000 as cy pres)	n/a	\$800,000
Spark Networks (Oct 2018)	\$500,000	\$985,000	\$75,000	\$1,560,000



Hemp / CBD

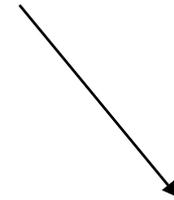




Hemp / CBD



Cannabis sativa L.



Hemp
[≤0.3% THC]



Marijuana

Hemp / CBD

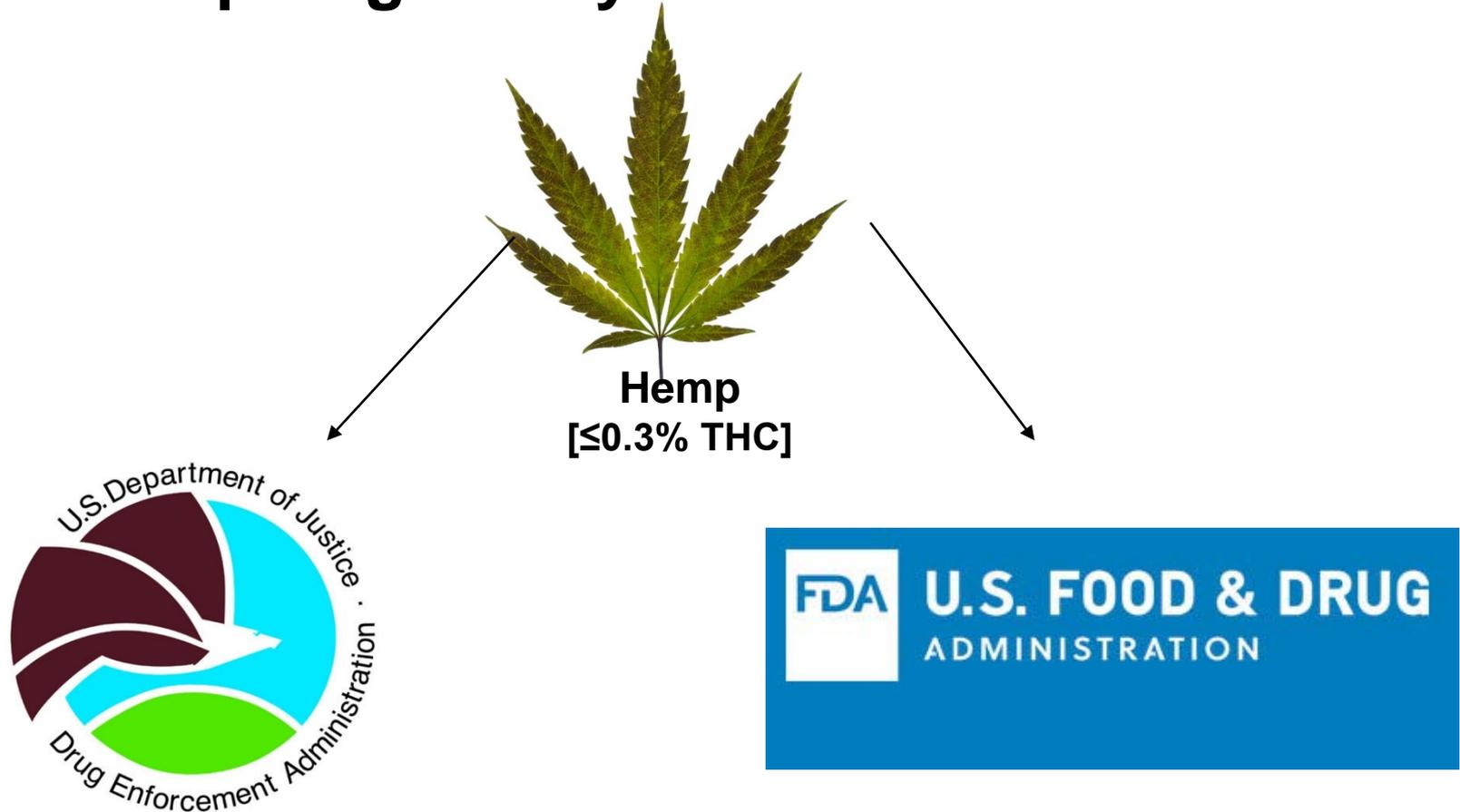
- **Federal background: The 2018 Farm Bill**
 - **Amended the Agricultural Marketing Act**
 - “The term ‘hemp’ means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”
 - Hemp acknowledged as an agricultural commodity under the federal purview of USDA (e.g., crop insurance, etc.)
 - Defines hemp “plans” to be submitted to USDA by States and Tribal governments.

Hemp / CBD

- **Federal background: The 2018 Farm Bill**
 - **Amended the Controlled Substances Act**
 - “The term ‘marihuana’ means all parts of the plant *Cannabis sativa* L., 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 ... **does not include (i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946;** or (ii) the mature stalks 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.”
 - “Tetrahydrocannabinols, **except for tetrahydrocannabinols in hemp...**” [re: CSA Schedule I]



Hemp Regulatory Controls: Historical



Hemp Regulatory Controls: Post Farm Bill 2018



Hemp
[$\leq 0.3\%$ THC]



50 Individual States (+ Tribes)

Hemp / CBD

- **State rules vary widely**
 - **California, North Carolina, and South Carolina have adopted FDA's position that CBD cannot be used in foods.**
 - **Idaho, Louisiana, Ohio, Nebraska, South Dakota, and Texas take a restrictive approach to CBD.**
 - **Several states (e.g., Oklahoma, Tennessee) only allow for the use of CBD under certain medical conditions; less clear for other uses.**
 - **New York requires CBD products to be labeled and manufactured as a dietary supplement.**
 - **Several states expressly allow hemp and CBD products, some with conditions:**
 - Kansas has a 0% THC requirement for CBD products.
 - Indiana and Utah have unique labeling requirements; Utah also requires registration.
 - Several states (e.g., Michigan and Maine) allow the use of hemp products in foods.

Hemp / CBD

- **CA DPH FDB – July 2018**

“Currently, the United States Food and Drug Administration (FDA) has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which tetrahydrocannabinol (THC) or CBD has been added. This is regardless of the source of the CBD – derived from industrial hemp or cannabis.

“Therefore, although California currently allows the manufacturing and sales of cannabis products (including edibles), the use of industrial hemp as the source of CBD to be added to food products is prohibited. Until the FDA rules that industrial hemp-derived CBD oil and CBD products can be used as a food or California makes a determination that they are safe to use for human and animal consumption, CBD products are not an approved food, food ingredient, food additive, or dietary supplement.”

Hemp / CBD

• CA AB 228

- Introduced January 17, 2019 (by Aguiar-Curry)
- Passed Assembly May 22, 2019 (77-0)
- Passed Senate Health Committee June 12, 2019 (8-0)
- Senate B&P Committee to hear week of June 17, 2019
- “Establishes a regulatory framework for industrial hemp products that contain no more than 0.3% tetrahydrocannabinol and is a cosmetic, food, food additive, dietary supplement, or herb.”
- Includes an urgency clause, so effective upon enactment.

Hemp / CBD

- **CA AB 228 – Regulatory framework**
 - Removes restriction on inclusion of hemp or CBD in food, beverages or cosmetics and states such products are not adulterated by the inclusion of these ingredients.
 - Defines “industrial hemp product” to include a cosmetic, food, food additive, dietary supplement, or herb containing “any part of the hemp plant” (including cannabinoids).
 - Manufacturer must be registered in CA as a food processing facility and to be able to document compliance of its source of hemp.
 - CoA required from independent lab; mandatory tests to confirm as hemp (i.e., THC NMT 0.3%) and that sample “did not contain contaminants that are unsafe for human consumption.”
 - Requires labeling if CBD is present: **“CANNABIDIOL USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. KEEP OUT OF REACH OF CHILDREN.”**

Thank You!!

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