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Texas Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

Re: Proposed Inspection Protocol for Hemp and Hemp By-Products in Food – On Behalf of the Texas Cannabis Industry Association

Dear Commissioner Hellerstedt:

Please be advised that I serve as the legal counsel for the Texas Cannabis Industry Association (TCIA) and provide the ensuing position on behalf of the organization.

BACKGROUND

The Texas Department of State Health Services ("DSHS") is seeking comments on a proposed inspection protocol for hemp and hemp by-products in food. Specifically, the DHSH offers a document on its website titled, "Proposed Inspection Protocol – Hemp and Hemp By-Products in Food." ("Protocol")[1] In the initial paragraph of the Protocol, DSHS states:

> "Two major by-products in hemp are cannabidiol (CBD) and tetrahydrocannabinol (THC). Both of these compounds are considered controlled substances by Drug Enforcement Agency (DEA) and adulterants in both conventional food and dietary supplements by the FDA. CBD is also considered to be a drug by the FDA."

DSHS is seeking comments on the Protocol from the public through April 16, 2018. At this time, the TCIA, offers its position on these issues, specifically identifying the flaws and concerns it has with the Protocol.

[1] https://www.dshs.texas.gov/foods/.

EXEMPT PARTS OF HEMP AND HEMP BY PRODUCTS UNDER THE CONTROLLED SUBSTANCES ACT

The federal Controlled Substances Act ("CSA") classifies marihuana as a Schedule I controlled substance and includes "all parts of the plant *Cannabis sativa* L…,"[2] while recognizing the exempt parts and the exceptions to the exempted parts of the plant.[3] Hemp is considered a variety of the species *Cannabis sativa* L. The exempt parts of the plant not deemed "marihuana" include "the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination."[4] The exempted parts are not regulated by the Drug Enforcement Agency ("DEA"), while the resin from the exempted parts of marihuana is regulated by the DEA.

It appears that the CSA takes on a rather broad interpretation of the term "marijuana." The statute identifies all of the *Cannabis sativa* L. plant, including every compound, as marihuana. While the statute identifies exempt parts of the plant (e.g. mature stalks, fibers, etc.), it also provides an exception to the exempt parts, particularly resin from the exempted parts. There is ample case law applying state level definition of marihuana, citing the exact language from the statute while applying the rule very broadly to the items (e.g. *Cannabis sativa* L. plant) in dispute in each case. Texas lacks such precedence. Currently, there are disputes regarding whether marihuana is considered monotypic versus polytypic with cannabis being categorized into three separate categories, *Cannabis sativa* L., *Cannabis indicia* and *Cannabis ruderalis*. The CSA only identifies *Cannabis sativa L*. as a Schedule I controlled substance.

It is presumed that CBD oil is an oil-based product composed of multiple substances, including compounds. Because compounds from the mature stalks of *Cannabis sativa* L. plants are exempt under the CSA, it is arguable CBD oil is exempt from being classified as marijuana, if the compounds in CBD comes solely from mature stalks. Thus, it would not be defined as a controlled substance under the CSA. However, if all or any portion of the compounds within CBD derives from the non-exempted parts of marihuana, or contains resins from the exempted parts, then it is likely to be considered marijuana under the CSA.

FOOD AND DRUG ADMINISTRATION – FOOD, DRUG & COSMETIC ACT AND DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

First, it is presumed that "FDA" referenced by DSHS is the Food and Drug Administration. Aside from the ambiguity (e.g. failure to identify the term "FDA"), DSHS provides an inaccurate statement regarding CBD being considered a drug by the FDA. As a point of clarification and

[2] 21 USC § 802.
[3] *Id.*
[4] *Id*.

contrary to the position taken by DSHS, the FDA considers CBD not receiving FDA approval in a drug product used to prevent, diagnose, treat, or cure a condition without evidence to support claimed outcomes.[5] FDA does not state "CBD is considered to be a drug" in accordance to its regulations.

The FDA is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines and many other health related products. The FDA was empowered by the United States Congress to enforce the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), which serves as the primary focus for the FDA. The FDA has expressed a concern for selling unapproved products with unsubstantiated therapeutic claims. This is a valid concern. However, the FD&C Act does not specifically address cannabis, marijuana, THC or CBD. The FD&C is entirely silent on the aforementioned compounds and items. It is arguable the FD&C Act may be inapplicable to the Protocol. However, assuming the FD&C Act applies to the Protocol, the FD&C Act should be restricted in its interpretation and applicable to CBD as it relates to hemp products (e.g. hemp seeds and hempseed oil).

The Protocol states DSHS will take action if a statement is on "…the label, in the ingredient statement, or any other material indicating that the products contains phytocannabinoids, CBD or THC." It is unclear whether DSHS is concerned about the issue of misbranding or adulterated products. Foods that are adulterated bears or contains any poisonous or deleterious substance which may render it injurious to health.[6] Applicable substances include, pesticide chemicals, new animal drug, product of a diseased animal or items held under insanitary conditions whereby it may have become contaminated with filth.[7] The substances at issue are CBD and THC derived from hemp products. These are merely natural compounds found in non-psychoactive industrial hemp, a *Cannabis* plant. It is blatantly clear the legislative intent behind the definition of adulterated products (e.g. foods) was to prevent dangerous substances that could cause adverse health effects or to create negative medical outcomes. While the FDA has yet to fully acknowledge the benefits of CBD, DSHS has not provided any evidence of adverse health effects of having CBD in food or other products processed by the human body.

Alternatively, if DSHS is concerned about misbranding, the Protocol does not clearly identify that concern. An product (e.g. food) is deemed misbranded if it contains a false or misleading statement regarding the quality, ingredients, packaging, along with many other applicable standards.[8] However, the main concern expressed by DSHS in the Protocol appears to be whether CBD is identified on labels. The Protocol expressly states that if "…the products

[5] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583295.htm.
[6] 21 U.S. Code § 342(a).
[7] *Id*.
[8] 21 U.S. Code § 343

contains phytocannabinoids, CBD or THC" DSHS will take action on the product. This standard is inconsistent with the FD&C Act, an indication of a secondary, yet unexpressed agenda and DSHS's failure to follow the guidelines established by the FDA. These shortcomings cannot be ignored especially when DSHS expressed on its website, "Regulatory authority has been granted to DSHS, under the Food, Drug, and Cosmetic Act… to prevent the unlawful manufacture or distribution of adulterated and misbranded food." DSHS clearly lacks the expertise and understanding of how the FD&C Act and the legislative intent behind the applicable statutes.

Because the FD&C Act is virtually silent on CBD and THC, it can be reasonably inferred that CBD and THC in products (e.g. oils or foods) may be governed by the less stringent guidelines of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). DSHEA amends the FD&C Act to alter the way dietary supplements are regulated and labeled.[9] Signing DSHEA into law on October 25, 1994, President Clinton said:[10]

> "After several years of intense efforts, manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level, have moved successfully to bring **common sense** to the treatment of dietary supplements under regulation and law."

The key words in this comment by President Clinton are "common sense." Through the passage of DSHEA, certain products that are defined as "dietary supplement" under the FD&C Act include vitamins, minerals, herbs or other botanical, amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake or a concentrate, metabolite, constituent, extract, or combination of the preceding substances.[11] While the FDA can remove products from the market, it must first establish that such products are adulterated (e.g., that the product is unsafe) or misbranded (e.g., that the labeling is false or misleading).[12] Moreover, the federal government must bear the burden of proof on each element to show that a dietary supplement is adulterated and a court will decide any issue on a de novo basis.[13]

DEPARTMENT OF STATE HEALTH SERVICES JURISDICTION AND ENFORCEMENT

It was established in the preceding paragraph that the first statement provided in the Protocol references CBD and THC. Specifically, the Protocol's first sentence states:

> "Two major by-products in hemp are cannabidiol (CBD) and tetrahydrocannabinol (THC)."

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[9] https://health.gov/dietsupp/ch1.htm.
[10] *Id*.
[11] 21 U.S. Code § 321(ff).
[12] https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/default.htm.
[13] 21 U.S. Code § 342(f)(D).

Traditionally, DSHS and the Texas Department of Health and Human Services ("DHHS") governs health care related entities and the regulatory landscape regarding licensure of those providers (e.g. hospitals, clinical laboratories). Although the DSHS ambit extends to public health (e.g. addressing zika virus epidemics) and public health records, this is unrelated to the regulation of CBD and THC from hemp products. More importantly, it should be noted that the Texas Department of Public Safety ("DPS") is the designated state agency to govern issues related to cannabis and cannabis related products under the Texas Compassionate Use Act,[14] not DSHS. In fact, DSHS is never once referenced or mentioned in any Texas statutes related to cannabis or the regulation of CBD or THC.[15]

In the Answer Brief filed by the United States Assistant Attorney General in *Hemp Industries Association v. DEA* the government asserts the petitioner lacked standing because it did not participate in the rulemaking proceedings, and failed to provide commentary in the process, resulting in any claims being waived.[16] Here, it is arguable the same analogy would apply to DSHS. DSHS was never involved in creation of Senate Bill 339. DSHS was never involved in the codification of the Texas Compassionate Use Act. DSHS was never involved in the issuance of licensure under the Texas Compassionate Use Act. In fact, up until the proposal of the Protocol, DSHS failed to establish any connection to the regulation or enforcement of CBD or THC. Based on the rationale provided by the Assistant Attorney General in *Hemp Industries Association v. DEA*, DSHS waived any position or proposed programs to regulate CBD or THC. Due to its non-existent involvement throughout the legislative process of Senate Bill 339, DSHS lacks the education and understanding of how CBD and THC from hemp products should be regulated. As such, DSH is an improper state agency to propose the Protocol.

PENDING LITIGATION & UNRESOLVED ISSUES- HEMP INDUSTRIES ASSOCIATION V. DEA

As previously stated, under the CSA, marihuana is classified as a Schedule I drug and is distinguished between controlled portions and exempted portions of the plant. Both marihuana and industrial hemp derives from the plant *Cannabis sativa* L. In 2001, the DEA published a rule regarding industrial hemp products in the Federal Register banning hemp seed and oil food products that contain any amount of trace residual THC. The Hemp Industry Association ("HIA") and other plaintiffs filed an urgent motion to stay the DEA's rule pending a final ruling. On February 6, 2004, United States Ninth Circuit Court of Appeals issued a unanimous decision in favor of the plaintiffs, stating:

[14] 6 Tex. Health & Safety Code § 487.001, *et.al.*

[15] DPS is the sole agency identified under 37 Tex. Admin. Code 1, Chap.12; 3 Tex. Occ. Code § 169.001, *et.al.*, both of which was codified for the purpose of regulating CBD products containing THC under the Texas Compassionate Use Act.

[16] Hemp Industries Association v. DEA (Filed June 2, 2017 Answer Brief; pages 11-12).

> "The **DEA cannot regulate** naturally-occurring THC not contained within or derived from marijuana – i.e non-psychoactive hemp is not included in Schedule I. The DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule a substance. The DEA's definition of "THC" contravenes the unambiguously expressed intent of Congress in the Controlled Substances Act and cannot be upheld."

Further, DSHS should acknowledge the Agricultural Act of 2014 (a.k.a. 2014 U.S. Farm Bill)[17] was signed into law by President Barack Obama on February 7, 2014. Section 7606 of the U.S. Farm Bill states:

> "Legitimacy of Industrial Hemp Research" defines industrial hemp as distinct from marijuana and authorizes institutions of higher education or state departments of agriculture to regulate and conduct industrial hemp research and pilot programs."

This statement in the U.S. Farm Bill clearly sets the tone and intent of the federal government to distinguish hemp from marijuana. In 2011, the DEA proposed a new rule to establish new drug codes, particularly marijuana extract, with the rule ("Final Rule") being finalized in December 2016. Immediately thereafter, a lawsuit was filed against the DEA on behalf of three petitioners, Hemp Industries Association, Centuria Natural Foods and R.M.H. Holdings, Inc.

That lawsuit is still currently pending in the United States Ninth Circuit Court of Appeals. On February 15, 2018, an oral argument was scheduled and a decision has not been reached. Because litigation is pending, and much of it involves the drug codes for CBD (along with CBG –cannabigerol, marijuana and marijuana extract), DSHS should refrain from implementing the Protocol. It is highly likely that CBD may not receive a drug code, receive a different classification or be classified in a completely different fashion, making the proposed actions in the Protocol inconsistent with federal law. Accordingly, until there is final disposition in the *Hemp Industries Association v. DEA* case, DSHS must not implement the Protocol.

Sincerely,

DYKEMA Cox Smith

Richard Y. Cheng

RYC

[17] Pub.L. 113–79; https://www.gpo.gov/fdsys/pkg/BILLS-113hr2642enr/pdf/BILLS-113hr2642enr.pdf.