HOBAN LAW GROUP
THE NATION'S PREMIER CANNABUSINESS FIRM

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Via US Certified Mail and Email

Mr. Ressler:

As you know, this firm represents numerous clients engaged in the cultivation, processing, manufacture, distribution of use of products which contain derivatives of industrial hemp (the "Products"). This letter is in response to a certain *Proposed Inspection Protocol – Hemp and Hemp By-products in Food* (the "Protocol") issued by the Texas Department of State Health Services (the "Department"). The Protocol specifically solicits public comment until April 16, 2018.

In short, the Protocol is, at its core, flawed beyond repair for many reasons including, without limitation, the following:

1. The Department gives inappropriate deference to the (erroneous) interpretations of law proffered by the Drug Enforcement Agency ("DEA") and other agencies, in contradiction of guidance provided explicitly and directly by Congress;
2. The Protocol baselessly cites standards of "trace" and "elevated" amounts of cannabinoids, neither of which are supported by the law and which creates issues of constitutionality;
3. The Department inappropriately treats cannabidiol ("CBD") as an adulterant;
4. The Department's conclusion that "trace" amounts of CBD do not pose a risk is correct, but is incomplete and fails to acknowledge that research demonstrates CBD does not pose a risk in greater in "trace" amounts; and
5. The Protocol creates unnecessary overregulation, which potentially exceeds the Department's jurisdiction.

Correspondingly, we implore you to seriously reconsider implementation of the Protocol in any way resembling its current form and to engage in further discussion with appropriate stakeholders to sensibly regulate the Products without implementing the Protocol. Implementation of the

Protocol would cause Texas to fall far behind the rest of the nation for years to come in its treatment and regulation of the Products. The adverse impact this Protocol would cause to the emerging hemp industry, its operators and those choosing to purchase and use such Products would be devastating and irreparable.

Factual Background

"Industrial hemp," as defined by Section 7606 of the Agricultural Act of 2014 (the "Farm Bill"), is a variety of *Cannabis sativa L.* which contains less than 0.3% tetrahydrocannabinol ("THC"), the psychoactive compound typically associated with "marihuana." The Farm Bill legalizes industrial hemp including, but not limited to, the cultivation, transport, processing, sale and use thereof.[1]

Moreover, the intent of Congress – as described by 29 bipartisan members of Congress in a congressional amicus brief – in enacting the Farm Bill was to confirm that industrial hemp, or cannabinoids derived from industrial hemp, are not to be treated as controlled substances.[2] Contrary to the treatment of controlled substances, the Farm Bill sought to specifically allow for many activities relating to industrial hemp, including but not limited to certain commercial activities, development of the Products, exploring the economic impact of hemp-derived cannabinoids including the Products and creating a retail marketplace for the Products.[3]

Cannabinoids – including THC and CBD – are compounds which naturally occur in *Cannabis*, both "marihuana" and "industrial hemp," but also an array of non-*Cannabis* sources including cacao, human breast milk, and even other flower varieties, as DEA acknowledges.[4] Naturally occurring cannabinoids, *per se*, are not controlled substances (with the exception of *synthetic* THC).[5]

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[1] *See* Pub. L. 113-79, §7606; *see also* Consolidated Appropriations Act, 2018 (Pub. L. No. 114-441 (Sec. 537, 729).

[2] *See Amicus Brief of Members of United States Congress in Support of Petitioners with Consent of All Parties* at 3, 26, *Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (argued February 15, 2018), available at: https://polis.house.gov/uploadedfiles/amicus_brief.pdf.

[3] *Id.* at 13-15.

[4] *See Denial of Petition to Initiate Proceedings to Reschedule Marijuana*, 81 Fed. Reg. 83,688-765, 53,692, 53,698, 53,753 (Aug. 12, 2016) (citing Giovanni Appendino et al., *Cannabinoids: occurrence and medicinal chemistry*, 18 Curr. Med. Chem. 1085 (2011)); *see also Brief of Petitioners* at 7, fn 3, *Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (argued February 15, 2018).

[5] *See Hemp Indus. Ass'n. v. DEA*, 357 F.3d 1012, 1014 (9th Cir. 2004); *Hemp Indus. Ass'n. v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003).

Below, this letter addresses certain flawed statements and assertions made in the Protocol, as well as flaws inherent to the Protocol. In light of these irreparable flaws, we respectfully request the Department not implement the Protocol, and instead engage in further dialogue with stakeholders, including our firm, to discuss a more appropriate regulatory scheme.

1. *Protocol Assertion: Upon deference to the DEA, cannabinoids such as CBD and THC are, unequivocally, controlled substances, even if derived from industrial hemp.*

   Response:

   Congress knew what it was doing and its intent to exclude nonpsychoactive hemp from regulation is entirely clear."[6]

   Or, alternatively, in DEA's own words, *"DEA is not seeking to schedule cannabinoids*."[7] Further, ĐEA "*does not purport to override the [Farm Bill]*."[8]

   To expound on the above points, the federal Controlled Substances Act ("CSA") does not illegalize the entire *Cannabis* plant. "Marihuana" only includes certain portions of the *Cannabis* plant, and neither includes "industrial hemp," pursuant to the Farm Bill, nor the exempted stalk, stem, fiber and non-viable seeds of the plant. Those exempted portions and varieties of the *Cannabis* plant are still lawful, *even if they contain naturally occurring cannabinoids such as THC*.[9] In these early 2000s cases, the Court found against DEA, and DEA did not appeal these decisions.

   Relatedly, the Court also found that although the CSA lists "THC" as a controlled substance, this reference is merely to *synthetic* THC, and not THC which naturally occurs in lawful portions and varieties of *Cannabis* – such as industrial hemp.[10]

   As noted above, in writing as well as during argument before the Ninth Circuit Court of Appeals, DEA itself has admitted that DEA is not seeking to control cannabinoids and that cannabinoids may be found in parts of the *Cannabis* plant, or other lawful sources, which

[6] *Id*.
[7] *See Brief for Respondents* at 29, *Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (argued February 15, 2018).
[8] *Id.* at 32.
[9] 357 F.3d at 1018; *Hemp Indus. Ass'n. v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003).
[10] *Id.*

DEA does not control.[11] Importantly, DEA also admits that where the Farm Bill applies, the DEA has no jurisdiction.[12]

The Farm Bill specifically makes lawful "industrial hemp" which includes all derivatives therefrom. It would, in fact, be a perverse interpretation of the Farm Bill for "industrial hemp" to be made lawful, but that the crop must then be destroyed because it contains alleged controlled substances.

For these reasons, the Protocol's deference to DEA is invalid because it fails to accurately reflect the law and fails to acknowledge that cannabinoids derived from "industrial hemp" are in fact lawful.

2. *Protocol Assertion: The Protocol distinguishes as between "trace" and "elevated" amounts of CBD and THC as the applicable standard in determining the appropriateness of marketing the Products.*

Response: There does not exist any legal basis – in the CSA or otherwise – to apply a "trace amount" standard, or to distinguish between "trace" and "elevated" amounts, as to the Products or derivatives of industrial hemp. In fact, such standard contradicts the existing *HIA v. DEA* caselaw from the early 2000s.[13] Moreover, there is not even any definition in law of "trace amount." The Department cites no such references (as there are none) and does not independently define "trace" or "elevated" amounts, either, despite creating these arbitrary standards.

The Farm Bill does not differentiate as between "trace" or "elevated" amounts of CBD or other naturally occurring cannabinoids in the Products, when derived from industrial hemp grown to contain below 0.3% THC. Conversely, the Farm Bill actually encourages product development exploring different hemp-derived cannabinoids.[14]

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[11] *See Brief for Respondents* at 26-29, *Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (argued February 15, 2018).
[12] *Id.* at 13-14, 32; *see also* Consolidated Appropriations Act, 2018 (Pub. L. No. 114-441 (Sec. 537, 729).
[13] *See* 357 F.3d 1012, 1014. There, the Court found "[DEA] cannot regulate naturally-occurring THC not contained within or derived from marijuana – i.e., non-psychoactive hemp products – because 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."
[14] *See Amicus Brief of Members of United States Congress in Support of Petitioners with Consent of All Parties* at 3, 26, *Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (argued February 15, 2018), available at: https://polis.house.gov/uploadedfiles/amicus_brief.pdf.

Without a legal basis or definition for a "trace amount" standard, the Protocol stands to arbitrarily create an impossibly nebulous standard for the Department to police and enforce against those engaging in lawful Farm Bill activities relating to industrial hemp. By doing so, various claims, including due process and other constitutional claims, are likely to ripen.

Instead, the appropriate standard should be premised upon derivation from lawful sources, such as industrial hemp – when grown below 0.3% THC by dry weight.

3. *Protocol Assertion: CBD is considered an "adulterant" in conventional foods and dietary supplements, and is instead considered a "drug," by the U.S. Food and Drug Administration ("FDA").*

   Response: For the reasons noted above, including DEA's own admissions, cannabinoids derived from "industrial hemp" are lawful. Thus, such cannabinoids cannot be deemed an "adulterant" by virtue of alleged illegality. Further, there are no other sources of federal or state law which specifically classify "CBD" or other hemp derivatives as an "adulterant."

   The Products would, at minimum, be appropriately regulated as dietary supplements pursuant to the Dietary Supplement Health and Education Act of 1994,[15] if not also as a conventional food pursuant to the Federal Food, Drug and Cosmetic Act.[16] This treatment would be appropriate given the longstanding prevalence of products containing derivatives of industrial hemp, including various amounts of cannabinoids. Such products were the subject of above-referenced litigation in the early 2000s.[17] Further to this end, there is evidence that FDA has been notified of self-affirmed GRAS status for products containing various derivatives of industrial hemp.

   Moreover, the Protocol inaccurately cites FDA; in fact, CBD has not been established to be a drug, in accordance with its governing statutes and regulations. Even in the event CBD became an ingredient in an FDA-approved drug product, there are, in fact, examples of the coexistence of the marketing of conventional products, such as supplements or nutraceuticals, and a drug product pursuant to FDA regulations.

   For the reasons noted above, the Protocol's determination that the Products do not comply with FDA regulations is both premature and in error. Thus, the Protocol should not be implemented to regulate upon these flawed determinations.

[15] *See generally Dietary Supplement Health and Education Act of 1994*, 108 Stat. 4325, Pub. L. No. 103-417 (1994).
[16] *See generally Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 301, *et seq.*
[17] *See* 357 F.3d at 1014; 333 F.3d at 1089.

4. *Protocol Assertion: The Department has been unable to find research that suggests trace amounts of CBD pose a risk to public health.*

   Response: Appropriately, the Department has failed to find research that suggests "trace amounts" of cannabinoids pose a risk to public health. This statement holds true for the Products as many contain non-detectable amounts of THC or, at most, less than 0.3% THC.

   However, the Department's findings are incomplete. In fact, that same research, if cited, would show that there is no evidence that CBD – in any amount – poses a risk to public health and has not been shown to cause dependence, abuse or harm.[18]

   The Protocol's assertion of a "trace amount" standard insinuates that a risk posed to public health by the Products is premised upon the potency of CBD in a given product. For the reasons noted above, the Department cannot plausibly substantiate (much less regulate) a non-existent distinction as between "trace" and "elevated" amounts of CBD in the Products.

5. *Protocol Assertion: The Protocol proposes to contact the state regulatory program from which any Products are shipped in conjunction with conducting surveillance of the detained Products.*

   Response: This proposal appears to be unnecessary overregulation, which creates additional burden, both in time and expense for the Department, other state regulatory programs and those who would be subjected to the Protocol. To the extent that this proposal contemplates the Department regulating activities outside of the State of Texas, the Department does not possess jurisdiction outside of its own state jurisdiction, nor do the state authorities that the Department proposes to contact. This component of the Protocol is unnecessarily burdensome and may exceed the Department's legal jurisdiction, and thus, should be stricken.

For the reasons set forth above, we implore the Department to not implement the Protocol, and instead propose that the Department engage in further dialogue with stakeholders to appropriately regulate hemp-derived products, such as the Products, in the State of Texas.

[18] S*ee e.g.* 21 CFR 53,693; *see also Researching Marijuana for Therapeutic Purposes: The Potential Promise of Cannabidiol (CBD)*, NATIONAL INSTITUTE OF DRUG ABUSE, available at: https://www.drugabuse.gov/about-nida/noras-blog/2015/07/researching-marijuana-therapeutic-purposes-potential-promise-cannabidiol-cbd (July 20, 2015).

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Thank you for your thoughtful consideration of this public comment. Our firm also extends a standing offer to further discuss this issue to ensure that any protocol considered and promulgated accurately reflects both the law and sensible policymaking regarding the Products. Please do not hesitate to contact myself or my colleague, Garrett Graff, with any questions. Thank you.

Very truly yours,

/s/ Robert T. Hoban
Robert T. Hoban