U.S. Hemp Roundtable

April 23, 2018

Division of Dockets Management
Food and Drug Administration
5630 Fishers Ln, Rm 1061
Rockville MD 20582

Re: Docket No. FDA-2018-N-1072-0001, 83 Fed. Reg. 15155 (April 9, 2018); International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; Cannabidiol; Request for Comments

To Whom It May Concern:

The U.S. Hemp Roundtable appreciates the opportunity to provide comments to the Food and Drug Administration ("FDA") on the use of cannabis and cannabis-related substances, which will be used by the FDA to prepare a scientific and medical evaluation in response to the World Health Organization's ("WHO") request for comments for its upcoming 40th Expert Committee on Drug Dependence ("ECDD"). Specifically, the FDA is requesting comments concerning the abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of the following substances: Cannabis plant and resin; Extracts and tinctures of cannabis; Delta -9-Tetrahydrocannabinol ("THC"); Stereoisomers of THC; Cannabidiol ("CBD"). WHO intends to use this information to consider whether to recommend certain international restrictions for these substances.

The U.S. Hemp Roundtable is the hemp industry's national business association that represents over thirty firms from across the country – at each link of the hemp supply and sales chain – and includes the ex officio membership of the industry's major grassroots organizations. Although our comments include some discussion of the safety and efficacy of CBD generally, our comments are intended to focus primarily on hemp-derived CBD and its legality.

We write to strongly urge FDA to recommend against the scheduling of hemp-derived CBD as an internationally controlled substance. As explained below, CBD

derived from hemp is not a controlled substance and has many medicinal and non-medicinal uses. We further urge FDA to include in its evaluation the evidence demonstrating the low abuse and dependence potential, safety, and health benefits of hemp-derived CBD – all of which were recognized by WHO in its recent report on CBD and have been confirmed by the totality of scientific evidence on CBD.[1]

Hemp-Derived CBD is Not Controlled as a Schedule I Substance Under the CSA

Although the Drug Enforcement Agency ("DEA") has listed both "Tetrahydrocannabinol" ("THC") and "Marihuana" as Schedule I controlled substances under the Controlled Substances Act ("CSA"), hemp-derived CBD does not fall under the CSA.

The CSA expressly excludes various portions of the *Cannabis sativa L.* plant and defines "marihuana" as follows:

> [A]ll 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. *Such term does not include 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.*[2] (emphasis added)

This interpretation of the CSA is also supported by two cases decided by the United States Court of Appeals for the Ninth Circuit.[3] Thus, while CBD found in marijuana is currently considered a Schedule I controlled substance, CBD derived from source material other than marijuana would not fall under the CSA. Therefore, CBD derived from industrial hemp and CBD found anywhere else in nature (i.e., flax seeds)[4] are not subject to the CSA.

In addition, Section 7606 of the Agricultural Act of 2014[5] defines "'industrial hemp'' as the plant *Cannabis sativa L.* and **any part of such plant**, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Section 7606 also permits the growth, cultivation, and marketing of industrial hemp by states with an Industrial Hemp Research Pilot Program or via an institution of higher education. Furthermore, industrial hemp that is grown and distributed pursuant to Section 7606 is specifically exempted from the CSA. This law permits the use of any part of such plant, and therefore hemp-derived CBD falls under this definition so long as it meets the 0.3 concentration limit for THC.

Hemp-Derived CBD Meets FDA's Definition of "Dietary Ingredient"

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[1] CANNABIDIOL (CBD) Pre-Review Report, Agenda Item 5.2, Expert Committee on Drug Dependence Thirty-ninth Meeting Geneva, 6-10 November 2017 ("WHO CBD Report"), available at: http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf.

[2] 21 U.S.C. § 802(16).

[3] *Hemp Industries Assn. v. Drug Enforcement Admin.*, 333 F.3d 1082, 1085 (9th Cir. 2003); *Hemp Industries Assn. v. Drug Enforcement Admin.*, 357 F.3d 1012 (9th Cir. 2004).

[4] https://www.ncbi.nlm.nih.gov/pubmed/22706678.

[5] https://hempsupporter.com/wp-content/uploads/2018/02/2014-Famr-Bill-7606.pdf.

With regard to the FDA's regulation of hemp-derived CBD, the Federal Food, Drug, and Cosmetic Act ("FD&CA") defines a dietary supplement in Section 201(ff) as a product intended to supplement the diet that contains one or more of the following "dietary ingredients":

> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A) through (E).[6]

Thus, we believe that hemp-derived CBD falls under subsection (E) as a dietary substance for use by man to supplement the diet by increasing the total dietary intake, and/or subsection (F) as an extract of the botanical plant *Cannabis sativa L.* As discussed below, one of the many health benefits of CBD is its ability to supplement the body's the endocannabinoid system.[7]

Although the FDA has taken the position that dietary supplements and food are precluded from containing CBD,[8] the Roundtable disagrees with the agency's position. Section 201(ff)(3)(B)(ii) of the FD&CA excludes from the definition of dietary supplement "an article authorized for investigation as a new drug…for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public," unless the article was previously marketed as a dietary supplement or as a food.[9] However, we contend that CBD does not fall under this preclusion because the clinical trials on CBD were extremely limited in scope and funding, and publication of these trials has also been limited. Further, to date, no drug with CBD as an active ingredient has been approved by FDA. Therefore, it is our position that CBD is a permissible dietary ingredient under the FD&CA.

CBD Does Not Meet the Qualifications for Scheduling Under the CSA

Regardless of the source material, i.e., whether CBD is derived from an exempted plant part or industrial hemp, it is important to note that CBD fails to meet the qualifications for scheduling under the CSA. In determining into which schedule a drug or other substance should be placed, or whether a substance should be decontrolled or rescheduled, the CSA requires that certain factors be considered, which are listed in Section 201 (c) of the CSA:

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[6] 21 U.S.C. § 321 (ff)(1).
[7] *See*, e.g., Mechoulam R, Parker LA. The endocannabinoid system and the brain. Annu Rev Psychol. 2013;64:21-47.
[8] FDA, Warning Letters and Test Results for Cannabidiol-Related Products (last updated Nov. 2, 2017), available at https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm; *see also* FDA, FDA and Marijuana: Questions and Answers (last updated Aug. 15, 2017), https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietary_supplements.
[9] 21 USC § 321(ff)(3)(B)(ii).

(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.[10]

As demonstrated by the evidence noted below, CBD – in particular, hemp-derived CBD – does not meet any of the required factors for scheduling under the CSA.

Abuse Potential and Actual Abuse of CBD

Because most hemp-derived CBD contains zero, or only a negligible amount of THC, the psychoactive component of cannabis, hemp-derived CBD products do not produce a "high" or the intoxicated effects associated with THC. Moreover, because CBD is non-psychoactive, it does not have the potential for abuse or dependency, and there is no potential for diversion.

A recent evaluation of CBD prepared by WHO's ECDD following its 39th Meeting ("WHO CBD Report") considered the pharmacology, toxicology, adverse reactions in humans, dependence potential, and abuse potential of CBD.[11] While there have been no controlled human studies investigating the potential physical dependence effect of CBD, an animal study found that no tolerance to CBD was observed at any dosage.[12] However, a review of acute and chronic studies in humans also found no tolerance to CBD.[13] The WHO CBD Report also notes that "there are no cases of abuse or dependence related to the use of pure CBD."[14]

Unlike THC, CBD shows a low affinity for the two primary cannabinoid receptors in the body, CB1 and CB2, which may explain why CBD does not exhibit the psychoactive effects associated with THC.[15] Further, both

[10] 21 U.S.C. § 811 (c).
[11] WHO CBD Report.
[12] *Id*. at 14, citing Hayakawa, K., et al., Repeated treatment with cannabidiol but not Δ9- tetrahydrocannabinol has a neuroprotective effect without the development of tolerance. Neuropharmacology, 2007. 52(4): p. 1079-1087.
[13] Bergamaschi MM, Queiroz RH, Zuardi AW, et al. Safety and side effects of cannabidiol, a Cannabis sativa constituent. Curr Drug Saf. 2011;6: 237–249.
[14] *Id*. at 19.
[15] Canadian Hemp Trade Alliance, Modernizing the Industrial Hemp Regime (Aug. 10, 2017) ("CHTA Report"), available at: http://www.hemptrade.ca/source/CHTA%20Position%20Paper%20-%20Modernizing%20the%20Industrial%20Hemp%20Regulations%20August%2011%202017.pdf, at 7; see also McPartland, J.M., et al., Are cannabidiol and Δ9-tetrahydrocannabivarin negative modulators of the endocannabinoid system? A systematic review. British Journal of Pharmacology, 2015. 172(3): p. 737-753; Pertwee, R., The diverse CB1 and CB2 receptor pharmacology of three plant cannabinoids: Δ9-tetrahydrocannabinol, cannabidiol and Δ9-tetrahydrocannabivarin. British journal of pharmacology, 2008. 153(2): p. 199-215.

animal and human studies confirm the low abuse potential of CBD. Even at high doses, CBD did not exhibit the same effects in the brain as drugs with high abuse potential such as cocaine, methamphetamine, and opioids.[16] Additional animal studies found that CBD failed to exhibit the same effects in the brain as THC.[17]

In a randomized, double-blind, placebo-controlled trial of healthy volunteers, 600 mg of CBD did not produce subjective levels of intoxication or psychotic symptoms, in contrast to THC.[18] Likewise, a study found that CBD acted like placebo on various performance and physical measures when compared to active smoked cannabis, the latter of which produced abuse-related subjective effects.[19] Of note, research suggests that CBD may provide support for addiction disorders.[20] Therefore, not only does CBD have a low potential for abuse and addiction, emerging research suggests that it may actually promote public health by countering some of the negative effects associated with addiction. The WHO CBD Report also found that "there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD."[21] Also notable is the recent decision by the World Anti-Doping Agency ("WADA") to remove CBD from its prohibited substances list, although THC will remain on the list.[22] WADA considered the effects on athletes and benefits that athletes may obtain from the use of CBD and found that CBD has no addictive property that would be detrimental to the athletes, and therefore it did not meet the criteria for prohibited substances.[23]

Trafficking of CBD

The WHO CBD Report notes that currently there are no published statistics or data available regarding the seizure of illicit CBD.[24] Although the regulation of CBD around the globe varies, several countries permit CBD products for medicinal purposes and some exempt CBD derived from industrial hemp from scheduling if the content of THC is below 0.3 percent.[25] Even in countries where CBD falls under a legal "gray" area, the trafficking of CBD is highly unlikely given that it lacks the characteristics of illicit substances that are often

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[16] Katsidoni, V., I. Anagnostou, and G. Panagis, Cannabidiol inhibits the reward facilitating effect of morphine: Involvement of 5-HT1A receptors in the dorsal raphe nucleus. Addiction Biology, 2013. 18(2): p. 286-296.

[17] French, E.D., K. Dillon, and X. Wu, Cannabinoids excite dopamine neurons in the ventral tegmentum and substantia nigra. Neuroreport, 1997. 8(3): p. 649-652; Vann, R.E., et al., Divergent effects of cannabidiol on the discriminative stimulus and place conditioning effects of Δ9-tetrahydrocannabinol. Drug and Alcohol Dependence, 2008. 94(1-3): p. 191-198; Klein, C., et al., Cannabidiol potentiates Δ 9-tetrahydrocannabinol (THC) behavioural effects and alters THC pharmacokinetics during acute and chronic treatment in adolescent rats. Psychopharmacology, 2011. 218(2): p. 443-457; Jarbe, T.U.C., B.G. Henriksson, and G.C. Ohlin, Δ9-THC as a discriminative cue in pigeons: effects of Δ8-THC, CBD, and CBN. Archives Internationales de Pharmacodynamie et de Therapie, 1977. 228(1): p. 68-72.

[18] Martin-Santos, R., et al., Acute effects of a single, oral dose of d9- tetrahydrocannabinol (THC) and cannabidiol (CBD) administration in healthy volunteers. Curr Pharm Des, 2012. 18(32): p. 4966-79.

[19] Babalonis, S., et al., Oral cannabidiol does not produce a signal for abuse liability in frequent marijuana smokers. Drug and alcohol dependence, 2017. 172: p. 9-13.

[20] Morgan CJ, Freeman TP, Schafer GL. Cannabidiol attenuates the appetitive effects of Δ9-tetrahydrocannabinol in humans smoking their chosen cannabis. Neuropsychopharmacology. 2010;35:1879–1885; Hurd YL, Yoon M, Manini AF. Early phase in the development of cannabidiol as a treatment for addiction: opioid relapse takes initial center stage. Neurotherapeutics. 2015;12:807–815.

[21] WHO CBD Report at 5.

[22] https://www.wada-ama.org/sites/default/files/prohibited_list_2018_summary_of_modifications_en.pdf.

[23] https://www.wada-ama.org/en/questions-answers/prohibited-list-qa#item-391.

[24] *Id*. at 20.

[25] CHTA Report at 11-12.

subject to illegal trade and trafficking. Individuals that seek out CBD do so primarily for its health benefits and because it does not exhibit the psychoactive effects associated with THC.

Health Benefits and Safety of CBD

Current scientific research confirms that hemp-derived CBD is safe and has provided health benefits to thousands of consumers around the world with little or no side effects. We are also not aware of any serious adverse events associated with CBD domestically or globally. While most of the evidence regarding the safety and efficacy of CBD is focused on disease populations – which is typical of dietary supplement research – more importantly, the evidence clearly demonstrates the overall safety of CBD and its vast potential for healthy and non-healthy populations alike. As the FDA is aware, dietary ingredients can be legally marketed (and studied) as drugs, food, or dietary supplements; the key consideration is the intended use of the product as reflected in the labeling claims,[26] rather than the use of disease endpoints in studies investigating these ingredients.

A growing body of scientific research demonstrates CBD's potential benefits for a wide range of health conditions, including mild, self-treating conditions in otherwise healthy people. Research indicates that CBD provides neuroprotective benefits, can help support a healthy inflammation response, and supports and maintains the endocannabinoid, cognitive, nervous, digestive, and immune systems (among others), which demonstrate its many health benefits.[27] In particular, CBD may also be effective for less serious issues such as nausea, occasional pain and discomfort, and mild anxiety and stress.[28] Clinical evidence has found that CBD may be an effective and well-tolerated for more serious medical conditions as well.[29] Moreover, CBD was found to be better tolerated, had milder side effects, and had comparable efficacy when compared to conventional medical treatment.[30] Studies have also found that CBD may counteract some of the side-effects associated with THC.[31]

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[26] 21 C.F.R. §§ 201.128 and 801.4, define intended use to refer to the "objective intent" of the manufacturer, which includes "labeling claims, advertising matter, or oral or written statements."

[27] Pisanti, S., et al., Cannabidiol: State of the art and new challenges for therapeutic applications. Pharmacol Ther, 2017. 175: p. 133-150; Izzo, A. A., Borrelli, F., Capasso, R., Di, Marzo, V and others. (2009). Non-psychotropic plant cannabinoids: new therapeutic opportunities from an ancient herb. Trends Pharmacol.Sci. 30: 515-527.

[28] Pisanti, S., et al., Cannabidiol: State of the art and new challenges for therapeutic applications. Pharmacol Ther, 2017. 175: p. 133-150.

[29] Leweke FM, Piomelli D, Pahlisch F, Muhl D, Gerth CW, Hoyer C, Klosterkötter J, Hellmich M, Koethe D. (2012) Cannabidiol enhances anandamide signaling and alleviates psychotic symptoms of schizophrenia. Transl Psychiatry 2:e94; Bumb JM, Enning F, Leweke FM. (2015) Drug repurposing and emerging adjunctive treatments for schizophrenia. Expert Opin Pharmacother. 16(7):1049-67; Manseau MW, Goff DC. (2015) Cannabinoids and Schizophrenia: Risks and Therapeutic Potential. Neurotherapeutics. 12(4):816-24; Devinsky O, Marsh E, Friedman D, Thiele E, Laux L, Sullivan J, Miller I, Flamini R, Wilfong A, Filloux F, Wong M, Tilton N, Bruno P, Bluvstein J, Hedlund J, Kamens R, Maclean J, Nangia S, Singhal NS, Wilson CA, Patel A, Cilio MR. (2015) Cannabidiol in patients with treatment-resistant epilepsy: an open label interventional trial. Lancet Neurol. Dec 23. pii: S1474-4422(15)00379-8; Paolino MC, Ferretti A, Papetti L, Villa MP, Parisi P. (2015) Cannabidiol as potential treatment in refractory pediatric epilepsy. Expert Rev Neurother. 2015 Dec 9:1-5.

[29] Luvone T, Esposito G, De Filippis D, Scuderi C, Steardo L.(2009) Cannabidiol: a promising drug for neurodegenerative disorders? CNS Neurosci Ther. 2009 Winter;15(1):65-75.

[30] Iffland, K. and F. Grotenhermen, An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies. Cannabis and Cannabinoid Research, 2017. 2(1): p. 139-154.

[31] Bhattacharyya S, Morrison PD, Fusar-Poli P, Martin-Santos R, Borgwardt S, Winton-Brown T, Nosarti C, O' Carroll CM, Seal M, Allen P, Mehta MA, Stone JM, Tunstall N, Giampietro V, Kapur S, Murray RM, Zuardi AW, Crippa JA, Atakan Z, McGuire PK.

With regard to safety, the WHO CBD Report determined that "CBD is generally well tolerated with a good safety profile."[32] In an early pilot study in humans, 10 mg of oral CBD for 21 days showed no significant change in neurological, clinical, mental, blood and urine examinations.[33] Another early study in humans examined the administration of 3mg/kg body weight on a weekly basis for 30 days and demonstrated similar results.[34] Since then, additional studies of CBD in humans have confirmed its excellent safety profile in both healthy and diseased populations at a variety of doses. In 2011, a comprehensive review of the safety and side effects of CBD showed that even at very high doses, this substance shows no toxicity and is well tolerated without significant side effects. In a total of 132 reviewed publications, CBD did not induce catalepsy or affect factors such as heart rate, blood pressure, body temperature, gastrointestinal transit, nor did it alter psychomotor and cognitive functions.[35] Even at dosages of up to 1,500 mg per day, CBD was found to be well tolerated in humans.[36]

A more recent scientific review, published in 2017, confirms the safety and relatively low toxicity of CBD for a number of conditions without serious side effects.[37] In addition, a review of studies on CBD's benefits for measures of behavioral health showed a positive effect and an absence of side effects.[38] Studies also suggest that CBD can help support healthy withdrawal and in some cases speed the progression of withdrawal, without any side effects.[39] The 2017 review also noted that of the available trials performed until September 2016, the side effects of CBD "were generally mild and infrequent," with some subjects reporting side effects such as tiredness, diarrhea, and weight loss/weight gain.[40] As demonstrated above, the scientific literature clearly demonstrates that CBD is a safe and medically useful option, especially for healthy populations.

(2010) Opposite Effects of Δ-9-Tetrahydrocannabinol and Cannabidiol on Human Brain Function and Psychopathology. Neuropsychopharmacology, 35:764–774; Fusar-Poli P, Crippa JA, Bhattacharyya S, Borgwardt SJ, Allen P, Martin-Santos R, Seal M, Surguladze SA, O'Carrol C, Atakan Z, Zuardi AW, McGuire PK (2009) Distinct effects of {delta}9-tetrahydrocannabinol and cannabidiol on neural activation during emotional processing. Arch Gen Psychiatry 66:95–105.

[32] WHO CBD Report at 5.

[33] Mincis M, Pfeferman A, Guimarães RX, et al. Chronic administration of cannabidiol in man. Pilot study. AMB Rev Assoc Med Bras 1973; 19(5): 185-90.

[34] Cunha JM, Carlini EA, Pereira AE, et al. Chronic administration of cannabidiol to healthy volunteers and epileptic patients. Pharmacology 1980; 21: 175-85.

[35] Machado Bergamaschi, M., et al., Safety and side effects of cannabidiol, a Cannabis sativa constituent. Current drug safety, 2011. 6(4): p. 237-249.

[36] Zuardi AW, Morais SL, Guimarães FS, Mechoulam R. Antipsychotic effect of cannabidiol. J Clin Psychiatry 1995; 56(10): 485-6.

[37] Iffland, K. and F. Grotenhermen, An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies. Cannabis and Cannabinoid Research, 2017. 2(1): p. 139-154; Zuardi AW, Crippa JAS, Hallak JEC, et al. Cannabidiol for the treatment of psychosis in Parkinson's disease. J Psychopharmacol. 2009;3:979–983; Cunha J, Carlini EA, Pereira AE, et al. Chronic administration of cannabidiol to healthy volunteers and epileptic patients. Pharmacology. 1980;21:175– 185.

[38] Iseger TA, Bossong MG. A systematic review of the antipsychotic properties of cannabidiol in humans. Schizophr Res. 2015;162:153–161.

[39] Manini AF, Yiannoulos G, Bergamaschi MM, et al. Safety and pharmacokinetics of oral cannabidiol when administered concomitantly with intravenous fentanyl in humans. J Addict Med. 2014;9: 204–210; Crippa JAS, Hallak JEC, Machado-de-Sousa JP, et al. Cannabidiol for the treatment of cannabis withdrawal syndrome: a case report. J Clin Pharm Ther. 2013;38:162–164; Morgan CJ, Das RK, Joye A, et al. Cannabidiol reduces cigarette consumption in tobacco smokers: preliminary findings. Addictive Behav. 2013;38:2433–2436.

[40] Iffland, K. and F. Grotenhermen, An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies. Cannabis and Cannabinoid Research, 2017. 2(1): p. 139-154.

Impact of Scheduling Changes on Availability

As noted above, the regulation of CBD around the globe varies, and most countries permit CBD products for medicinal purposes. In fact, many are currently seeking to ease restrictions on CBD products, such as hemp-derived CBD, in recognition of its benefits and safety, especially given that THC is only present in trace amounts.[41] As a result of this evidence regarding the benefits of CBD, seventeen states in the U.S. have enacted laws that legalized therapeutic uses of CBD.[42] Some state legislatures in the U.S. have also enacted laws that allow residents to buy, sell and possess CBD, so long as the products meet labeling requirements and contain no more than 0.3 percent THC.[43]

Thus, the classification of CBD as a controlled substance by WHO would create unnecessary obstacles to the international trade, manufacture, and availability of hemp-derived CBD products and disadvantage researchers and consumers alike. While statistics are not readily available, it is estimated that US sales of products containing CBD were over $100 Million in 2017, with a likely doubling of that in 2018. The economic impact of improperly scheduling CBD would be significant to US growers, processors and those developing and marketing hemp-derived CBD products.

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In closing, given that hemp-derived CBD is not a controlled substance under CSA and has tremendous potential to improve public health, the international scheduling of CBD would serve as an impediment to research and development purposes. Again, we urge FDA to recommend against the scheduling of CBD in its evaluation to WHO and recognize the safety and benefits of CBD both in the U.S. and internationally.

We thank FDA for the opportunity to comment on this matter and would be happy to answer any questions or discuss our comments with the agency in more detail.

Respectfully submitted,

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[41] WHO CBD report at 20-21.
[42] National Organization for the Reform of Marijuana Laws, List of States with Medical CBD Laws, available at: http://norml.org/laws.
[43] *See*, e.g., Indiana Senate Enrolled Act No. 52.

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