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VIA ELECTRONIC SUBMISSION AND FEDEX

State of California
Office of Administrative Law
Attention: Reference Attorney
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Sacramento, CA 95814
E-mail: staff@oal.ca.gov

RE: Written Comments and Objections – Notice of Proposed Emergency Regulatory Action, Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp, DPH-24-005E

To the Office of Administrative Law ("OAL") Reference Attorney:

Please be advised that Frost Brown Todd LLP represents 7 Generations Producers LLC, Boldt Runners Corporation, Cheech and Chong's Global Holdings, Good Stuff Manufacturing, Juicetiva, Inc., Rose Los Angeles, Inc., SunFlora, Inc., and the U.S. Hemp Roundtable, Inc. ("USHRT"), (collectively, "Clients"). USHRT, the hemp industry's national advocacy organization, consists of 82 member companies and organizations, including dozens of companies that are domiciled and/or manufacture, distribute, or sell hemp products in California. The below written comments are being submitted on behalf of our Clients in opposition to the "Notice of Proposed Emergency Regulatory Action; Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp; DPH-24-005E," which was posted to Office of Administrative Law's website on Friday, September 13, 2024.

I. INTRODUCTION

On September 6, 2024, Governor Gavin Newsom announced that his administration would issue an emergency prohibition against the sale of intoxicating hemp products to minors. Shortly thereafter, the California Department of Public Health ("Department") posted the "Notice of Proposed Emergency Regulatory Action;;Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp, DPH-24-005E," the accompanying "Finding of Emergency," and the Proposed Emergency Regulations (collectively, "Emergency Regulations") on the Office of Administrative Law's ("OAL") website on September 13, 2024.

The Emergency Regulations actually proposed by the Department go much further than

the Governor's announcement, banning not just the sale of intoxicating hemp products to minors, but also prohibiting the manufacture, warehousing, distribution, advertising, or sale of ***any*** hemp final form ingestible products that contain ***any detectable*** amount of tetrahydrocannabinol ("THC"), whether or not such products are intended ***for sale in California***. The Emergency Regulations, if enacted, will eliminate nearly every ingestible hemp product currently for sale in California, even though the vast majority of the products are non-intoxicating. And, even though the products are intended for sale in other states. This has the potential to decimate the entire hemp industry in California.

At the outset, the Emergency Regulations are illegal because they violate provisions of the Administrative Procedure Act ("APA") and the California Health & Safety Code, as detailed below. To implement the Emergency Regulations' proposed restrictions, the Department must utilize the APA's regular rulemaking process, not the emergency procedures. Hence, the OAL must reject the Emergency Regulations in their entirety on grounds of illegality.

Our Clients—indeed a consensus of the hemp industry—support fair and reasonable regulations for hemp products that contain THC, including a 21-or-older age restriction for all hemp products. But the Emergency Regulations would wreak economic devastation on hemp farmers and small businesses in California, as well as deny millions of dollars of tax revenues for a struggling state budget. The Emergency Regulations would also harm consumers who rely on these products for their health and wellness.

The OAL must overrule the Emergency Regulations for three reasons. First, the Emergency Regulations may not be enacted on an emergency basis because the APA and California Health & Safety Code section 110065 expressly prohibit it. While it may have been possible for the Department to implement the proposed age restriction and THC serving and package limits in its initial rulemakings in 2022, the Department chose not to and cannot now rely on section 110065 for rulemaking on an emergency basis. Cal. Health & Safety Code §§ 110065, 111921.3., 111922.

Further, the Department is proposing to adopt the Emergency Regulations on an emergency basis but has failed to provide the specific facts and substantial evidence required under Cal. Govt. Code section 11346.1 to demonstrate that an emergency situation exists. There is no emergency here. Age limits can be imposed through the regular rulemaking process. The same applies to regulations about THC content and serving sizes. Hemp products that may have impairing effects can continue to be sold to adults, alongside other intoxicating products such as beer, wine, and liquor.

Second, contrary to federal law supremacy and conflicts of law principles, the Emergency Regulations violate U.S. federal law and California state law, including the Agriculture Improvement Act of 2018 ("2018 Farm Bill").

Third, the Emergency Regulations' standard prohibiting "any detectable amount of" THC is unconstitutionally vague and therefore void.

The California State Assembly, which, upon Governor Newsom's support and signature, launched the state's hemp industry in its 2021 enactment of AB 45, has rejected repeated efforts to ban hemp products. Even the Department, which has been authorized for three years to regulate hemp products, has taken no action to this point, despite adult products being on the market for more than two years.

The current Emergency Regulations are a backdoor method to engage in illegal and unconstitutional rulemaking. The Department has chosen a legally improper path. ***Any effort to impose limits or bans on hemp products should proceed through the regular rulemaking process, not the emergency rulemaking process***.

II. THE EMERGENCY REGULATIONS

On Friday, September 13, 2024, the Department posted the Emergency Regulations on the OAL's website. The Emergency Regulations consist of three documents:(i) a Notice, (ii) Findings of Emergency, and (iii) text of the Emergency Regulations.

A. The Notice

The Notice states, "Pursuant to Government Code section 11346.1(a)(2), and California Code of Regulations, Title 1, section 48, notice is hereby given that the California Department of Public Health (Department) proposes to adopt on an emergency basis Title 17, Chapter 5, Division 1 of the California Code of Regulations." As required by the Notice, these written comments are being submitted to the OAL within five calendar days of the Emergency Regulations being posted to the OAL's website on Friday, September 13, 2024.

B. The Findings of Emergency

Along with the Notice, the Department issued the following Findings of Emergency:

> DEEMED EMERGENCY
>
> The Department has statutory authority to adopt emergency regulations to implement the industrial hemp program, and such emergency regulations are deemed to be an emergency and necessary for the immediate preservation of the public health and safety. Section 110065, subdivision (b), paragraph (3) of the Health and Safety Code states that "the initial adoption of emergency regulations and the readoption of emergency regulations authorized by this section shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare."
>
> FINDINGS

The Department may adopt regulations imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health, pursuant to Health and Safety Code section 111921.3. Additionally, the Department may include any other cannabinoid, in addition to those expressly listed in subdivision (l) of Section 111920, in the definition of "THC" if the Department determines that the cannabinoid causes intoxication, pursuant to Health and Safety Code section 111921.7(b)-(d). Accordingly, the Department discusses its findings below.

<u>Age requirement</u>

The Department proposes to impose an age requirement for the sale of certain industrial hemp products, as defined in Health and Safety Code section 111920. The proposed age requirement of 21 years of age for industrial hemp extract in its final form and industrial hemp final form food products intended for human consumption, including food, food additives, beverages, and dietary supplements, is necessary due to ongoing brain development in adolescents and young adults. Studies show that use of these products can negatively impact cognitive functions, memory, and decision-making abilities in developing brains. In California and nationwide, there have been significant reports of hospitalizations among teenagers and young adults, highlighting the health risks for these age groups. The proposed age requirement protects vulnerable populations from adverse effects on still-maturing brains and reduces associated public health threats. This finding is consistent with the Legislature's finding, in Section 110065, subdivision (b), paragraph (3) of the Health and Safety Code, that "the initial adoption of emergency regulations and the readoption of emergency regulations authorized by this section shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare."

Additionally, there could be compounds not dangerous for adults, and not included in the list of intoxicating cannabinoids, that could harm youth. For example, for CBD, despite being a more widely studied compound, health effects on youth continue to be uncertain.

Therefore, because the Department's proposed list of intoxicating cannabinoids does not include all compounds, and because research on effects on youth are ongoing, the Department determined an age requirement serves to protect youth from what could be permanent and irreparable adverse health impacts.

<u>List of intoxicating cannabinoids</u>

> The Department proposes to include additional cannabinoids in the definition of "THC" or "THC or comparable cannabinoid" defined at Health and Safety Code section 111920(l). The proposed additional cannabinoids cause intoxication at various levels, as supported by scientific and clinical research data. These cannabinoids have similar chemical structures to cannabinoids known to cause intoxication. Additionally, the proposed cannabinoids can cause serious side effects including seizures, organ damage, hallucinations, paranoia, vomiting, agitation, and in extreme cases even death, all of which are signs of intoxication that has led to an increase in hospitalization, poisoning, and increased emergency department visits across California and nationwide, highlighting the urgent need for regulation.

C. The Text of the Proposed Emergency Regulations

The Emergency Regulations purport to change the law in three regards by adding new regulations to the California Code Of Regulations, Title 17, Chapter 5, Subchapter 2.6 Industrial Hemp, in the following areas.

1. New Age Restriction Added

First, the Emergency Regulations create a new regulation implementing an age restriction of 21 years for the purchase and consumption of all industrial hemp extract final form products and hemp final form food products intended for human consumption:

> **Section 23005. Age Requirement for Extract and Human Food.**
> A person shall not offer or sell industrial hemp extract in its final form or industrial hemp final form food products intended for human consumption, including food, food additives, beverages, and dietary supplements, to a person under 21 years of age.

2. Definition of THC Expanded Significantly

Second, the Emergency Regulations add a new regulation expanding California's definition of "THC" to include thirty additional substances deemed intoxicating:

Section 23010. List of Intoxicating Cannabinoids.

(a) In addition to delta-8 tetrahydrocannabinol (THC), delta-9 tetrahydrocannabinol (THC), delta-10 tetrahydrocannabinol (THC), and tetrahydrocannabinolic acid (THCA), the following are included in the definition of "THC" or "THC or comparable cannabinoid" and include any metabolites, derivatives, salts, isomers, and any salt or acid of an isomer of:

(1) Delta-5 tetrahydrocannabinol (THC);
(2) Delta-6 tetrahydrocannabinol (THC);
(3) Delta-6a tetrahydrocannabinol (THC);

(4) Delta-7 tetrahydrocannabinol (THC);
(5) Delta-10a tetrahydrocannabinol (THC);
(6) Delta-11 tetrahydrocannabinol (THC);
(7) Delta-11-Hydroxy-tetrahydrocannabinol (THC);
(8) Exo-tetrahydrocannabinol;
(9) 1-pentyl-3-(1-naphthoyl)indole (JWH-018);
(10) 1-butyl-3-(1-naphthoyl)indole (JWH-073);
(11) 1-pentyl-3-(4-methoxynaphthoyl)indole (14-JWH-200);
(12) 1-pentyl-3-(2-methoxynaphthoyl)indole (JWH-250);
(13) 1-pentyl-3-(4-chloronaphthoyl)indole (JWH-398);
(14) 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497)
(15) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c] chromen-1-ol (HU-210);
(16) (6a,10a)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7 ,10,10atetrahydro-6H-benzo[c]chromen-1-ol (HU-211);
(17) All tetrahydrocannabivarins (THCV), including but not limited to delta-8 tetrahydrocannabivarin and similar;
(18) All metabolites of tetrahydrocannabinol (THC), including but not limited to 11- hydroxy-THC, 3-hydroxy-THC, and 7- hydroxy-THC;
(19) Any combination of the compounds, including but not limited to hexahydrocannabiphorol-O-ester and this list;
(20) All hydrogenated forms of tetrahydrocannabinol (THC), including but not limited to hexahydrocannabinol (HHC), hexahydrocannabiphorol (HHCP), and hexahydrocannabihexol (HHCH);
(21) All hydrogenated forms of hexahydrocannabinol (HHC) including but not limited to 8-hydroxyhexahydrocannabinol, 10-hydroxyhexahydrocannabinol;
(22) All ester forms of tetrahydrocannabinol (THC), including but not limited to delta-8 THC-O-acetate, delta-9 THC-O-acetate, and hexahydrocannabinol-O-acetate;
(23) Analogues of tetrahydrocannabinols with alkyl chain of four or more carbon atoms, including but not limited to tetrahydrocannabiphorols (THCP), tetrahydrocannabioctyls, tetrahydrocannabihexols (THCH), tetrahydrocannabidiol (THC-JD), and tetrahydrocannabutols;
(24) Tetrahydrocannabinol acetate (THC-O);
(25) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-ind ole-3- carboxamide (XRL-11 &15);
(26) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-ind ole-3- carboxamide (UR-144);
(27) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-ind ole-3- carboxamide (FUB-144);
(28) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-ind

ole-3- carboxamide (AMB-FUBINACA);

(29) (3-[(1R,4R)-Isopropyl-2-methyl-1,3-benzodioxol-5-yl]-N-(2,4-dimeth yl-3-methylbenzoyl)-N-methyl-1,2,3,4-tetrahydroisoquinolin-6-amine) ; and

(30) (3-[(1R,4R)-Isopropyl-2-methyl-1,3-benzodioxol-5-yl]-N-(2,4-dimeth yl-3-methylbenzoyl)-N-methyl-1,2,3,4-tetrahydroisoquinolin-6-amine) (RCS-4).

3. Serving Sizes and New Standard for Hemp Products Implemented

Third, the Emergency Regulations add a new provision creating serving size and package requirements for all hemp final form food products intended for human consumption. Significantly, the Emergency Regulations create a brand new standard for hemp products in California, i.e., hemp products must now contain "no detectable levels of total THC." This new standard essentially bans the manufacture, warehousing, distribution, offer, advertisement, marketing, or sale of hemp products in California that contain any "detectable levels of THC" which applies to the vast majority of hemp products in California.

Section 23100. Serving and Package Requirements.

(a) An industrial hemp final form food product intended for human consumption including food, food additives, beverages, and dietary supplements shall have the following:

(1) Each serving in a package shall have no detectable amount of total THC, and

(2) Each package shall have no more than five servings, and

(3) The serving and package sizes shall be determined using the same federal standards as non-industrial hemp food products unless specified in this subchapter or Part 5 of Division 104 of the Health and Safety Code.

(b) An independent testing laboratory shall calculate and establish the limit of detection for all analytes in accordance with section 15731 of Title 4 of the California Code of Regulation as part of the chemical method verification or analysis.

(c) A manufacturer of industrial hemp final form food product shall provide documentation that includes a certificate of analysis from an independent testing laboratory to confirm the amount of total THC in the final form food product does not exceed the total THC per serving size limits as set forth in this subchapter.

(d) A person shall not manufacture, warehouse, distribute, offer, advertise, market, or sell industrial hemp final form food products intended for human consumption including food, food additives, beverages, and dietary supplements that are above the limit of detection for total THC per serving.

Related to this new standard, the Emergency Regulations add new definitions to clarify "no detectable amount of THC":

Section 23000. Definitions.

> (a) For the purposes of this subchapter, the following definitions apply regarding industrial hemp:
> (1) “Detectable” means any amount of analyte, subject to the limit of detection.
> (2) “Limit of detection” means the lowest quantity of a substance or an analyte that can be reliably distinguished from the absence of that substance within a specified confidence limit.

III. THE EMERGENCY REGULATIONS VIOLATE CALIFORNIA LAW

There should be no mistake—our Clients support fair and reasonable regulations for hemp-derived THC products, including a 21-or-older age restriction for all hemp products—as does most of the hemp industry. However, because the Department is proceeding with the emergency rulemaking process instead of the regular rulemaking process, the Emergency Regulations must be overruled.

A. Implementing the Emergency Regulations Through Emergency Rulemaking Violates the Administrative Procedure Act.

Nearly three years after the enactment of AB 45, and more than two years after the Department promulgated its initial emergency regulations and initial regulations under AB 45, the Department must now adhere to the APA’s regular rulemaking process.

First, section 110065 does not permit implementing the Emergency Regulations through emergency rulemaking. This is true under either of two possible readings of section 110065.

Second, even if the Department may proceed through the emergency rulemaking process, which it cannot, it has failed to identify any factual reasons or grounds for an emergency.

1. The Emergency Regulations Are No Longer Permitted Under Section 110065.

The Department claims authority for the Emergency Regulations under Cal. Health & Safety Code § 110065. Effective October 6, 2021, AB 45 amended section 110065 to read as follows:

> 110065. (a) The department may adopt any regulations that it determines are necessary for the enforcement of this part. The regulations shall be adopted by the department in the manner prescribed by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The department shall, insofar as practicable, make these regulations conform with those adopted under the federal act or by the United States Department of Agriculture or by the Internal Revenue Service of the United States Treasury Department.
> (b)(1) The department may adopt emergency regulations to implement this

> division.
>
> (2) The department may readopt any emergency regulation authorized by this section that is the same as, or substantially equivalent to, an emergency regulation previously adopted as authorized by this section. That readoption shall be limited to one time for each regulation.
>
> (3) Notwithstanding any other law, the initial adoption of emergency regulations and the readoption of emergency regulations authorized by this section shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations and the readopted emergency regulations authorized by this section shall be each submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect for no more than 180 days, by which time final regulations shall be adopted.
>
> (c) Initial regulations regarding industrial hemp shall be exempt from the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), except that the department shall post the proposed regulations on its internet website for public comment for 30 days. The comments received shall be considered by the department and the final adopted regulations shall be filed with the Office of Administrative Law for publication in the California Code of Regulations. This exemption does not apply to regulations adopted pursuant to Section 111921.3 or 111922.

Sections 111921.3 and 111922, which are referenced in section 110065(c), provide as follows:

> 111922. (a) The department, through regulation, may determine maximum serving sizes for hemp-derived cannabinoids, hemp extract, and products derived therefrom, active cannabinoid concentration per serving size, the number of servings per container, and any other requirements for foods and beverages.
> (b) Food and beverages shall be prepackaged and shelf stable.
>
> . . .
>
> 111921.3. The department may adopt regulations imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health.

There are two possible readings of section 110065. Under the first reading, section 110065(c) "exempt[s]" from the APA's regular rulemaking process "[i]nitial regulations" that are promulgated by the Department to implement AB 45. But the "exemption does not apply to regulations adopted pursuant to Section 111921.3 or 111922," which allow for regulations imposing an age restriction and THC maximum serving and package limits, respectively. Accordingly, the Emergency Regulations' proposed age restriction and THC serving and

package limits are not "exempted" from the APA's regular rulemaking process and therefore must adhere to it. The Department has not followed the regular rulemaking process here.

Under the second reading, section 110065(c)'s exemption from the APA's regular rulemaking process applies to "initial regulations," not "the initial adoption of emergency regulations" contemplated in section 110065(b). But even assuming under this reading that initial emergency regulations proposing an age restriction and THC serving and package limits, the Emergency Regulations again fail. This is because, the Department's initial emergency regulations and initial regulations did not contain the age restriction or THC serving or package restrictions being proposed now on an emergency basis. Indeed, on April 20, 2022, the Department promulgated initial emergency regulations for implementing AB 45. The initial emergency regulations did not contain age restrictions or maximum THC serving and package restriction. Pursuant to section 110065, the initial emergency regulations were readopted as emergency regulations and then permanently adopted as a regular rulemaking.

In other words, the Department already utilized section 110065's procedure for adopting initial emergency regulations and initial regulations for implementing AB 45—more than two years ago. Because the Department chose to not implement such restrictions in its initial emergency regulations and initial regulations, section 110065 no longer permits the Emergency Regulations on an emergency basis. The Emergency Regulations must proceed through the APA's regular rulemaking process, which requires a 45-day notice and comment period.

2. **Even if the Emergency Regulations Are Permitted Under Section 110065, the Department Has Failed to Demonstrate That an Emergency Situation Exists.**

Even if the Department could theoretically utilize the emergency rulemaking process, its attempts to do so fail here. An agency can adopt emergency regulations without complying with the 45-day notice and comment procedures required by the APA. The emergency rulemaking process generally includes a brief public notice period, a brief public comment period, review by OAL and an OAL decision. Emergency regulations are governed by Govt. Code sections 11346.1, 11349.5 and 11349.6.

The APA defines an "emergency" as a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare. Cal. Govt. Code § 11342.545. In order for an emergency regulation to be approved, an emergency situation must be shown to exist. Office of Administrative Law, About the Emergency Rulemaking Process, https://oal.ca.gov/emergency_regulations/Emergency_Regulation_Process/.

Emergency regulations require only a five-day public notice. *Western Growers Association v. Occupational Safety and Health Standards Board* (2021) 73 Cal.App.5th 916. At least five working days before submitting an emergency regulation to the OAL, the Department must send a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the Department. The notice shall include both of the following:

(1) The specific language proposed to be adopted; and (2) The finding of emergency required by subdivision (b). *Id.* at 11346.1(a).

If the Department makes a finding that the regulation is necessary to address an emergency, the regulation may be adopted as an emergency regulation. *Id.* at 11346.1(b). Any finding of an emergency shall include a "written statement" that contains the information required by Section 11346.5 (a) (2)-(6), as well as a description of the "specific facts demonstrating the existence of an emergency and the need for immediate action," and demonstrating, by "substantial evidence," the need for the proposed regulation to effectuate the statute being implemented, interpreted, or made specific and to address only the demonstrated emergency. *Id.* at 11346.1(b). The burden of demonstrating there is "substantial evidence" for the emergency rests with the Department. *California Med. Assn. v. Brian* (1973) 30 Cal.App.3d 637, 652.

"A statement [to the OAL] by the submitting agency confirming that the emergency situation addressed by the regulations clearly poses such an immediate, serious harm that delaying action to allow notice and public comment would be inconsistent with the public interest. The statement shall include:

> 1. Specific facts demonstrating by substantial evidence that failure of the rulemaking agency to adopt the regulation within the time periods required for notice pursuant to Government Code section 11346.1(a)(2) and for public comment pursuant to Government Code section 11349.6(b) will likely result in serious harm to the public peace, health, safety, or general welfare; and
>
> 2. Specific facts demonstrating by substantial evidence that the immediate adoption of the proposed regulation by the rulemaking agency can be reasonably expected to prevent or significantly alleviate that serious harm."
> Cal. Code Regs. tit. 1, § 50 (b)(3(B).

The finding of emergency shall also identify each technical, theoretical, and empirical study, report, or similar document, if any, upon which the agency relies. *Id.* at 11346.1(b). A finding of emergency based only upon expediency, convenience, best interest, general public need, or speculation, shall not be adequate to demonstrate the existence of an emergency. *Ibid.*

An agency is exempt from these provisions if a situation is expressly deemed by statute to meet the emergency standard. *See* OAL's Emergency APA Rulemaking Checklist. In the case of a 'deemed emergency,' the emergency filing is subject to OAL review and the various procedural requirements for adopting emergency regulations, but does not have to satisfy the strict statutory standard defining emergencies. The Rutter Guide's "Practice Pointer for Agencies" states: "If a statute simply calls for the adoption of emergency regulations, without expressly declaring that the situation is an emergency, agencies should take care to document that the situation is a true emergency as that term is defined in the APA." California (Rutter) Practice Guide, Administrative Law, Ch. 26-E, ¶ 26.171.

The finding of emergency must also include a written statement containing the information required by Govt. Code § 11346.5(a)(2)-(6). *Id.* at § 11346.1(b)(2). Thus, the finding of emergency must contain the following:

> • Citations to the statutory provision that authorizes the regulatory action and the particular statute (or other provision of law) that the proposed regulation will implement, interpret or make specific *Id.* at § 11346.5(a)(2);
> • An "informative digest drafted in plain English" that includes, among other items, a summary of existing laws and regulations related to the proposed action and the effect of the proposed action *Id.* at § 11346.5(a)(3);
> • "Any other matters as are prescribed by statute applicable to the specific state agency or to any specific regulation or class of regulations" *Id.* at § 11346.5(a)(4));
> • A determination whether the regulation imposes a mandate on local agencies or school districts and, if so, whether the mandate requires state reimbursement (*Id.* at § 11346.5(a)(5); which must be reflected by filing Form 399 with the submission to OAL; and
> • An estimate of the cost or savings to any state agency and in federal funding to the state, the cost to any local agency or school district that must be reimbursed and other nondiscretionary cost or savings imposed on local agencies *Id.* at § 11346.5(a)(6).

"[T]he Second Partial Report by the Senate Interim Committee on Administrative Regulations in 1953 makes it clear that the wording of Government Code section [11346.1] was changed for the specific purpose of trying to eliminate abuses by administrative agencies of the power to make emergency regulations by expanding the scope of the judicial inquiry. The wording was changed to 'the facts recited in the statement' from 'findings and statement' because the Legislature intended the courts to have the power to judge the facts claimed by the agency as well as the statement of emergency." *California Med. Assn. v. Brian* (1973) 30 Cal.App.3d 637, 652. "[T]he facts stated in the declaration of an emergency are not conclusive on the courts and thus the court [does] not err in receiving evidence tending to impeach the facts recited in the declaration." *Ibid*.

If the situation identified in the finding of emergency existed and was known by the Department in sufficient time to have been addressed through nonemergency regulations adopted in accordance with the provisions of Article 5 (commencing with Section 11346), the finding of emergency shall include facts explaining the failure to address the situation through nonemergency regulations. *Id.* at 11346.1(b). The emergency regulation becomes effective upon filing it with the OAL or upon any later date specified by the agency in writing. *Id.* at § 11346.1(d).

The OAL must review emergency regulations within 10 calendar days and make a decision on the proposed emergency rulemaking file. *Id.* at § 11349.6(b), 1 CCR § 56(a)(1). If the OAL approves the emergency rulemaking, the OAL will file the approved regulation with the Secretary of State for publication. *Id.* at 11349.1(a). The OAL shall not approve any emergency

regulation submitted with a subsection (b)(3)(B) statement that does not satisfy the requirements of Cal. Code Regs. tit. 1, § 50(b)(3)(B). Cal. Code Regs. tit. 1, § 50(c). If the OAL disapproves the regulation, it must write a decision explaining the reasons for disapproval, including if it determines that the agency failed to comply with the requirements for emergency regulations in Govt. Code § 11346.1. *Id.* at 11349.1.

In reviewing regulations pursuant to this section, the OAL shall restrict its review to the regulation and the record of the rulemaking proceeding. The OAL shall approve the regulation if it complies with the standards set forth in Govt. Code. *Ibid*.

The OAL reviews the file for the following:

i. Does the agency's finding of emergency demonstrate that the situation addressed by the regulations is an emergency?

ii. Do the proposed emergency regulations comply with the six substantive standards of Government Code section 11349.1?

iii. Did the agency comply with the procedural requirements of Government Code section 11346.1?

Id. at 11349.6(b).

An emergency regulation usually becomes effective when filed with the Secretary of State. Emergency regulations cannot remain effective for more than 180 days unless the agency has complied with applicable APA procedures during that period. *Id.* at 1346.1(h).

But here, the Department has not satisfied the requirements under Govt. Code sections 11346.1, 11349.5 and 11349.6 for emergency rulemaking. The Emergency Regulations would prohibit not just the sale of intoxicating hemp products to minors, but would also prohibit manufacturing, warehousing, distributing, advertising, or selling any final form food product that contains any detectable amount of any THC—even products that are manufactured but not intended for sale in California. The Department has not demonstrated that an emergency situation exists for such a sweeping ban. For instance, the Department has not offered a scintilla of evidence that there is an emergency in the provision of ingestible hemp-derived THC products to adults or the manufacture of such products that are not sold to California consumers.

When it comes to the proposed ban on hemp final form food products that contain THC, and the proposed serving and package limits, the Department offers no case for an emergency. Its Findings of Emergency discuss only the proposed age requirement and list of intoxicating cannabinoids. There is no discussion of the emergency need for maximum serving or package limits for hemp final form food products, or of the emergency need to ban the manufacture, warehousing, distribution, advertising, or sale of products that are not intended for sale to California consumers. The Department has wholly failed to meet Cal. Govt. Code section 11346.1's requirements as to the proposed serving or package limits. These sections of the emergency regulations must be summarily rejected.

But even with respect to the proposed age restriction, the Emergency Regulations fail to meet section 11346.1's requirements in at least two ways. First, the Department has not provided "the specific facts demonstrating the existence of an emergency and the need for immediate action" or "demonstrat[ed], by substantial evidence, the need for the proposed regulation." Cal. Govt. Code § 11346.1(b)(1). Rather, the Findings of Emergency summarily state that "[s]tudies show that use of these products can negatively impact cognitive functions, memory, and decision-making abilities in developing brains. In California and nationwide, there have been significant reports of hospitalizations among teenagers and young adults, highlighting the health risks for these age groups." The Department's conclusory statement is not a demonstration by "substantial evidence."

While the Department's "Finding of Emergency" document includes a section listing the "documents relied upon" by the Department, none of the documents are cited in the Finding of Emergency section discussing the emergency basis for the proposed age restriction. The Department has not specified which of the documents, if any, it relied upon for the proposed age restriction or which of the documents, if any, are the "studies" showing the emergency need for the proposed age restriction. The Department's burden is heavy because, unlike the Emergency Regulations, which would implement an age restriction for ***all*** hemp final form food products that contain any amount of any THC, the legislature clearly intended AB 45 to legalize hemp products with up to 0.3 percent THC in final form without an age restriction.

The Department also fails to comply with the requirement to address why it could not address the situation through nonemergency regulations. Cal. Govt. Code § 11346.1(b)(2). The "documents relied upon" section lists studies as far back as 2018 to justify the supposed emergency. It cites no documents dated in 2024. The Department references no newly discovered information which necessitated this emergency declaration.

Instead of a legitimate need due to an emergency, the Emergency Regulations look more like an exercise of "expediency, convenience, best interest, general public need, or speculation," which "shall not be adequate to demonstrate the existence of an emergency." Cal. Govt. Code § 11346.1(b)(2). It is no secret that the legislature has chosen each of the past three legislative sessions since AB 45 became law to not enact an age restriction for hemp final form food products. Yet, less than three weeks after the legislature ended its latest session without passing AB 2223, which would have implemented an age restriction, the Department issued the Emergency Regulations. The Department cannot infringe on legislative powers by end-running the legislature, and certainly cannot do so as a matter of "convenience, best interest, general public need, or speculation."

Additionally, the Emergency Regulations do not adequately describe the substantial differences from existing federal law that would be effectuated. Cal. Govt. Code § 11346.5(3)(B). The Findings of Emergency refer to part of the 2018 Farm Bill's definition of "hemp," but it does not recite the definition in full. In addition to the partial definition, the document does not explain that the Emergency Regulations' broad expansion of the definition of "THC" to include 30 additional cannabinoids directly conflicts with the 2018 Farm Bill's

determination of hemp based only on its concentration of 0.3 percent of delta-9 THC on a dry weight basis and not on the presence of any other cannabinoids. In other words, the Department has not addressed that the Emergency Regulations would prohibit a hemp final form food product that contains more than 0.3 percent delta-8 THC but that does not contain more than 0.3 percent delta-9 THC, when the same product is legally under and protected by the 2018 Farm Bill.

B. The Emergency Regulations Violate the 2018 Farm Bill.

The 2018 Farm Bill legalized all hemp products with a delta-9 THC concentration of 0.3 percent or less on a dry weight basis and prohibited states from impeding the transportation and shipment of hemp or hemp products through interstate commerce. The Emergency Regulations violate both of these aspects of the 2018 Farm Bill.

First, the Emergency Regulations alter the 2018 Farm Bill's determination of what constitutes "hemp" by prohibiting an industrial hemp final form food product intended for human consumption, including food, food additives, beverages, and dietary supplements, from containing any "detectable amount of THC" and by expanding California's definition of "THC" to include "any metabolites, derivatives, salts, isomers, and any salt or acid of an isomer of" any of the 30 listed cannabinoids deemed to be intoxicating.

In effect, the Emergency Regulations impermissibly prohibit an industrial hemp final form food product intended for human consumption based on whether the product contains any detectable of any THC, not based on its concentration of delta-9 THC on a dry weight basis. The Emergency Regulations' expanded definition of "THC" inherently conflicts with and is contrary to the 2018 Farm Bill's and California law's identical definitions of "hemp" as "an agricultural product, whether growing or not, that is limited to types of the plant Cannabis sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plant, cannabinoids, isomers, acids, salts, and salts of isomers, with a delta-9 tetrahydrocannabinol concentration of no more than 0.3 percent on a dry weight basis." Cal. Health & Safety Code § 11018.5(a); 7U.S.C. § 16390(1).

Second, the Emergency Regulations impeded interstate commerce of federally legal hemp or hemp products to, in, and through California by criminalizing an industrial hemp final form food product intended for human consumption that contains a "detectable amount of THC," even if such product contains 0.3 percent or less delta-9 THC on a dry weight basis. The expansion of the definition of "THC" is an impermissible narrowing of the 2018 Farm Bill's determination of what constitutes "hemp," despite Congress prohibiting states from altering the definition of "hemp" and from impeding interstate commerce involving hemp or hemp products that contain 0.3 percent or less delta-9 THC on a dry weight basis.

If states like California were permitted to selectively criminalize hemp or hemp products that do not contain more than 0.3 percent of delta-9 THC on a dry weight basis, then it would render Congress's clearly intended protections in the 2018 Farm Bill meaningless and

subordinate to states' laws. Federal law, including the Supremacy Clause of the U.S. Constitution and conflicts of laws principles, preempts the Emergency Regulations because they are in direct conflict with the 2018 Farm Bill.

C. The Emergency Regulations Violate Existing California Law (AB 45) on Industrial Hemp.

The Emergency Regulations violate current California law - AB 45 - in at least five ways. First, unlike the Emergency Regulations, AB 45 does not limit hemp products to a non-detectable level of THC. The State Assembly has rejected all legislative efforts to impose such a restriction, which would effectively destroy the hemp industry in California.

Second, unlike the Emergency Regulations, AB 45 does not restrict hemp products in the form of food, food additives, beverages, or dietary supplements to persons 21 years or older. While, as discussed above, AB 45 authorized the Department to "adopt regulations imposing an age requirement for the sale of certain [] hemp products upon a finding of a threat to public health," the Department did not attempt to do so until its issuance of the Emergency Regulations—three years after AB 45 became effective. In other words, the Department has sat by while bad actors targeted minors with their products, and yet the Department claims an emergency situation now exists.

As discussed above, the Department may only adopt an age requirement for some or all hemp products—something our clients strongly support—through the regular rulemaking process. AB 45 requires this explicitly, either because the Emergency Regulations' age restriction is not "exempted" from the APA's regular rulemaking process and therefore must follow it) or because the Department's initial emergency regulations for implementing AB 45, which were promulgated more than two years ago, did not contain an age restriction. Despite being authorized to adopt an age restriction at the time that AB 45 became law, the Department declined to do so then.

Third, unlike the Emergency Regulations, AB 45 does not distinguish between intoxicating cannabinoids and non-intoxicating cannabinoids. The Emergency Regulations' "List of Intoxicating Cannabinoids" is not based on statute, but rather is created from thin air. Apart from referring generally to unspecified "scientific and clinical research data," the Emergency Regulations do not address why the listed cannabinoids are deemed intoxicating. Nor do the Emergency Regulations provide any criteria by which intoxicating cannabinoids are determined.

Fourth, unlike the Emergency Regulations, AB 45 does not impose serving or package requirements for hemp products in the form of food, food additives, beverages, or dietary supplements. While AB 45 authorized the Department to, "through regulation, . . . determine maximum serving sizes for hemp-derived cannabinoids, hemp extract, and products derived therefrom, active cannabinoid concentration per serving size, the number of servings per container, and any other requirements for foods and beverages," the Department did not attempt to issue any such regulations until its issuance of the Emergency Regulations three years later.

Like for an age restriction, as discussed above, the Department may only adopt THC maximum serving and package limits through the regular rulemaking process. AB 45 requires this explicitly, either because the Emergency Regulations' THC serving and package limits are not "exempted" from the APA's regular rulemaking process (and therefore must follow it) or because the Department's initial emergency regulations for implementing AB 45, which were promulgated more than two years ago, did not include THC serving or package limits. Despite being authorized to adopt THC limits time that AB 45 became law, the Department declined to do so then.

Fifth, unlike the Emergency Regulations, AB does not prohibit the manufacture, warehousing, distribution, offer, advertising, marketing, or sale of hemp products in the form of food, food additives, beverages, and dietary supplements based on a detectable level of total THC.

D. The Emergency Regulations' THC Standard Is Void For Vagueness

The Emergency Regulations' "no detectable amount of THC" standard is unconstitutionally vague. The Due Process Clause of the Fifth Amendment, as incorporated to the states through the Due Process Clause of the Fourteenth Amendment, prohibits criminal enforcement of statutory and/or regulatory requirements that are unconstitutionally vague and that do not give fair warning of their requirements. U.S. Const. Amend. V, XIV.

The Emergency Regulations prohibit a person from manufacturing, warehousing, distributing, offering, advertising, marketing, or selling any industrial hemp final form food product intended for human consumption including food, food additives, beverages, and dietary supplements, that is "above the limit of detection for total THC per serving." The Emergency Regulations' definitions of "detectable" and "limit of detection" are of no help. "Detectable" means "any amount of analyte, subject to the limit of detection," referring to the defined term of "limit of detection." "Limit of detection" means "the lowest quantity of a substance or an analyte that can be reliably distinguished from the absence of that substance within a specified confidence limit," but there is no definition for what it means to be "reliably distinguished" or what the "specified confidence limit" is or may be.

In Article 3, Section 23100, which relates to "Serving and Package Requirements" for "Manufacture," the Emergency Regulations state that "an independent testing laboratory shall calculate and establish the limit of detection for all analytes in accordance with section 15731 of Title 4 of the California Code of Regulation as part of the chemical method verification or analysis." However, it is not clear whether the laboratory's limit of detection applies to industrial hemp final form food products that are not manufactured in California.

Moreover, section 15731 of Title 4 of the California Code of Regulation allows a laboratory to calculate a limit of detection using any one of three possible methods, including (1) Signal-to-noise ratio of between 3:1 and 2:1; (2) Standard deviation of the response and the slope of calibration curve using a minimum of 7 spiked blank samples calculated as follows;

LOD = (3.3 x standard deviation of the response) / slope of the calibration curve; (3) A method published by the United States Food and Drug Administration or the United States Environmental Protection Agency. The Emergency Regulations do not specify which of the three methods a laboratory must use, meaning a person is left to guess how the limit of detection for his or her hemp products will be calculated.

In general, the Emergency Regulations criminalize industrial hemp final form food products intended for human consumption that are "above the limit of detection for total THC per serving," but they fail to give fair warning of what the limit of detection is or how a laboratory will calculate it. Individuals and companies are therefore exposed to criminal prosecution for manufacturing, warehousing, distributing, offering, advertising, marketing, or selling their hemp products, yet it is impossible for them to know prior to conducting their activities whether their products are illegal under the Emergency Regulations. The Emergency Regulations' "no detectable amount of THC" standard is therefore void as unconstitutionally vague.

E. The Emergency Regulations Have Caused, And Will Continue To Cause, Irreparable Injury to the Legitimate Hemp Industry in California.

The Emergency Regulations will cause our Clients immediate and irreparable injury. "The term 'irreparable injury' means that species of damages whether great or small, that ought not to be submitted to on the one hand or inflicted on the other." *Wind v. Herbert* (1960) 186 Cal. App. 2d 276, 285. A consideration of interim harm includes the inadequacy of other remedies, including damages, and the degree of irreparable injury that would be suffered by a party. *Intel Corp. v. Hamidi* (2003) 30 Cal.4th 1342, 1352.

Here, the Emergency Regulations would be devastating for hemp cultivation, manufacturing, distribution, and retail sale in California. The Emergency Regulations would eliminate up to 90-95% of hemp products, including non-intoxicating products. They would shutter opportunities for hemp farmers and manufacturers because the Emergency Regulations prohibit not just hemp final form food products intended for sale in California, but also products manufactured in California that are intended for sale exclusively outside the state. California has long recognized that curtailment of business operations constitutes irreparable injury. *McCammon v. City of Redwood City* (1957) 149 Cal.App.2d 421, 424. The Emergency Regulations would not merely curtail our Clients' business operations, but would also completely halt their operations, thereby causing irreparable injury. We anticipate that written comments submitted by others in the hemp industry will describe the full extent of the economic harm caused by the Emergency Regulations.

IV. HISTORICAL BACKGROUND OF HEMP LEGISLATIVE EFFORTS IN CALIFORNIA

The manufacture, distribution, and commercial sale of hemp and hemp products in

California is not new, but rather has been occurring legally for years. Indeed, there is a long and well-documented history of regulating hemp and hemp products in California, under both federal and state regulatory regimes, such that hemp products may be manufactured, distributed, and sold at retail. This factual background is critical for understanding why the Emergency Regulations must be overruled.

A. 2014 Farm Bill and 2018 Farm Bill

On February 7, 2014, President Barack Obama signed into law the Agricultural Act of 2014, Pub. L. No. 113-79 ("2014 Farm Bill"). The 2014 Farm Bill provided that, "[n]notwithstanding the Controlled Substances Act . . . or any other Federal law, an institution of higher education ... or a State department of agriculture may grow or cultivate industrial hemp," provided it is done "for purposes of research conducted under an agricultural pilot program or other agricultural or academic research" and those activities are allowed under the relevant state's laws. 7 U.S.C. § 594o(a). The 2014 Farm Bill defined "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." 7 U.S.C. § 594o(a)(2). Anticipating the passage of the 2014 Farm Bill, California enacted the California Industrial Hemp Farming Act in 2013, which, upon authorization under federal law, redefined "marijuana" to exclude hemp and provided for the cultivation of hemp in California.

While the 2014 Farm Bill made clear that Congress intended to legalize the production of hemp as an agricultural commodity once again in the United States, it did not distinguish between hemp and marijuana for purposes of the federal Controlled Substances Act ("CSA") or the commercial sale of hemp-derived finished products. That changed four years later, when, on December 20, 2018, President Donald Trump signed into law the 2018 Farm Bill.

The 2018 Farm Bill permanently removed hemp and THCs in hemp from the CSA, leaving no role for the U.S. Drug Enforcement Administration ("DEA") to enforce against lawful hemp or hemp products. The 2018 Farm Bill expanded the definition of "hemp" by defining it as 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." 7 U.S.C. § 16390(1) (emphasis added). Thus, the 2018 Farm Bill's expansion broadly redefined "hemp" as including ***all*** products derived from hemp, so long as their delta-9 THC concentration does not exceed 0.3% on a dry weight basis.

In general, as courts throughout the country have affirmed, the only relevant statutory metric in analyzing whether a product is to be considered hemp under the 2018 Farm Bill is its concentration of delta-9 THC on a dry weight basis. If the product has 0.3% delta-9 THC or less on a dry weight basis, then it is hemp and is legal under the 2018 Farm Bill. If the product contains more than 0.3 percent Delta-9 THC, then it is not hemp.

The Conference Report for the 2018 Farm Bill made clear that Congress intended to preclude a state from adopting a more restrictive definition of hemp: "state and Tribal governments are authorized to put more restrictive parameters on the production of hemp ***but are not authorized to alter the definition of hemp*** or put in place policies that are less restrictive." Conference Report for Agricultural Improvement Act of 2018, p. 738 (emphasis added). Likewise, the Final Rule promulgated by the U.S. Department of Agriculture ("USDA") to implement the 2018 Farm Bill clarifies that, while the 2018 Farm Bill preserved the authority of states to regulate the act of producing hemp if they chose to do so, states may not alter the definition of "hemp" or regulate in a manner that reaches beyond production. In other words, the 2018 Farm Bill permits states to regulate the production, i.e., cultivation, of hemp if they chose to do so, but nothing more.

Significantly, the 2018 Farm Bill expressly prohibits states from interfering with or impeding the transportation or shipment of hemp and hemp products produced in accordance with the 2018 Farm Bill:

> SEC. 10114. INTERSTATE COMMERCE.
> Rule of Construction. Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp (as defined in section 297 A of the Agricultural Marketing Act of 1946 (as added by section 10113)) or hemp products.
> Transportation of Hemp and Hemp Products. No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.

This explicit protection for hemp and hemp products in interstate commerce would be rendered meaningless if states were permitted to criminalize hemp or hemp products by, for example, altering their definition of "hemp" in a manner that conflicts with the 2018 Farm Bill's definition and would frustrate Congress's overarching goal of the 2018 Farm Bill to protect commerce involving hemp and hemp products and treat them once again like a commodity.

Indeed, the General Counsel for the USDA authored a legal memorandum discussing the 2018 Farm Bill's prohibition on states restricting the transportation or shipment of hemp, concluding that any state law purporting to do so has been preempted by Congress. A copy of the memorandum is attached as **Exhibit A**.

In short, the 2018 Farm Bill (1) broadly defined "hemp" as including all cannabinoids, extracts, and derivatives of the plant, whether growing or not; (2) legalized hemp and hemp products with a delta-9 THC concentration of not more than 0.3% on a dry weight basis; (3) did not prohibit any hemp product based on the manufacturing process used to manufacture it; and

(4) mandated that no state or Indian tribe may prohibit the transportation or shipment of hemp and hemp products in interstate commerce.

B. AB 45

In the spring of 2018, the Department issued a Frequently Asked Questions ("FAQ") guidance document declaring that "the use of industrial hemp as the source of [cannabidiol ("CBD")] to be added to food products is prohibited. Until the [U.S. Food and Drug Administration ("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." Later that year, then-Lieutenant Governor Gavin Newsom, while also a gubernatorial candidate, promised to reverse the Department's prohibition against food products that contain hemp-derived CBD. Upon becoming Governor, Newsom formally engaged with hemp industry advocates to negotiate legislation that protects hemp-derived CBD food products.

Ultimately, Newsom could not deliver on his promise until October 6, 2021, when he signed AB 45 into law. Authored and carried in the State Assembly by Cecilia Aguiar-Curry, who had previously introduced legislation protecting hemp-derived CBD food products (AB 228), AB 45 goes even further than what hemp industry advocates initially sought—it legalizes the manufacture or sale of ***all*** ingestible hemp products, not just the sale of hemp-derived CBD food products.

AB 45 matters. First, AB 45 expressly legalizes dietary supplement, food, beverage, cosmetic, and pet food products that contain hemp or hemp derived cannabinoids by mandating that "a dietary supplement, food, beverage, cosmetic, or pet food is not adulterated by the inclusion of industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp if those substances meet specified requirements[.]"

Second, AB 45 "prohibit[s] restrictions on the sale of dietary supplements, food, beverages, cosmetics, or pet food that include industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp based solely on the inclusion of those substances."

Third, AB 45 matches the 2018 Farm Bill by defining "hemp" as an agricultural product, whether growing or not, that is limited to types of the plant Cannabis sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plant, cannabinoids, isomers, acids, salts, and salts of isomers, with a delta-9 tetrahydrocannabinol concentration of no more than 0.3 percent on a dry weight basis.[1]

AB 45 defines "hemp product" as

[1] Hemp "does not include cannabinoids produced through chemical synthesis." However, the term "chemical synthesis" is not defined.

a finished product containing industrial hemp that meets all of the following conditions:
Is a cosmetic, food, food additive, dietary supplement, or herb.
(B)(i) Is for human or animal consumption.
(ii) "Animal" does not include livestock or a food animal as defined in Section 4825.1 of the Business and Professions Code.
(iii) Does not include THC isolate as an ingredient.[2]

Fourth, AB 45 vested in the Department broad authority to regulate hemp products. But in the three years since AB 45 was signed into law, the Department has taken no action to implement an age restriction or THC serving or package limits, and indeed has failed to take any steps under its existing authority to protect the public against products manufactured or sold by bad actors that have illegally targeted children.

C. Unsuccessful Legislative Efforts to Enact THC Limits

Following AB 45's enactment, legislative efforts to impose THC limits for intoxicating hemp-derived THC products have failed. Specifically, in February 2023, in the wake of intoxicating hemp-derived THC products being sold in California, Assemblywoman Aguiar-Curry introduced AB 420. The bill would have prohibited the manufacture, distribution, or sale of a hemp product that contains any non-naturally occurring cannabinoid and set a 0.3% total THC limit for hemp products. The legislature chose not to pass the bill.

A year later, in February 2024, Assemblywoman Aguiar-Curry introduced AB 2223. Largely similar to AB 420, AB 2223 would have set a 0.3% total THC limit for hemp products and imposed a five-serving-per-package limit for hemp food and beverage products in final form.

Amendments to AB 2223 would have limited all hemp products, not just food and beverage products, to one milligram of total THC per package and 0.25 milligrams of THC per serving. While USHRT opposed the amounts of the per-serving and per-package limits, it engaged with Assemblywoman Aguiar-Curry to propose an age restriction for certain hemp products and to encourage meaningful enforcement of regulations.

Later in the legislative session, Governor Newsom's administration proposed hemp industry-killing amendments that would have prohibited all hemp products from containing any traceable amount of THC, despite California's defining "hemp" based on its 0.3% or less delta-9 THC concentration on a dry weight basis.

Unsurprisingly, the administration's amendments torpedoed AB 2223's legislative prospects. Just three weeks ago, the legislature ended its session without passing AB 2223, thereby choosing not to enact the administration's proposed prohibition against hemp products

[2] Hemp products do not include "hemp or a hemp product that has that has been approved by the United States Food and Drug Administration or a hemp product that includes industrial hemp or hemp that has received Generally Recognized As Safe (GRAS) designation."

that contain any traceable amount of THC. The Department, which is part of Governor Newsom's Executive Branch, is now trying to illegally end-run the legislature's decision to not enact AB 2223, and bills before it, that would have set age restrictions and/or THC limits for some hemp products.

V. CONCLUSION

To be clear, our Clients support fair and reasonable regulations for hemp-derived THC products, including a 21-or-older age restriction for hemp products, provided that such regulations emerge from the regular rulemaking process that is required in these circumstances by California law. Our Clients oppose the Emergency Regulations here because the Department is proceeding down the legally improper path of the emergency rulemaking process. For the reasons stated above, the Emergency Regulations are legally improper for the emergency rulemaking process. The OAL should overrule the Emergency Regulations and require that they be submitted through the regular rulemaking process.

We appreciate the OAL's consideration of the written comments above, as well as other written comments that will be submitted in opposition to the Emergency Regulations.

Sincerely,

Monisha A. Coelho
Jonathan S. Miller
Nolan M. Jackson
Drew M. Jones

Copy via e-mail to: CDPH, Office of Regulations (regulations@cdph.ca.gov)

Enc.:

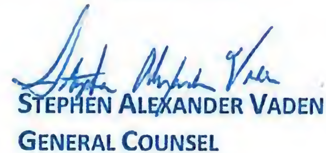
0135776.0793708 4889-0549-2965v1

EXHIBIT A

United States Department of Agriculture

Office of the General Counsel

Washington, D.C. 20250-1400



STEPHEN ALEXANDER VADEN
GENERAL COUNSEL

May 28, 2019

MEMORANDUM

SUBJECT: EXECUTIVE SUMMARY OF NEW HEMP AUTHORITIES

On December 20, 2018, President Trump signed into law the Agriculture Improvement Act of 2018, Pub. L. 115-334 (2018 Farm Bill). The 2018 Farm Bill legalized hemp production for all purposes within the parameters laid out in the statute.

The Office of the General Counsel (OGC) has issued the attached legal opinion to address questions regarding several of the hemp-related provisions of the 2018 Farm Bill, including: a phase-out of the industrial hemp pilot authority in the Agricultural Act of 2014 (2014 Farm Bill) **(Section 7605)**; an amendment to the Agricultural Marketing Act of 1946 to allow States and Indian tribes to regulate hemp production or follow a Department of Agriculture (USDA) plan regulating hemp production **(Section 10113)**; a provision ensuring the free flow of hemp in interstate commerce **(Section 10114)**; and the removal of hemp from the Controlled Substances Act **(Section 12619)**.

The key conclusions of the OGC legal opinion are the following:

1. As of the enactment of the 2018 Farm Bill on December 20, 2018, hemp has been removed from schedule I of the Controlled Substances Act and is no longer a controlled substance.

2. After USDA publishes regulations implementing the new hemp production provisions of the 2018 Farm Bill contained in the Agricultural Marketing Act of 1946, States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under a State or Tribal plan or under a license issued under the USDA plan.

3. States and Indian tribes also may not prohibit the interstate transportation or shipment of hemp lawfully produced under the 2014 Farm Bill.

4. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under the Agricultural Marketing Act of 1946. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill **before December 20, 2018**, and whose conviction also occurred before that date.

With the enactment of the 2018 Farm Bill, hemp may be grown only (1) with a valid USDA-issued license, (2) under a USDA-approved State or Tribal plan, or (3) under the 2014 Farm Bill industrial hemp pilot authority. That pilot authority will expire one year after USDA establishes a plan for issuing USDA licenses under the provisions of the 2018 Farm Bill.

It is important for the public to recognize that the 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the **production** of hemp that are more stringent than Federal law. Thus, while a State or an Indian tribe cannot block the shipment of hemp through that State or Tribal territory, it may continue to enforce State or Tribal laws prohibiting the growing of hemp in that State or Tribal territory.

It is also important to emphasize that the 2018 Farm Bill does not affect or modify the authority of the Secretary of Health and Human Services or Commissioner of Food and Drugs to regulate hemp under applicable U.S. Food and Drug Administration (FDA) laws.

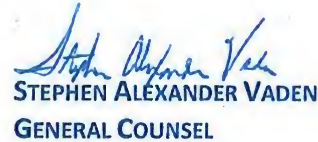
USDA expects to issue regulations implementing the new hemp production authorities in 2019.

Attachment

United States Department of Agriculture

Office of the General Counsel

Washington, D.C. 20250-1400



STEPHEN ALEXANDER VADEN
GENERAL COUNSEL

May 28, 2019

MEMORANDUM FOR SONNY PERDUE
SECRETARY OF AGRICULTURE

SUBJECT: LEGAL OPINION ON CERTAIN PROVISIONS OF THE AGRICULTURE IMPROVEMENT ACT OF 2018 RELATING TO HEMP

This memorandum provides my legal opinion on certain provisions of the Agriculture Improvement Act of 2018 ("2018 Farm Bill"), Pub. L. No. 115-334, relating to hemp.

As explained below, this memorandum concludes the following:

1. As of the enactment of the 2018 Farm Bill on December 20, 2018, hemp has been removed from schedule I of the Controlled Substances Act ("CSA") and is no longer a controlled substance. Hemp is defined under the 2018 Farm Bill to include any cannabis plant, or derivative thereof, that contains not more than 0.3 percent delta-9 tetrahydrocannabinol ("THC") on a dry-weight basis.

2. After the Department of Agriculture ("USDA" or "Department") publishes regulations implementing the hemp production provisions of the 2018 Farm Bill contained in subtitle G of the Agricultural Marketing Act of 1946 ("AMA"), States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under a State or Tribal plan or under a license issued under the Departmental plan.

3. States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under the Agricultural Act of 2014 ("2014 Farm Bill").

4. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under subtitle G of the AMA. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

This memorandum also emphasizes two important aspects of the 2018 Farm Bill provisions relating to hemp. First, the 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the **production** (but not the interstate transportation or shipment) of hemp that are more stringent than Federal law. For example, a State law prohibiting the growth or cultivation of hemp may continue to be enforced by that State. Second, the 2018 Farm Bill does not affect or modify the authority of the Secretary of Health and Human Services or Commissioner of Food and Drugs under applicable U.S. Food and Drug Administration laws.

I. BACKGROUND

The 2018 Farm Bill, Pub. L. No. 115-334, enacted on December 20, 2018, includes several provisions relating to hemp.[1] This legal opinion focuses on sections 7605, 10113, 10114, and 12619, summarized below.

- **Section 7605** amends section 7606 of the 2014 Farm Bill (7 U.S.C. § 5940), which authorizes institutions of higher education or State departments of agriculture to grow or cultivate industrial hemp under certain conditions — namely, if the hemp is grown or cultivated for research purposes in a State that allows hemp production. Among other things, section 7605 amends 2014 Farm Bill § 7606 to require the Secretary of Agriculture ("Secretary") to conduct a study of these hemp research programs and submit a report to Congress. Section 7605 also repeals 2014 Farm Bill § 7606, effective one year after the date on which the Secretary establishes a plan under section 297C of the AMA.[2]

- **Section 10113** amends the AMA by adding a new subtitle G (sections 297A through 297E) (7 U.S.C. §§ 1639o – 1639s) relating to hemp production. Under this new authority, a State or Indian tribe that wishes to have primary regulatory authority over the production of hemp in that State or territory of that Indian tribe may submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. *See* AMA § 297B. For States or Indian tribes that do not have approved plans, the Secretary is directed to establish a Departmental plan concerning the monitoring and regulation of hemp production in those areas. *See* AMA § 297C. The

[1] The 2014 Farm Bill 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." 7 U.S.C. § 5940(a)(2). The 2018 Farm Bill added a new, slightly different definition of **"hemp"** in section 297A of the AMA, defined as "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." 7 U.S.C. § 1639o(1). Both definitions require a THC concentration of not more than 0.3 percent for a Cannabis sativa L. plant to be considered hemp versus marijuana. For purposes of this legal opinion, I use the terms **"hemp"** and **"industrial hemp"** interchangeably.

[2] The Conference Report accompanying the 2018 Farm Bill explains the effect of the repeal as follows: "The provision also repeals the hemp research pilot programs one year after the Secretary publishes a final regulation allowing for full-scale commercial production of hemp as provided in section 297C of the [AMA]." H.R. REP. NO. 115-1072, at 699 (2018).

Secretary is also required to promulgate regulations and guidelines implementing subtitle G. *See* AMA § 297D. The new authority also provides definitions (*see* AMA § 297A) and an authorization of appropriations (*see* AMA § 297E).

- **Section 10114** (7 U.S.C. § 1639o note) is a freestanding provision stating that nothing in title X of the 2018 Farm Bill prohibits the interstate commerce of hemp or hemp products. Section 10114 also provides that States and Indian tribes shall not prohibit the interstate transportation or shipment of hemp or hemp products produced in accordance with subtitle G through the State or territory of the Indian tribe.

- **Section 12619** amends the CSA to exclude hemp from the CSA definition of marijuana. Section 12619 also amends the CSA to exclude THC in hemp from Schedule I.[3]

In passing the 2018 Farm Bill, Congress legalized hemp production for all purposes within the parameters of the statute but reserved to the States and Indian tribes authority to enact and enforce more stringent laws regulating production of hemp.

II. ANALYSIS

A. <u>As of the Enactment of the 2018 Farm Bill on December 20, 2018, Hemp Has Been Removed from Schedule I of the Controlled Substances Act and Is No Longer a Controlled Substance.</u>

CSA § 102(6) defines "controlled substance" to mean "a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title. . . ." 21 U.S.C. § 802(6). Marijuana[4] is a controlled substance listed in schedule I of the CSA. *See* CSA § 202(c)(10), schedule I (21 U.S.C. § 812(c), Schedule I (c)(10)); 21 C.F.R. § 1308.11(d)(23).

The 2018 Farm Bill amended the CSA in two ways.

- First, 2018 Farm Bill § 12619(a) amended the CSA definition of marijuana to exclude hemp. Before enactment of the 2018 Farm Bill, CSA § 102(16) (21 U.S.C. § 802(16)) defined marijuana as follows:

> (16) 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. 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,

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[3] For additional background on hemp production prior to enactment of the 2018 Farm Bill, *see* Congressional Research Service, "Hemp as an Agricultural Commodity" (RL32725) (updated July 9, 2018), *available at* https://crsreports.congress.gov/product/pdf/RL/RL32725.

[4] This opinion uses the common spelling of "marijuana" except when quoting the CSA, which uses the "marihuana" spelling.

> or the sterilized seed of such plant which is incapable of germination.

As amended by the 2018 Farm Bill, the CSA definition of marijuana now reads:

> (A) Subject to subparagraph (B), 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.
>
> (B) The term 'marihuana' 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.

- Second, 2018 Farm Bill § 12619(b) amended the CSA to exclude THC in hemp from the term "tetrahydrocannabinols" in schedule I. As amended by the 2018 Farm Bill, CSA § 202(c)(17), schedule I (21 U.S.C. § 812(c)(17), schedule I) now reads:

> Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946).

By amending the definition of marijuana to exclude hemp as defined in AMA § 297A, Congress has removed hemp from schedule I and removed it entirely from the CSA. In other words, hemp is no longer a controlled substance. Also, by amending schedule I to exclude THC in hemp, Congress has likewise removed THC in hemp from the CSA.

It is important to note that this decontrolling of hemp (and THC in hemp) is self-executing. Although the CSA implementing regulations must be updated to reflect the 2018 Farm Bill amendments to the CSA, neither the publication of those updated regulations nor any other action is necessary to execute this removal.

I address here two principal objections to the view that the decontrolling of hemp is self-executing. The first objection is that, because regulations have not been published under CSA § 201, the legislative changes to schedule I regarding hemp are not effective. This objection is not valid.

The typical process for amending the CSA schedules is through rulemaking. Under CSA § 201(a), the Attorney General "may by rule" add to, remove from, or transfer between the schedules, any drugs or other substances upon the making of certain findings. 21 U.S.C. § 811(a). However, the schedules also can be amended directly by Congress through changes to the statute; and Congress has done so several times.[5]

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[5] *See, e.g.*, Pub. L. 112-144, § 1152 (amending schedule I to add cannabimimetic agents); Pub. L. 101-647, § 1902(a) (amending schedule III to add anabolic steroids).

The second objection is that, because the legislative changes to schedule I regarding hemp are not yet reflected in 21 C.F.R. § 1308.11, the removal is not yet effective. This objection also is not valid.

It is axiomatic that statutes trump regulations. *See Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Gonzales*, 468 F.3d 826, 829 (D.C. Cir. 2006) ("[A] valid statute always prevails over a conflicting regulation[.]"). Congress established the five CSA schedules in statute, providing that "[s]uch schedules shall initially consist of the substances listed in this section." 21 U.S.C. § 812(a).[6] Congress further provided that "[t]he schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter." 21 U.S.C. § 812(a). The requirement to update and republish the schedules, however, is not a prerequisite to the effectiveness of the schedules "established by [the statute]." *Id.* In other words, where Congress itself amends the schedules to add or remove a controlled substance, the addition or removal of that controlled substance is effective immediately on enactment (absent some other effective date in the legislation); its addition to or removal from a schedule is not dependent on rulemaking.[7]

To illustrate, Congress amended the CSA in 2012 to add "cannabimimetic agents" to schedule I. That amendment was enacted as part of the Synthetic Drug Abuse Prevention Act of 2012 (Pub. L. 112-144, title XI, subtitle D), which was signed into law on July 9, 2012. Almost six months later, the Drug Enforcement Administration ("DEA") published a final rule establishing the drug codes for the cannabimimetic agents added to schedule I by Congress and making other conforming changes to schedule I as codified in 21 C.F.R. § 1308.11. *See* 78 Fed. Reg. 664 (Jan. 4, 2013). In explaining why notice-and-comment rulemaking was unnecessary, DEA noted that "the placement of these 26 substances in Schedule I **has already been in effect since July 9, 2012.**" *Id.* at 665 (emphasis added). In other words, the legislative changes to schedule I were effective immediately upon enactment. The reflection of those changes in 21 C.F.R. § 1308.11, although required by 21 U.S.C. § 812(a), was not necessary for the execution of those changes to schedule I.

Accordingly, enactment of the 2018 Farm Bill accomplished the removal of hemp (and THC in hemp[8]) from the CSA. Conforming amendments to 21 C.F.R. § 1308.11, while required as part

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[6] "Marihuana" and "Tetrahydrocannabinols" were both included in the initial schedule I established by Congress in 1970.

[7] *Cf. United States v. Huerta*, 547 F.2d 545, 547 (10th Cir. 1977) ("[F]ailure to publish the 'updated' schedules as required by Section 812(a) had no effect upon the validity of those substances initially listed in the five schedules."); *United States v. Monroe*, 408 F. Supp. 270, 274 (N.D. Cal. 1976) ("Thus, while section 812(a) clearly orders the controlled substance schedules to be republished, it is clear that Congress did not intend republication to serve as a reissuance of the schedules, which if done improperly would cause those schedules to lapse and expire. . . . [T]he requirement that the schedules, once 'updated,' be 'republished' was solely for the purpose of establishing one list which would reflect all substances which were currently subject to the Act's provisions. . . .").

[8] Schedule I, as published in 21 C.F.R. § 1308.11, includes a definition of "tetrahydrocannabinols" in paragraph (d)(31) that does not appear in the CSA. Notwithstanding the presence of that definition in the current regulations, I

of DEA's continuing obligation to publish updated schedules, are not necessary to execute the 2018 Farm Bill changes to schedule I.[9]

B. After the Department of Agriculture Publishes Regulations Implementing the Hemp Production Provisions of the 2018 Farm Bill Contained in Subtitle G of the Agricultural Marketing Act of 1946, States and Indian Tribes May Not Prohibit the Interstate Transportation or Shipment of Hemp Lawfully Produced Under a State or Tribal Plan or Under a License Issued Under the Departmental Plan.

AMA § 297D(a)(1)(A) directs the Secretary to issue regulations and guidelines "as expeditiously as possible" to implement subtitle G of the AMA. 7 U.S.C. § 1639r(a)(1)(A). These regulations will address the approval of State and Tribal plans under AMA § 297B and the issuance of licenses under the Departmental plan under AMA § 297C. As explained below, once these regulations are published, States and Indian tribes may not prohibit the transportation or shipment of hemp (including hemp products) produced in accordance with an approved State or Tribal plan or produced under a license issued under the Departmental plan.

Transportation of hemp is addressed in 2018 Farm Bill § 10114.[10] Subsection (a) provides:

> (a) RULE OF CONSTRUCTION.—Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp (as defined in section 297A of the Agricultural Marketing Act of 1946 (as added by section 10113)) or hemp products.

7 U.S.C. § 1639o note. This provision states that nothing in title X of the 2018 Farm Bill

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am of the opinion that THC in hemp is excluded from THC as a schedule I controlled substance under the CSA by virtue of the 2018 Farm Bill amendments.

[9] Schedule I, as reflected in 21 C.F.R. § 1308.11, includes a separate listing of "marihuana extract" in paragraph (d)(58). Marijuana extract is not reflected in schedule I in the statute because it was added after 1970 by regulation under CSA § 201. The term "marihuana extract" is defined in regulation as "an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant." The 2018 Farm Bill amended the definition of "marihuana" to exclude hemp, but because the regulatory definition of "marihuana extract" in schedule I does not use the words "marihuana" or "tetrahydrocannabinols" to define the term, a question arises whether **hemp extract** is still considered to be listed as a schedule I controlled substance. While the issue is not further addressed in this opinion, I think that the revised statutory definition of "marihuana" has effectively removed hemp extract from schedule I, and that reflecting such in 21 C.F.R. § 1308.11(d)(58) would be merely a conforming amendment.

[10] Hemp transportation is also addressed in annual appropriations acts, which restrict Federal appropriated funds from being used to prohibit the transportation of hemp. However, those provisions are limited in scope because they address only hemp produced under the 2014 Farm Bill authority, and they address only **Federal** government actions. That is, while the provisions prohibit Federal actors from blocking the transportation of so-called "2014 Farm Bill hemp," they do not restrict State action in that regard. *See* Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2019, Pub. L. 116-6, div. B, § 728 (prohibiting funds made available by that Act or any other Act from being used in contravention of 2014 Farm Bill § 7606 or "to prohibit the transportation, processing, sale, or use of industrial hemp, or seeds of such plant, that is grown or cultivated in accordance with [2014 Farm Bill § 7606], within or outside the State in which the industrial hemp is grown or cultivated"). *See also* Commerce, Justice, Science, and Related Agencies Appropriations Act, 2019, Pub. L. 116-6, div. C, § 536 ("None of the funds made available by this Act may be used in contravention of [2014 Farm Bill § 7606] by the Department of Justice or the Drug Enforcement Administration.").

prohibits the interstate commerce of hemp. However, this provision, standing alone, does not have the effect of sanctioning the transportation of hemp in States or Tribal areas where such transportation is prohibited under State or Tribal law.

Subsection (b), however, specifically prohibits States and Indian tribes from prohibiting the transportation of hemp through that State or Tribal territory. Subsection (b) provides:

> (b) TRANSPORTATION OF HEMP AND HEMP PRODUCTS.—No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.

7 U.S.C. § 1639o note. In effect, this provision preempts State law to the extent such State law prohibits the interstate transportation or shipment of hemp that has been produced in accordance with subtitle G of the AMA.

As a matter of constitutional law, "[t]he Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any [S]tate to the Contrary notwithstanding. . . .' Under this principle, Congress has the power to preempt [S]tate law." *Arizona v. United States*, 567 U.S. 387, 398-99 (2012) (citing U.S. Const. art. VI, cl. 2). "Under the doctrine of federal preemption, a federal law supersedes or supplants an inconsistent [S]tate law or regulation." *United States v. Zadeh*, 820 F.3d 746, 751 (5th Cir. 2016).

Federal courts generally recognize three categories of preemption: (1) express preemption (where Congress "withdraw[s]" powers from the State through an "express preemption provision");[11] (2) field preemption (where States are "precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance");[12] and conflict preemption (where State laws are preempted when they conflict with Federal law, which includes situations "where 'compliance with both federal and [S]tate regulations is a physical impossibility'" or situations "where the challenged [S]tate law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'").[13] *Arizona*, 567 U.S. at 399-400 (citations omitted); *see also Zadeh*, 820 F.3d at 751.

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[11] *See, e.g.*, 7 U.S.C. § 1639i(b) ("(b) Federal preemption.—No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.").

[12] *See, e.g.*, *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 212 ("[T]he federal government has occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the [S]tates.").

[13] *See, e.g.*, 21 U.S.C. § 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is

Section 10114(b) of the 2018 Farm Bill satisfies the definition of conflict preemption because a State law prohibiting the interstate transportation or shipment of hemp or hemp products that have been produced in accordance with subtitle G of the AMA would be in direct conflict with section 10114(b), which provides that no State may prohibit such activity.[14] Therefore, any such State law has been preempted by Congress. The same result applies to Indian tribes.[15]

In sum, once the implementing regulations are published, States and Indian tribes may not prohibit the shipment of hemp lawfully produced under an approved State or Tribal plan or under a license issued under the Departmental plan.

C. States and Indian Tribes May Not Prohibit the Interstate Transportation or Shipment of Hemp Lawfully Produced Under the Agricultural Act of 2014.

Because the 2018 Farm Bill does not immediately repeal the hemp pilot authority in 2014 Farm Bill § 7606 — and because the publication of regulations implementing the hemp production provisions of the 2018 Farm Bill will likely not occur until later in 2019 — the question arises whether States and Indian tribes are prohibited from blocking the interstate transportation or shipment of hemp (including hemp products) lawfully produced under the 2014 Farm Bill. The answer depends on the meaning of the phrase "in accordance with subtitle G of the Agricultural Marketing Act of 1946" in 2018 Farm Bill § 10114(b) (7 U.S.C. § 1639o note). Only hemp produced in accordance with subtitle G is covered by the preemption provision discussed above. As explained below, it is my opinion that the answer to this question is yes, by operation of AMA § 297B(f).

AMA § 297B(f) states the legal effect of the provisions authorizing States and Indian tribes to develop plans for exercising primary regulatory authority over the production of hemp within that State or territory of the Indian tribe. Specifically, section 297B(f) provides:

> (f) EFFECT.—Nothing in this section prohibits the production of hemp in a State or the territory of an Indian tribe—
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> (1) for which a State or Tribal plan is not approved under this section, if the production of hemp is in accordance with section 297C **or other Federal laws** (including regulations); and
>
> (2) if the production of hemp is not otherwise prohibited by the State or Indian tribe.

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a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.").

[14] Alternatively, section 10114(b) might be considered an express preemption provision because the statute expressly withdraws the power of a State to prohibit the transportation or shipment of hemp or hemp products through the State.

[15] AMA § 297B(a)(3) contains an anti-preemption provision stating that nothing in § 297B(a) "preempts or limits any law of a State or Indian tribe" that "regulates the production of hemp" and "is more stringent than [subtitle G]." 7 U.S.C. § 1639p(a)(3). However, that anti-preemption provision is limited to the **production** of hemp — not the **transportation** or shipment of hemp — and thus does not conflict with 2018 Farm Bill § 10114(b).

7 U.S.C. § 1639p(f) (emphasis added).

This provision addresses the production of hemp in a State or Tribal territory for which the State or tribe does not have an approved plan under AMA § 297B. This provision acknowledges that, in such a scenario, the production of hemp in that State or Tribal territory is still permissible if it is produced **either** in accordance with the Departmental plan under AMA § 297C **or** in accordance with other Federal laws, and the State or tribe does not otherwise prohibit its production.

The plain language of subtitle G of the AMA, as added by the 2018 Farm Bill, thus clearly contemplates a scenario in which hemp is neither produced under an approved 297B plan nor under a license issued under the Department's 297C plan, but is still legally produced under "other Federal laws." It is my opinion that "other Federal laws" encompasses 2014 Farm Bill § 7606.[16]

To my knowledge, before enactment of 2014 Farm Bill § 7606, the CSA was the only Federal law that authorized the production of hemp. Indeed, the production of hemp — as the "manufacture" of a schedule I controlled substance — was generally prohibited under the CSA except to the extent authorized under a registration or waiver under the CSA. *See* 21 U.S.C. §§ 802(15), 802(22), 822, and 823; 21 C.F.R. part 1301. Given (1) the removal of hemp as a controlled substance under the CSA, (2) the delayed repeal of the 2014 Farm Bill § 7606 authority, and (3) the enactment of the new hemp production authorities in subtitle G of the AMA, it is my opinion that "other Federal laws" refers to the provisions of 2014 Farm Bill § 7606, which are still in effect. Such an interpretation gives immediate effect to the phrase "other Federal laws." It is a "cardinal principle of interpretation that courts must give effect, if possible, to every clause and word of a statute." *See, e.g., Loughrin v. United States*, 573 U.S. 351, 358 (2014) (internal quotations and citations omitted).

Therefore, reading AMA § 297B(f) in harmony with 2018 Farm Bill § 10114(b), if the hemp is legally produced in accordance with 2014 Farm Bill § 7606 ("other Federal law"), then, by virtue of AMA § 297B(f), its production is not prohibited. Such hemp would have been produced "in accordance with subtitle G," which specifically addresses just such a scenario, as AMA § 297B(f) is part of subtitle G. Accordingly, under 2018 Farm Bill § 10114(b), a State or Indian

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[16] That Congress envisioned such a scenario is apparent given the language in 2018 Farm Bill § 7605(b) delaying the repeal of 2014 Farm Bill § 7606 until 12 months **after** the Secretary establishes the 297C plan. Accordingly, this interpretation is not precluded by AMA § 297C(c)(1), which provides: "[i]n the case of a State or Indian tribe for which a State or Tribal plan is not approved under section 297B, it shall be unlawful to produce hemp in that State or the territory of that Indian tribe without a license issued by the Secretary under subsection (b)." Given the reference to "or other Federal laws" in AMA § 297B(f)(1) — and the fact that 2014 Farm Bill § 7606 is still in effect — it would be an absurd reading of AMA § 297C(c)(1) to conclude that hemp produced in accordance with Federal law (2014 Farm Bill § 7606) is, at the same time, unlawful without a separate license issued by the Secretary under the 297C plan. As courts have long recognized, statutory interpretations that "produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available." *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982).

tribe may not prohibit the transportation or shipment of so-called "2014 Farm Bill hemp" through that State or Tribal territory.[17]

Recent Developments

I acknowledge that this conclusion is in tension with a recent decision in a case in the District of Idaho, but it also is consistent with a recent decision in a case in the Southern District of West Virginia. Neither court addressed the "other Federal laws" language in AMA § 297B(f)(1), which I find conclusive.

In *Big Sky Scientific LLC v. Idaho State Police*, Case No. 19-CV-00040 (D. Idaho), a magistrate judge found that a shipment of Oregon hemp bound for Colorado and interdicted by Idaho State Police could not have been produced "in accordance with subtitle G" because the State of origin does not yet have an approved plan under AMA § 297B and the Secretary has not yet established a plan under AMA § 297C.[18] The magistrate acknowledged Oregon law authorizing the cultivation of hemp, noting the plaintiff's assertion that the hemp was produced by a grower licensed by the Oregon Department of Agriculture (and, thus, presumably in compliance with 2014 Farm Bill § 7606 requirements).[19] However, in denying the plaintiff's motion for a preliminary injunction, the magistrate concluded that, in enacting the 2018 Farm Bill, Congress intended to "create a regulatory framework around the production and interstate transportation of hemp for purposes of federal law, and that framework is to be contained in the federal (or compliant [S]tate or [T]ribal) plan for production of hemp found in the 2018 Farm Bill."[20] Although the 2018 Farm Bill allows hemp to be transported across State lines, the magistrate found those interstate commerce protections apply only to hemp produced under regulations promulgated under the authority of the 2018 Farm Bill.[21] Therefore, because those regulations do not yet exist, the interdicted hemp is subject to Idaho law prohibiting its transportation.

USDA is not a party in the *Big Sky* case, and this office does not concur with the reasoning of the magistrate regarding the shipment of hemp lawfully produced under the 2014 Farm Bill. In

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[17] This conclusion seems to be supported in the legislative history as well. In explaining the effect of the preemption provision, the Conference Report states: "While [S]tates and Indian tribes may limit the production and sale of hemp and hemp products within their borders, the Managers, in Sec. 10112 [sic], agreed to not allow [S]tates and Indian tribes to limit the transportation or shipment of hemp or hemp products through the [S]tate or Indian territory." H.R. REP. NO. 115-1072, at 738 (2018). Notably, the Managers referred to hemp generally, not merely hemp produced under a plan developed under subtitle G of the AMA.

[18] *See Big Sky*, ECF Doc. #32, Memorandum Decision and Order Re: Plaintiff's Motion for Preliminary Injunction; *see also* ECF Doc. #6, Memorandum Decision and Order Re: Plaintiff's Emergency Motion for Temporary Restraining Order and Preliminary Injunction and Plaintiff's Motion to File Overlength Brief (*available at* 2019 WL 438336 (Feb. 2, 2019)).

[19] *Big Sky*, ECF Doc. #32, at 5, 7-8.

[20] *Id.* at 3.

[21] *Id.* at 19-26.

interpreting the statutory language, the magistrate correctly noted the well-recognized principle of statutory construction that statutes should not be interpreted "in a manner that renders other provisions of the same statute inconsistent, meaningless, or superfluous."[22] However, seemingly ignoring that guiding principle of interpretation, the magistrate did not address the effect of the "other Federal laws" language in AMA § 297B(f) or attempt to give that language any meaning. The Idaho court failed to read the statute as a whole and did not consider the "other Federal laws" clause that I find conclusive. Given the preliminary nature of the magistrate's ruling, I find his opinion denying a preliminary injunction unpersuasive.[23]

Conversely, the interpretation of 2018 Farm Bill § 10114 advanced by this legal opinion is consistent with a decision issued in the Southern District of West Virginia. In *United States v. Mallory*, Case No. 18-CV-1289 (S.D. W. Va.), the Department of Justice filed a civil action to seize hemp allegedly grown in violation of the CSA and also outside the scope of the 2014 Farm Bill. At issue in that case was hemp purportedly grown by a producer licensed by the State of West Virginia under a 2014 Farm Bill § 7606 pilot program, where the hemp seeds were shipped from a Kentucky supplier licensed by the Commonwealth of Kentucky under a 2014 Farm Bill § 7606 pilot program. The court relied on a combination of laws — the 2014 Farm Bill, the appropriations acts provisions,[24] and the 2018 Farm Bill — to dissolve a preliminary injunction against the defendant[25] and to dismiss entirely the government's case.[26] In dissolving the preliminary injunction, the court permitted the defendants to transport the hemp product across State lines to Pennsylvania for processing and sale.[27]

Although the *Mallory* court did not have occasion to address any State attempts to block the transportation of hemp, the court did reference 2018 Farm Bill § 10114, noting that it "expressly allows hemp, its seeds, and hemp-derived products to be transported across State lines."[28] The district judge's opinion addressed hemp produced under 2014 Farm Bill § 7606 and not hemp produced under State, Tribal, or Departmental plans. The conclusion reached by the *Mallory* court is consistent with my interpretation that States cannot block the shipment of hemp, whether

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[22] *Id.* at 21-22 (citing *Padash v. I.N.S.*, 258 F.3d 1161, 1170-71 (9th Cir. 2004)). The magistrate continued:

> It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant. . . . It is our duty to give effect, if possible, to every clause and word of a statute.

Id. at 23 (internal quotations and citations omitted).

[23] Indeed, the magistrate's ruling is under appeal. *See Big Sky Sci. LLC v. Bennetts*, Case No. 19-35138 (9th Cir.).

[24] *See supra* footnote 10.

[25] *Mallory*, ECF Doc. #60, Memorandum Opinion and Order, 2019 WL 252530 (S.D. W. Va. Jan. 17, 2019).

[26] *Mallory*, ECF Doc. #72, Memorandum Opinion and Order, 2019 WL 1061677 (S.D. W. Va. Mar. 6, 2019).

[27] *Mallory*, ECF Doc. #60, 2019 WL 252530, at *3.

[28] *Mallory*, ECF Doc. #72, 2019 WL 1061677, at *6.

that hemp is produced under the 2014 Farm Bill or under a State, Tribal, or Departmental plan under the 2018 Farm Bill. It is also a final judgment of the Southern District of West Virginia court, and not a preliminary ruling as with the District of Idaho magistrate's opinion.[29]

In matters of statutory interpretation, the text of the statute governs. One must read that text in its entirety and give every word meaning. The reference to "other Federal laws" must be given meaning, and that language clearly refers to the Federal law that currently authorizes the production of hemp — 2014 Farm Bill § 7606. Therefore, hemp produced under that pilot authority is hemp produced in accordance with subtitle G of the AMA. States and Indian tribes may not prohibit the transportation or shipment of such hemp through that State or Tribal territory.

D. The 2018 Farm Bill Places Restrictions on the Production of Hemp by Certain Felons.

The 2018 Farm Bill added a new provision addressing the ability of convicted felons to produce hemp. The 2014 Farm Bill is silent on the issue. AMA § 297B(e)(3)(B) (hereafter, "Felony provision"), as added by the 2018 Farm Bill, provides:

> (B) FELONY.—
>
> (i) IN GENERAL.—Except as provided in clause (ii), any person convicted of a felony relating to a controlled substance under State or Federal law before, on, or after the date of enactment of this subtitle shall be ineligible, during the 10-year period following the date of the conviction—
>
> (I) to participate in the program established under this section or section 297C; and
>
> (II) to produce hemp under any regulations or guidelines issued under section 297D(a).
>
> (ii) EXCEPTION.—Clause (i) shall not apply to any person growing hemp lawfully with a license, registration, or authorization under a pilot program authorized by section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before the date of enactment of this subtitle.

7 U.S.C. § 1639p(e)(3)(B) (emphasis added). The references to "the date of enactment of this subtitle" are to subtitle G of the AMA, as added by section 10113 of 2018 Farm Bill. Therefore, the "date of enactment of this subtitle" is the date of enactment of the 2018 Farm Bill — December 20, 2018.

In explaining the Felony provision, the Conference Report notes:

> Any person convicted of a felony relating to a controlled substance shall be ineligible to participate under the [S]tate or [T]ribal plan for a 10-year period following the date of the conviction. However, this prohibition shall not apply to producers who have been lawfully participating in a [S]tate hemp pilot program as authorized by the Agricultural Act of 2014, prior to enactment of this subtitle. Subsequent felony convictions after the date of enactment of this subtitle will trigger a 10-year

[29] *Mallory*, ECF Doc. #72, 2019 WL 1061677, at *9 (denying the United States' motion to amend and granting the defendants' motion to dismiss). *Big Sky*, ECF Doc. #32, at 28 (denying the plaintiff's motion for preliminary injunction and noting that the court will separately issue an order setting a scheduling conference to govern the case going forward).

> nonparticipation period regardless of whether the producer participated in the pilot program authorized in 2014.

H.R. REP. NO. 115-1072, at 737 (2018).

In sum, a person convicted of a State or Federal felony relating to a controlled substance — regardless of when that conviction occurred — is ineligible to produce hemp under subtitle G of the AMA for a period of 10 years following the date of the conviction. An exception exists in clause (ii) of the Felony provision that applies to a person who was lawfully producing hemp under the 2014 Farm Bill **before December 20, 2018**, and who had been convicted of a felony relating to a controlled substance before that date. States and Indian tribes now have a responsibility to determine whether a person wishing to produce hemp in that State or Tribal territory has any Federal or State felony convictions relating to controlled substances that would make that person ineligible to produce hemp.

III. OTHER ISSUES

There are two additional important aspects of this issue that should be emphasized.

First, the 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the production of hemp that are more stringent than Federal law. *See* AMA § 297B(a)(3) (7 U.S.C. § 1639p(a)(3)) ("Nothing in this subsection preempts or limits any law of a State or Indian tribe that . . . (i) regulates the production of hemp; and (ii) is more stringent than this subtitle."). For example, a State may continue to prohibit the growth or cultivation of hemp in that State.[30] As discussed above, however, while a State or Indian tribe may prohibit the production of hemp, it may not prohibit the interstate shipment of hemp that has been produced in accordance with Federal law.

Second, the 2018 Farm Bill does not affect or modify the authority of the Secretary of Health and Human Services ("HHS Secretary") or Commissioner of Food and Drugs ("FDA Commissioner") under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) and section 351 of the Public Health Service Act (42 U.S.C. § 262). *See* AMA § 297D(c) (7 U.S.C. § 1639r(c)). While AMA § 297D(b) provides that the Secretary of Agriculture shall have "sole authority" to issue Federal regulations and guidelines that relate to the production of hemp, this authority is subject to the authority of the HHS Secretary and FDA Commissioner to promulgate Federal regulations and guidelines under those FDA laws. 7 U.S.C. § 1639r(b).

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[30] Certain states continue to prohibit the cultivation of hemp. *See* National Conference of State Legislatures, "State Industrial Hemp Statutes," *available at* http://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx#state (updated Feb. 1, 2019).

IV. CONCLUSION

I have analyzed the hemp provisions enacted as part of the 2018 Farm Bill and reach the following conclusions:

1. As of the enactment of the 2018 Farm Bill on December 20, 2018, hemp has been removed from schedule I of the CSA and is no longer a controlled substance.

2. After USDA publishes regulations implementing the hemp production provisions of the 2018 Farm Bill contained in subtitle G of the AMA, States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under a State or Tribal plan or under a license issued under the Departmental plan.

3. States and Indian tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under the 2014 Farm Bill.

4. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under subtitle G of the AMA. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

The 2018 Farm Bill preserves the authority of States and Indian tribes to enact and enforce laws regulating the production of hemp that are more stringent than Federal law. Additionally, the 2018 Farm Bill does not affect or modify the authority of the HHS Secretary or FDA Commissioner to regulate hemp under applicable FDA laws.