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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES

U.S. HEMP ROUNDTABLE, INC., a non-profit corporation; CHEECH AND CHONG'S, a corporation; JUICETIVA INC., a corporation; BLAZE LIFE LLC, a limited liability company; BOLDT RUNNERS CORPORATION, a corporation; LUCKY TO BE BEVERAGE CO., a corporation; and SUNFLORA, INC., a corporation,

Plaintiff,

v.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, a state agency, TOMÁS J. ARAGÓN, M.D., Dr.P.H., an individual in his capacity as Director and State Public Health Officer of the CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, and DOES 1-50,

Defendants

CASE NO.:

Assigned for all purposes to:
Honorable
Department

VERIFIED PETITION AND COMPLAINT FOR:

(1) **DECLARATORY RELIEF (CODE CIV. PRO., § 1060, GOV. CODE, § 11350);**
(2) **DECLARATORY RELIEF – VIOLATION OF THE 2018 FEDERAL FARM BILL**
(3) **WRIT OF TRADITIONAL MANDATE (CODE CIV. PRO., § 1085), or, in the alternative, WRIT OF ADMINISTRATIVE MANDATE (Code Civ. Proc. §1094.5];**
(4) **VIOLATION OF CALIFORNIA ADMINISTRATIVE PROCEDURE ACT (GOV. CODE, § 11340, ET SEQ.);**
(5) **REGULATORY TAKING**
(6) **DECLARATORY RELIEF – VIOLATION OF THE COMMERCE CLAUSE**
(7) **VIOLATION OF DUE PROCESS (U.S. CONST. AMEND. XIV, § 2)**
(8) **VOID FOR VAGUENESS**

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I. INTRODUCTION

1. In 2021, California's legislature passed AB 45 to deal with a wide range of matters relating to the regulation of hemp products in California. While adopting a detailed definition of "industrial hemp products," "hemp products," and "THC or comparable cannabinoids," AB 45 did not distinguish between intoxicating and non-intoxicating cannabinoids. **Exhibit B.**

2. AB 45, now codified in various sections of the California Health & Safety Code, also broadly addressed the manufacture, warehousing, distribution, offering, advertisement and sale of hemp products. Such a broad-based act could not deal with a number of practical details.

3. As a result, AB 45 contained a provision authorizing California's Department of Public Health, ("Department") shortly after adoption of AB 45, to promulgate regulations necessary to administer the California Health & Safety Code provisions, its restrictions, limitations and other specifics.

4. Such regulatory details, of course, require a considered procedure to assure that the regulations promulgated are both authorized and appropriate. The Department went forward and issued regulatory provisions on a number of topics in 2021, shortly after AB 45 was codified in the Health & Safety Code.

5. However, there were a series of issues, a number of which are described below, that the Department's regulations did not touch. This, despite the fact that the Department has had nearly three years since 2021 to address them.

6. To reach such issues outside the constraints of the regular rulemaking process, the Department proclaimed on September 13, 2024 that emergency circumstances exist so that the issues may be dealt with on a truncated basis under the Administrative Procedure Act's emergency resolutions provisions. The Department issued sweeping emergency regulations on that basis. **Exhibit A**.

7. The Office of Administrative Law adopted the Department's emergency regulations yesterday, September 23, 2024, such that the emergency regulations are now official regulations in the California Code of Regulations. The emergency regulations took effect yesterday, September 23, 2024.

8. The Department's inaction over the last three years hardly serves as a sufficient basis for declaring a sudden emergency and circumventing the meticulous procedures of regular rulemaking.

9. Significantly, at the core of the Department's emergency regulations is a provision that goes far beyond the limits contemplated in AB 45 to ban *all* hemp products unless they contain no "detectable levels of THC."[1] This draconian regulation alone will essentially devastate an emerging industry that consists largely of small business owners. It's akin to requiring candy to stop containing sugar … starting tomorrow.

10. Other draconian provisions are the change to the statutory definition of hemp and an illegal distinction between intoxicating and non-intoxicating cannabinoids. These emergency regulations contradict express California and federal law.

11. Plaintiffs, a trade organization and several small businesses, bring this action to seek relief from this Court to avert the decimation of this sector of the California economy because, whatever the merits of the general issues addressed by these emergency regulations, the Department has acted entirely outside the boundaries of California's applicable law to adopt and issue them. Plaintiffs and their members will suffer losses in the millions of dollars over existing products, pending manufacturing, and future sales of hemp and hemp products that legally contained THC, as per existing California and federal law, but have now been banned overnight by the emergency regulations.

12. If allowed to remain in effect, the emergency regulations will eliminate nearly every ingestible hemp product currently for sale in California, including the vast majority of non-intoxicating products, and even though some products subject to the emergency regulations are not sold in California. Many small businesses will have to close operations immediately with millions in losses.

13. Relief is thus warranted because the emergency regulations are substantially unlawful and have in any event been adopted by drastically unlawful means.

14. This action challenges the Emergency Regulations - both on form and substance -

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[1] 7. *What is the Difference Between Marijuana (termed "Cannabis" in California Law) and Industrial Hemp*? Industrial Hemp and marijuana are both Cannabis sativa L. However, they are differentiated by their variety of Cannabis sativa and their varying levels of cannabinoid composition. Marijuana contains tetrahydrocannabinol (THC), including, but not limited to Delta-8-tetrahydrocannabinol, Delta-9-tetrahydrocannabinol, and Delta-10-tetrahydrocannabinol, that has a psychoactive effect on the user. Marijuana may have greater than 0.3% THC. On the other hand, industrial hemp must have 0.3% or less THC and has no psychoactive impact. http://www.publichealth.lacounty.gov/eh/faq/industrial-hemp-derived-products.htm

because they violate the California and U.S. constitutions and state and federal laws.

II. PARTIES

15. Plaintiff U.S. HEMP ROUNDTABLE, INC. ("USHRT"), is a Kentucky non-profit corporation. USHRT is the nation's leading business advocacy organization for the hemp and hemp products' industries. USHRT's members conduct activities at all stages of the seed-to-sale hemp supply chain. Of USHRT's at least eighty-two (82) members, over three dozen of them manufacture, warehouse, distribute, offer, advertise, market, and/or sell, in California, products that contain hemp-derived tetrahydrocannabinol ("THC").

16. Plaintiff CHEECH AND CHONG GLOBAL HOLDINGS INC. ("Cheech and Chong") is a Nevada corporation that does business in California. Cheech and Chong manufacture and sells beverage products that contain hemp-derived THC. Cheech and Chong manufactures, distributes, and sells its hemp-derived THC beverage products in California and sells its hemp-derived THC beverage products in other states.

17. Plaintiff JUICETIVA INC. ("JuiceTiva") is a California corporation, owned and operated by a husband and wife, who are long time hemp farmers. JuiceTiva manufactures, distributes, and sells hemp juice powder food supplement products that contain hemp-derived tetrahydrocannabinolic acid ("THCA") and other hemp-derived cannabinoids. JuiceTiva manufactures its hemp juice powder products in California using hemp that is cultivated in California. JuiceTiva distributors and sells its hemp juice powder products in California.

18. Plaintiff BLAZE LIFE LLC ("Blaze Life") is a California limited liability company. Blaze Life is a co-manufacturer/co-packer of beverage products that contain hemp-derived THC. Blaze Life manufactures, distributes, and sells its hemp-derived THC beverage products in California. Indeed, Blaze Life has invested more than $20,000,000 in a California production facility for the state-of-the-art manufacture of its hemp-derived THC beverage products.

19. Plaintiff BOLDT RUNNERS CORPORATION ("Boldt Runners") is a Delaware corporation that does business in California. Boldt Runners manufactures, distributes, and sells tobacco-free and nicotine-free oral pouches that contain hemp-derived CBD and hemp-derived THC. Boldt Runners' line of non-intoxicating, hemp-derived CBD oral pouches are manufactured,

distributed, and sold in California. Boldt Runners' line of intoxicating, hemp-derived THC oral pouches are manufactured in California but are exclusively sold to consumers outside California and are not sold in California. Despite Boldt Runners' oral pouches being labeled as a supplement, the Department authorized and issued Boldt Runners an Industrial Hemp Enrollment and Oversight license as an "IH Food" registrant. Accordingly, Boldt Runners' oral pouches are or may be subject to the Emergency Regulations.

20. Plaintiff LUCKY TO BE BEVERAGE CO. ("Lucky To Be"), formerly known as Good Stuff Manufacturing, is a Nevada corporation that does business in California. Lucky to Be manufactures, distributes, and sells beverage products that contain hemp-derived THC and other hemp products that contain hemp-derived THC and other hemp-derived cannabinoids. Lucky To Be manufactures, distributes, and sells its hemp-derived THC beverage products in California and distributes and sells its hemp-derived THC beverage products in other states.

21. Plaintiff SUNFLORA, INC. ("SunFlora"), is a Florida corporation that does business in California. SunFlora manufactures and sells ingestible gummies, tinctures, water solubles, and seltzer products that contain hemp-derived THC and other hemp-derived cannabinoids. SunFlora sells its ingestible hemp products in California and other states through independently owned franchisees.

22. Defendant CALIFORNIA DEPARTMENT OF PUBLIC HEALTH is a California state agency tasked with protecting the public's health in the Golden State.

23. Defendant TOMÁS J. ARAGÓN, M.D., Dr.P.H. is the Director of the California Department Of Public Health and the State Public Health Officer. He has held this role since January 4, 2021. In his role as Director, Dr. Aragón is responsible for implementing the policies and programs of the Department.

24. Each of these Plaintiffs/members conducts business in California in compliance with existing federal and state laws governing hemp and hemp products. Each of these Plaintiffs will suffer immediate and irreparable harm because of Emergency Regulations. The Emergency Regulations violate the California Health & Safety Code, as well as federal law codified at 7 U.S.C. § 16390(1).

25. If the Emergency Regulations are allowed to remain in effect, specifically, the expanded definition of THC, the change in serving sizes, and the requirement that hemp products

contain "no detectable limits of THC," then Plaintiffs and their members will be forced to stop all or part of the operations of their legal hemp businesses in California immediately. Thus, even if Plaintiffs sought to manufacture hemp or hemp products in California, for sale anywhere in the country, which is now illegal under the Emergency Regulations. Plaintiffs' businesses will now be rendered worthless or nearly worthless.

III. JURISDICTION, VENUE, AND STANDING

26. This Court has jurisdiction over this action pursuant to Cal. Government Code section 11350 and Cal. Code of Civil Procedure sections 526, 1085, and 1060.

27. Plaintiff USHRT has standing to bring this action: (a) Plaintiffs' members are directly impacted by Defendants' conduct and would have standing on their own to seek the relief requested herein; (b) the case is germane to Plaintiffs' organizational purpose of advocating for the interests of their members; and (c) the case does not require the participation of all of Plaintiffs' individual members because this case does not involve a question driven by individualized factors, but rather involves the overarching questions of whether Defendants had the authority to promulgate the Emergency Regulations (at all or on an emergency basis) and whether the Emergency Regulations violate the Administrative Procedure Act, the California Health and Safety Code, the California and U.S. Constitutions, and the 2018 Farm Bill.

28. Plaintiffs U.S. Hemp Roundtable, Inc., 7 Generations Producers LLC, Boldt Runners Corporation, Cheech and Chong's Global Holdings, Lucky to Be Beverage Co., Blaze Life, LLC, Juicetiva Inc., and Sunflora, Inc., have standing to bring this action. Each of these Plaintiffs validly conducts business in California. Each of these Plaintiffs will suffer immediate and irreparable harm, as detailed herein, because of Emergency Regulations.

29. Plaintiffs are "interested persons" under Government Code section 11350(a), and therefore may obtain a judicial declaration as to the validity of the Emergency Regulations based on its "substantial failure to comply" with the requirements of the Administrative Procedure Act, or "upon the ground that the facts recited in the finding of emergency . . . do not constitute an emergency" under Government Code section 11346.1.

IV. FACTS COMMON TO ALL COUNTS

A. The Emergency Regulations

30. On Friday, September 13, 2024, 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. Attached hereto and incorporated by this reference collectively as **Exhibit A** is a copy of the Emergency Regulations.

31. The Emergency Regulations went into effect yesterday, September 23, 2024. Basically, overnight, major swaths of the hemp and hemp products industries in California became immediately illegal.

32. The Emergency Regulations amend and/or modify California Code of Regulations, Title 17, Sections 23000, 23005, 23010, 23015, 23100. The OAL Law File No. is Z-2024-0913-02E.

33. The Emergency Regulations consist of three documents: (i) a Notice, (ii) Findings of Emergency, and (iii) text of the Emergency Regulations.

B. The Notice

34. The Notice states, "[p]ursuant 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, Plaintiffs submitted written comments to the OAL on September 16, 2024, within five calendar days of the Emergency Regulations being posted to the OAL's website on Friday, September 13, 2024.

35. As required by the Notice, some or all of Plaintiffs submitted to the OAL written comments and objections to the Emergency Regulations within five calendar days of the Emergency Regulations being posted to the OAL's website on September 13, 2024.

C. The Findings of Emergency

36. 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.

Age requirement

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.

List of intoxicating cannabinoids

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.

D. The Text of the Emergency Regulations

37. The Emergency Regulations purport to change the law in three regards by adding new regulations to the California Code of Regulations ("CCR"), Title 17, Div. 1, Chap. 5, Subchap. 2.6, Industrial Hemp, in the following areas: (i) increase the age restriction to 21 years; (ii) expand the definition of THC; (iii) make significant changes in the Serving Sizes and Packaging of hemp products.

i. **A New Age Restriction is Added**

38. 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:

> *C.C.R. 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.

ii. **The Definition of THC is Expanded Significantly**

39. The Emergency Regulations add a new regulation expanding California's definition of "THC" to include thirty additional substances deemed intoxicating:

> *C.C.R. 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);
> 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,7,10,10a-
> tetrahydro-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-indole-3-carboxamide (XRL-11 &15);
(26) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3-carboxamide (UR-144);
(27) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3-carboxamide (FUB-144);
(28) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3-carboxamide (AMB-FUBINACA);
(29)(3-[(1R,4R)-Isopropyl-2-methyl-1,3-benzodioxol-5-yl]-N-(2,4-dimethyl-3-methylbenzoyl)-N-methyl-1,2,3,4-tetrahydroisoquinolin-6-amine) (THJ-220); and
(30)(3-[(1R,4R)-Isopropyl-2-methyl-1,3-benzodioxol-5-yl]-N-(2,4-dimethyl-3-methylbenzoyl)-N-methyl-1,2,3,4-tetrahydroisoquinolin-6-amine) (RCS-4).

iii. **Serving Sizes and New Standards for Hemp Products are Implemented**

40. 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.

C.C.R. 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.

C.C.R. Section 23100, emphasis added.

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

> *C.C.R. 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.

E. Prior Legislative Efforts to Enact Age Restrictions and THC Limits Were Unsuccessful in the California Legislature

42. To be clear, Plaintiffs ***do not oppose*** fair and reasonable regulations for intoxicating hemp-derived THC products, including age restrictions, provided that such regulations comport with California's regular rulemaking process.

43. However, following AB 45's enactment, legislative efforts to impose age restrictions and THC limits for intoxicating hemp-derived THC products have failed. Attached hereto and incorporated by this reference as **Exhibit B** is a true and correct copy of AB 45.

44. 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 declined to pass the bill.

45. A year later, in February 2024, Assemblywoman Aguiar-Curry introduced AB 2223.

Largely similar to AB 420, AB 2223 would have excluded synthetically derived cannabinoids from the definition of "hemp," 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.

46. 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 achieve a compromise but was unsuccessful.

47. Later in the legislative session, Governor Newsom's administration proposed hemp industry-killing amendments to AB 2223 that are nearly identical to the Emergency Regulations. The amendments 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.

48. Just three weeks ago, on August 31, 2024, the legislature ended its latest regular session without passing AB 2223, thereby choosing not to enact the administration's proposed prohibition against hemp products that contain any traceable amount of THC.

49. Despite having known for years that hemp-derived THC products are being manufactured, distributed, and sold in California, the Department has wholly failed to do anything about it.

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

V. APPLICABLE LAW

A. The Emergency Regulations Violate the Administrative Procedure Act

51. The Emergency Regulations violate the Administrative Procedures Act ("APA"), Government Code §§ 11340 *et seq*. (Title 2, Div. 3, Part 1, Chap. 3.5), as detailed below. The APA establishes the basic minimum procedural requirements for adoption of administrative regulations. *Ibid.*

52. However, the adoption of an emergency regulation is not subject to any of the provision

of Article 5 or Article 6 (Gov. Code §§ 11349-11349.6), *except for Sections 11346.1, 11349.5 and 11349.6.* Gov. Code § 11346.1.

i. **Adoption of Emergency Regulations under the APA**

53. Government Code section 11346.1(a)(1) states that the adoption, amendment or repeal of an emergency regulations are subject only to Gov. Code sections 11346.1, 11349.5 and 11349.6.:

54. Section 11346.1(a)(2) specifies the requisite procedures for adoption of an emergency regulation. At least five working days before submitting an emergency regulation to the OAL, the Department (as adopting agency) 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. Gov. Code I§ 11346.1(a)(2). The notice must include both of the following: (A) The specific language proposed to be adopted: (B) The finding of emergency required by subdivision (b). Gov. Code §11346.1(a)(2)(A) and (B).

55. Subdivision (b) requires that, if the Department makes a finding that the regulation is necessary to address an emergency, the regulation may be adopted as an emergency regulation. Gov. Code § 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. Gov. Code § 11346.1(b)(2).

56. The finding of emergency shall also identify each technical, theoretical, and empirical study, report, or similar document, if any, upon which the agency relies. Gov. Code § 11346.1(b)(2). 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. Gov. Code § 11346.1(b)(2).

57. 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. Gov. Code §11346.1(b)(2).

58. Section 11349.1 provides that the OAL shall review all regulations adopted pursuant to Article 5 and submitted to it for publication in the CCR Supplement and for transmittal to the Secretary of State. Gov. Code § 11349.1(a). 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 the Gov. Code. *Ibid.*

59. To initiate a review of a decision by the OAL, the Department shall file a written Request for Review with the Governor's Legal Affairs Secretary within 10 days of receipt of the written opinion provided by the OAL. Gov. Code § 11349.5(a). Emergency regulations must be reviewed by the office within 10 calendar days after their submittal to the office. Gov. Code § 11349.6(b).

60. If the Department has complied with Sections 11346.2 to 11347.3, inclusive, prior to the adoption of the emergency regulation, then the OAL shall approve or disapprove the emergency regulation in accordance with the article. Gov. Code § 11349.6(a).

61. Emergency regulations cannot remain effective for more than 180 days unless the agency has complied with applicable APA procedures during that period.

ii. **Judicial Review of Regulations**

62. Any interested person may obtain a judicial declaration as to the validity of any regulation by bringing an action for declaratory relief in the superior court in accordance with the Code of Civil Procedure. The right to judicial determination shall not be affected by the failure either to petition or to seek reconsideration of a petition filed pursuant to Section 11340.7 before the agency (the Department) promulgating the regulation or order of repeal. The regulation or order of repeal may be declared to be invalid for a substantial failure to comply with this chapter, or, in the case of an emergency regulation, upon the ground that the facts recited in the finding of emergency do not constitute an emergency within the provisions of Section 11346.1. Gov. Code § 11350(a).

63. The approval of a regulation by the OAL or the Governor's overruling of a decision of the OAL shall not be considered by a court in any action for declaratory relief brought with respect to a regulation or order of repeal. Gov. Code § 11350(c).

64. Emergency regulations can be challenged by scrutinizing both the procedural adherence during the regulation's formulation and the substantiation of the emergency claim itself. Gov. Code § 11350(a). In addition, an emergency regulation must be deemed invalid if the adopting agency's determination is not supported by, or contradicts, substantial evidence in the record.

B. <u>The Emergency Regulations Violate California Health & Safety Code & AB 45</u>

65. The Emergency Regulations must be stricken because they expressly contradict and violate provisions of the California Health & Safety Code dealing with hemp which were enacted into law by AB 45 in 2021.

i. **Emergency Regulations Cannot Be Invoked to Circumvent the Regular Rulemaking Process Where the Department Has Failed to Address the Subject of the Emergency Regulation Over the Course of the Three-Year Period Since It Was Authorized to Do So**

66. At the outset, the Department has long had the authority to issue regulations addressing the issues herein. But it has failed to do so for three years now since the passing of AB 45. As detailed herein, the Legislature rejected various attempts at enacting laws addressing similar issues. Any attempts to circumvent the Legislature through backdoor emergency rulemaking must be nullified by this Court.

ii. **The Procedure for Adopting Regulations & Emergency Regulations Under the Health & Safety Code**

67. The Health & Safety Code § section 110065 authorizes the Department to adopt regulations as follows:

> *§ 110065. Adoption of regulations; law governing; conformance with federal regulations; emergency regulations; initial regulations regarding industrial hemp*
> (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 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 . . . .
>
> (b)(1) The department may adopt emergency regulations to implement

> this division.
> (2) [¶]
> (3) Notwithstanding any other law, the initial adoption of emergency regulations . . . shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The initial emergency regulations . . . 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 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***. (Emphasis added.)

68. Thus, section 110065 of the Health & Safety Code explicitly excludes age restrictions and serving sizes and packaging from the emergency regulations.

> *§ 111921.3. Regulations imposing age requirement*
> 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.
>
> *§ 111922. Regulation of serving sizes, active cannabinoid concentration per serving size, number of servings per container, and other requirements; food and beverage to be prepackaged and shelf stable*
> (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.

69. Section 110065 enables the Department to issue emergency regulations for the Sherman Law *only*. Health & Safety Code §§ 109875 *et seq.* The definition of hemp is governed by the Controlled Substances Act, Health & Safety Code § 11018.5(a). It does not authorize the Department, under the guise of emergency regulations, to alter and amend the substance of duly enacted legislation.

Hence, Section 110065 cannot, under the guise of an emergency regulation, nullify provisions of another statute or modify the definitions set forth in the statute.

iii. **The Emergency Regulations Illegally Change the Definition of Hemp in the Health & Safety Code**

70. First, the Emergency Regulations illegally amend and modify the definition of hemp by requiring "no detectable levels of THC" in hemp products, contrary to Health & Safety Code § 11018.5's definition of "hemp" which expressly permits 0.3% THC in hemp products. Federal law also permits up to 0.3% delta-9 THC on a dry weight basis in hemp products. 7 U.S.C. § 16390(1).

71. Specifically, the *Uniform Controlled Substances Act*, Div. 10, section 11018.5(a) of the Health & Safety Code, defines hemp as follows:

> (a) "*Industrial hemp*" or "*hemp*" means 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***. Emphasis added.

The term "hemp" does not include cannabinoids produced through chemical synthesis. Health & Safety Code § 111920 (f).

72. AB 45's definition of "*hemp product*" is now codified at Health & Safety Code § 111920(g)(1) in Div. 104, Part 5, Chap. 9 of the *Sherman Food, Drug, and Cosmetic Law* ("Sherman Law") and is defined as:

> (g)(1) "*Industrial hemp product*" or "*hemp product*" means a finished product containing industrial hemp that meets all of the following conditions:
> (A) 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.

The term does not include hemp or a hemp product that has that has been approved by the FDA or a hemp product that includes industrial hemp or hemp that has received Generally Recognized As Safe (GRAS) designation. Health & Safety Code § 111920(g)(2). "Final form product" is a product

intended for consumer use to be sold at a retail premise. Cal. Health & Safety Code § 111920(c).

73. AB 45's definition of THC is codified at Cal. Health & Safety Code § 111920(l) as follows:

> (l) "*THC*" or "*THC or comparable cannabinoid*" means any of the following:
> (1) Tetrahydrocannabinolic acid.
> (2) Any tetrahydrocannabinol, including, but not limited to, Delta–8–tetrahydrocannabinol, Delta–9–tetrahydrocannabinol, and Delta–10–tetrahydrocannabinol, however derived, except that the department may exclude one or more isomers of tetrahydrocannabinol from this definition under subdivision (a) of Section 111921.7.
> (3) Any other cannabinoid, except cannabidiol, that the department determines, under subdivision (b) of Section 111921.7, to cause intoxication.

74. Thus, unlike the Emergency Regulations, AB 45 and Health & Safety Code § 11018.5(a) do not limit hemp products to a non-detectable level of THC. While the Department may cap THC levels in hemp products, it may not do so in a way that alters what is considered a hemp product by requiring hemp products to have a delta-9 tetrahydrocannabinol concentration of ***no more than 0.3 percent on a dry weight basis***. Health & Safety Code § 11018.5(a).

75. Also, it is important to note, Health & Safety Code § 110065 gives the Department power (Health & Safety Code § 111921.7) to issue emergency regulations for the Sherman Law *only*. Health & Safety Code §§ 109875 *et seq.* The definition of hemp is governed by the Controlled Substances Act, Health & Safety Code § 11018.5(a). Hence, Section 110065 cannot regulate provisions of another statute and illegally modify definitions.

76. Health & Safety Code § 111921.7 gives the Department the following powers with respect to the inclusion of other cannabinoids in the definition of THC. However, these powers do not authorize the Department to alter the definition of hemp entirely:

> b) 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*, consistent with subdivisions (c) and (d), that the *cannabinoid causes intoxication*.
>
> (c) In making a determination under subdivision (a) or (b), the department *shall consider scientific evidence* concerning the pharmacological effects of the tetrahydrocannabinol or other cannabinoid in humans or other animals, if that evidence is available.

> (d) *Any initial determination under subdivision (a) or (b) shall not be subject to the administrative rulemaking requirements of Chapter 3.5* (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, but the department, without being subject to those administrative rulemaking requirements, *shall establish a process to receive public comment regarding those determinations, and shall publicly post all determinations on its internet website*. However, *any initial determination* shall be confirmed subject to the administrative rulemaking requirements no later than 18 months following the date of the initial determination. Emphasis added.

77. The Department is further authorized to regulate and cap THC concentration by Health & Safety Code section 111925(a)(3) and (b) as follows:

> (a)(3) The manufacturer of the hemp extract in its final form or the final form industrial hemp product shall be able to prove total THC concentration does not exceed 0.3 percent. [ ]
>
> (b) The department may regulate and restrict the cap on extract and *may cap the amount of total THC concentration at the product level* based on the product form, volume, number of servings, ratio of cannabinoids to THC in the product, or other factors, as needed. Emphasis added.

Cal. Health & Safety Code § 111925.

78. *However, none of these powers permit the Department to alter existing provisions of the California Health & Safety Code or federal law, via emergency rulemaking, without the usual 45-day notice and comment period, and without input from hemp businesses that will be irreparably harmed by the Emergency Regulations*.

iv. **The Emergency Regulations Illegally Restrict Hemp Dietary Supplements**

79. Health & Safety Code § 110611 expressly legalizes dietary supplement, food, beverage, cosmetic, and pet food products that contain hemp or hemp derived cannabinoids by mandating, "[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[.]" Health & Safety Code § 110611.

80. Health & Safety Code § 110611 "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." Health & Safety Code § 110611.The Emergency Regulations illegally amend and modify the Health & Safety Code provisions by criminalizing final form food products based solely on their containing "any detectable amount of any THC." In other words, the Emergency Regulations restrict the sale of final form food products, including beverages in a manner that is prohibited by Health & Safety Code § 110611.

81. Additionally, the Emergency Regulations illegally amend and modify the Health & Safety Code provisions by criminalizing final form food products based solely on their containing "any detectable amount of any THC" without clarifying whether dietary supplements are considered "food."

82. Neither federal law nor AB 45 distinguishes between intoxicating hemp-derived cannabinoids and non-intoxicating hemp-derived cannabinoids. See generally 2018 Farm Bill, AB 45. In fact, both the 2018 Farm Bill and AB 45—using identical definitions—define "hemp" to include the "plant Cannabis sativa L. and ***any part of that plant***, including . . . ***all derivatives, extracts, cannabinoids***, isomers, acids, salts, and salts of isomers," whether or not the cannabinoid is intoxicating. Therefore, the Emergency Regulations illegally distinguish between intoxicating hemp-derived cannabinoids and non-intoxicating hemp-derived cannabinoids by criminalizing final form food products that contain "any detectable amount of any THC" and expanding California law's definition of "THC" to include "any metabolites, derivatives, salts, isomers, and any salt or acid of an isomer of" any of the 30 substances listed in C.C.R. Section 23010 as "intoxicating cannabinoids."

v. **The Emergency Regulations Impose Age Restrictions that Have Not Been Adopted in the Health & Safety Code**

83. Unlike the Emergency Regulations, Health & Safety Code § 111920 (g)(1) does not restrict hemp products in the form of food, food additives, beverages, or dietary supplements to persons 21 years or older. While Health & Safety Code § 111921.3 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 these Emergency Regulations three years after AB 45 became law in 2021.

84. While Plaintiffs agree there must be some age restrictions in place, the circumstances,

including in particular the Department's failure to utilize the *regular rulemaking process* to enact appropriate age limit restrictions, prohibit the Department from capitalizing on its own inaction by resorting to the emergency rulemaking process. Especially, given that the Department has done nothing on this issue since 2021, it must follow the regular rulemaking process.

vi. **The Emergency Regulations Illegally Distinguish Between Intoxicating and Non Intoxicating Cannabinoids**

85. AB 45 does not distinguish between intoxicating cannabinoids and non-intoxicating cannabinoids. *See* AB 45 *generally*. To the extent such a distinction is appropriate, the Department has again done nothing on this topic for the past three years. Nonetheless, the Emergency Regulations adopt precisely such a distinction, which if appropriate could have easily been considered under the regular rulemaking process during the last three years. Thus, for the reasons noted herein, the Emergency Regulations illegally distinguish between intoxicating cannabinoids and non-intoxicating cannabinoids.

vii. **The Emergency Regulations Impose Serving Sizes & Packaging Restrictions Contrary to the Health & Safety Code**

86. Health & Safety Code section 111922 does not impose serving or package requirements for hemp products in the form of food, food additives, beverages, or dietary supplements. Nonetheless, the Emergency Regulations impose such restrictions, once again circumventing the regular rulemaking process in doing so.

87. While Health & Safety Code section 111922 authorizes 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 on this topic either, until its issuance of these Emergency Regulations, three years after the fact.

88. The Emergency Regulations on serving sizes that require "no detectable" levels of THC in final form food products violates the provisions of the Health & Safety Code, which have never adopted such a requirement or the elimination of detectable levels. Health & Safety Code § 11018.5(a).

These Emergency Regulations also violate Federal law which expressly permits hemp and hemp products to contain up to 0.3% delta-9 THC on a dry weight basis. 7 U.S.C. § 16390(1).

viii. **The Emergency Regulations Illegally Prohibit the Manufacture of Hemp**

89. Unlike the Emergency Regulations, AB 45 and the Health & Safety Code do 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. *See* AB 45, Health & Safety Code, *generally*. *No provision of AB 45 contemplated such a sweeping regulation that, in its effect, eliminates such activities*.

ix. **Most Problematic, the Emergency Regulations Are Ultra Vires**

90. The most profound defect of the Emergency Regulations is that the Department no longer has the authority to issue them in the first place. As discussed in detail below, the Department is no longer able to issue emergency regulations under § 110065. The Emergency Regulations are unsupportable in the first instance because they constitute ultra vires acts.

a. <u>The Department Already Enacted Initial, and Initial Emergency, Regulations in 2021</u>

91. The Health & Safety Code § 110065 permits the Department to implement *initial emergency regulations* under the APA's emergency rulemaking process (Health & Safety Code § 110065(b)(1)), as well as *initial regulations* that are "exempt from the [APA] except that the department shall post the proposed regulations on its internet website for public comment for thirty days" (Health & Safety Code § 110065(c)).

92. The Department enacted *initial emergency regulations* and *initial regulations* in 2021. These *initial emergency regulations* and *initial regulations* did not contain the age restriction or THC serving or package restrictions being proposed in the current Emergency Regulations. Because the Department chose to not implement an age restriction or THC serving or package restrictions in its *initial emergency regulations* and *initial regulations*, the Department relinquished its right to do so pursuant to law and cannot now enact such provisions by means of the Emergency Regulations, utilizing the emergency rulemaking procedures rather than the procedures that were statutorily mandated. Health & Safety Code § 110065 (b), (c). The Department must follow the regular

rulemaking process mandated by subsection (a) of Section 110065. Health & Safety Code § 110065(a).

93. Specifically, on April 20, 2022, the Department promulgated its initial emergency regulations for implementing AB 45. The initial emergency regulations did not contain age restrictions or maximum THC serving and package restriction, despite the Department's authorization at that time to adopt them on an emergency basis. Pursuant to section 110065, the initial emergency regulations were readopted as emergency regulations and then permanently adopted as a regular rulemaking.

94. More than two years ago, the Department utilized Health & Safety Code section 110065's procedure for adopting initial emergency regulations and initial regulations for implementing AB 45. Because the Department already did so, it cannot now rely on section 110065 to implement the Emergency Regulations as "initial emergency regulations" or "initial regulations." Because the Department failed to adopt the Emergency Regulations in its initial emergency regulations and initial regulations, the Emergency Regulations must proceed through the APA's regular rulemaking process, which requires a 45-day notice and comment period.

95. It is now 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. Having taken those steps in accordance with the structure mandated by the statute, the Department can only adopt the substantive changes that should have been, and could have been, addressed in those initial measures, by adhering to the regular rulemaking process.

b. The Department Has Failed to Provide Specific Facts Demonstrating An Emergency And Need For Immediate Action

96. Even if the Department could theoretically utilize the emergency rulemaking process, its attempts to do so here fail to even meet minimally satisfy the emergency rulemaking procedures detailed above.

97. Emergency regulations require only a five-day public notice, as opposed to the forty five day notice period required for regular rulemaking. Gov. Code §§ 11346.1, 11349.5, 11349.6. *Western Growers Association v. Occupational Safety and Health Standards Board* (2021) 73 Cal.App.5th 916.

98. Thus, at least five working days before submitting an emergency regulation to the OAL, the Department was required to 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 must include both of the following: (1) The specific language proposed to be adopted; and (2) The finding of emergency required by subdivision (b). Gov. Code § 11346.1(a).

99. Only if the Department makes a proper finding that the regulation is necessary to address a clearly delineated emergency, may a regulation be adopted as an emergency regulation. Gov. Code § 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. Gov. Code § 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.

100. "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).

101. The finding of emergency shall also identify each technical, theoretical, and empirical study, report, or similar document, if any, upon which the agency relies. Gov. Code § 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.

102. An agency is exempt from these provisions only 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.

103. The finding of emergency must also include a written statement containing the information required by Gov. Code § 11346.5(a)(2)-(6). Gov. Code § 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 Gov. Code § 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 Gov. Code § 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" Gov. Code § 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 (Gov. Code § 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 Gov. Code § 11346.5(a)(6).

104. "[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.*

105. 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 Gov. Code § 11346), the finding of emergency shall include facts explaining the failure to address the situation through nonemergency regulations. Gov. Code § 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. Gov. Code § 11346.1(d).

106. The OAL must review emergency regulations within 10 calendar days and make a decision on the proposed emergency rulemaking file. Gov. Code § 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. Gov. Code § 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 Gov. Code § 11346.1. Gov. Code § 11349.1.

107. 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 Gov. Code. Gov. Code § 11349.1.

108. 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?

Gov. Code § 11349.6(b).

109. 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. Gov. Code § 1346.1(h).

110. Here, the Department has not satisfied the requirements under Gov. 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.

c. There is no Emergency for Rulemaking on Detectable Limits of THC in Hemp

111. 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. Gov. Code section 11346.1's requirements as to the proposed serving or package limits. These sections of the emergency regulations must be summarily rejected.

d. There is no Emergency for Rulemaking on Age Restrictions

112. 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. Gov. 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."

113. 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.

114. The Department also fails to comply with the requirement to address why it could not address the situation through nonemergency regulations. Gov. 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.

115. 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." Gov. Code § 11346.1(b)(2).

116. 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, just ***one week*** after the legislature ended its latest regular session without passing AB 2223, which would have implemented an age restriction, the Department publicly issued the Emergency Regulations, which were posted to the OAL's website one week later. 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." Code § 11346.1(b)(2).

117. Additionally, the Emergency Regulations do not adequately describe the substantial differences from existing federal law that would be effectuated. Gov. 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.

C. AB 45

118. In the spring of 2018, the Department issued a Frequently Asked Questions ("FAQ") guidance document declaring, "[T]he 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."

119. Later that year, the then-Lieutenant Governor and gubernatorial candidate Gavin Newsom promised to reverse the Department's prohibition against food products that contain hemp-derived CBD.

120. 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.

121. 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.

122. AB 45 matters and is significant for assessing the legality and propriety of the Emergency Regulations. 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[.]"

123. 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."

124. 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.[2]

AB 45 defines "hemp product" as

> 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.[3]

125. 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

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

[3] 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."

existing authority to protect the public against products manufactured or sold by bad actors that have illegally targeted children.

D. 2014 Farm Bill

126. 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).

127. 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).

128. 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.

129. 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 (cannabis) for purposes of the federal Controlled Substances Act ("CSA") or the commercial sale of hemp-derived finished products.

E. 2018 Farm Bill

130. That changed four years later, when, on December 20, 2018, President Donald Trump signed into law the Agricultural Improvement Act of 2018 ("2018 Farm Bill").

131. 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.

132. 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.

133. In general, as courts throughout the country have affirmed, the only relevant statutory metric in analyzing whether a product is to be considered hemp or 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.

134. *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).

135. 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.*

136. 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.
> (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 297 A of the Agricultural Marketing Act of 1946 (as added by section 10113)) or hemp products.
> (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.

137. 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.

138. 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. Attached hereto and incorporated by this reference as **Exhibit C** is a true and correct copy of the General Counsel's legal memorandum.

139. 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.

FIRST CAUSE OF ACTION

DECLARATORY RELIEF

Cal. Civ. Proc. § 1060, Cal. Gov. Code § 11350

(Against All Defendants)

140. Plaintiffs incorporate by reference and reallege each allegation set forth above.

141. Code of Civil Procedure section 1060 authorizes this Court to render a declaratory judgment in cases of actual controversy relating to the legal rights and duties of the respective parties.

142. Government Code section 11350(a) permits "any interested person" to "obtain a judicial declaration as to the validity of any regulation . . . by bringing an action for declaratory relief in the superior court . . . ." Section 11350(a) further authorizes s Court to render a declaratory judgment

as to any regulation and "declare it to be invalid for a substantial failure to comply with this chapter [3.5 of the APA], or, in the case of an emergency regulation . . . , upon the ground that the facts recited in the finding of emergency ... do not constitute an emergency within the provisions of [Government Code] Section 11346.1."

143. At the outset, Plaintiffs want to emphasize that they 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 lack the precision and care that must be given to the process of adopting such regulations to assure that they are not over-reaching, unsupportable in their particulars, or in conflict with existing law. These Emergency Regulations are deeply flawed due to the Department's having bypassed the regular rulemaking process to address it topic it was authorized to consider three year earlier; as a result, the Emergency Regulations must be declared null and void.

144. Defendants have promulgated and are enforcing regulations in a manner that interferes with Plaintiffs' and their members' rights and violates California statutory law and the California and U.S. Constitutions.

145. An actual and substantial controversy exists between Plaintiffs and Defendants as to the parties' respective rights and responsibilities. A judicial determination of the parties' rights and the constitutionality of the Emergency Regulations, as applied to Plaintiffs and their members, will give relief from the uncertainty and insecurity giving rise to this controversy.

146. Plaintiffs seek a declaration as to whether the Emergency Regulations were promulgated in violation of the APA and the California Health & Safety Code, and whether those regulations exceed Defendants' statutory authority, violates the California Constitution, and/or violates the U.S. Constitution.

147. As a further proximate result of Defendants' actions and omissions, Plaintiffs have incurred and will incur fees and costs for attorneys and experts, said fees / costs being legally compensable pursuant to California law, in the course of enforcing Plaintiffs' rights herein.

SECOND CAUSE OF ACTION

DECLARATORY RELIEF

Violation of the 2018 Farm Bill

(Against All Defendants)

148. Plaintiffs incorporate by reference and reallege each allegation set forth above.

149. An actual and justiciable controversy exists between Plaintiffs and the Department regarding the lawfulness of hemp extracts and hemp final form food products intended for human consumption that contain hemp-derived THC.

150. 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.

151. The Emergency Regulations *nullify* both of these aspects of the 2018 Farm Bill.

152. *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 following 30 substances:

(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-indole-3- carboxamide (XRL-11 &15);
(26) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3- carboxamide (UR-144);
(27) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3- carboxamide (FUB-144);
(28) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3- carboxamide (AMB-FUBINACA);
(29) (3-[(1R,4R)-Isopropyl-2-methyl-1,3-benzodioxol-5-yl]-N-(2,4-dimethyl-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-dimethyl-3-methylbenzoyl)-N-methyl-1,2,3,4-tetrahydroisoquinolin-6-amine) (RCS-4).

153. 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.

154. 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); 7 U.S.C. § 16390(1).

155. *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.

156. The Emergency Regulations' expansion of the definition of "THC" is an impermissibly 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.

157. 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.

158. 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.

159. As a further proximate result of Defendants' actions and omissions, Plaintiffs have incurred and will incur fees and costs for attorneys and experts, said fees and costs being legally compensable pursuant to California law, in the course of enforcing Plaintiffs' rights under California law.

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THIRD CAUSE OF ACTION

ORDINARY MANDAMUS (Code Civ. Proc. §1085) or, in the alternative, WRIT OF ADMINISTRATIVE MANDATE (Code Civ. Proc. §1094.5)

(Against All Defendants)

160. Plaintiffs incorporate by reference and reallege each allegation set forth above.

161. Plaintiffs seek a writ of traditional mandamus under Code of Civil Procedure section 1085, which provides that a writ of traditional mandamus is available to compel public agencies to perform acts required by law, for failure to perform a mandatory duty, or for review of quasi-legislative action by a local agency. A writ of traditional mandamus "may be issued by any court to any inferior tribunal, corporation, board, or person, to compel the performance of an act which the law specially enjoins, as a duty resulting from an office, trust, or station, or to compel the admission of a party to the use and enjoyment of a right or office to which the party is entitled, and from which the party is unlawfully precluded by that inferior tribunal, corporation, board, or person." Code Civ. Proc. § 1085(a). The procedure set forth in section 1085 is used to review adjudicatory decisions when the agency is not required by law to hold an evidentiary hearing. *Scott B. v. Bd. Of Trustees of Orange Cty. High Sch. Of the Arts* (2013) 217 Cal.App.4th 117, 122-23. A decision that was "arbitrary, capricious, or entirely lacking in evidentiary support" will not be upheld. *Ibid.*

162. The Department's promulgation of the Emergency Regulations is invalid, and a judgment should be entered directing that a writ issue to command that the Emergency Regulations be rescinded and/or set aside. The adoption of the Emergency Regulations is void and of no effect, for the reasons detailed above.

163. The results, findings and determinations sought to be reviewed by this complaint were the result of unlawful, arbitrary and/or capricious action on the part of the Department. As a further proximate result of Defendants' actions and omissions, Plaintiffs have incurred and will incur fees and costs for attorneys and experts, said fees and costs being legally compensable pursuant to California Government Code section 800 and other provisions of California law. In the event that any of the relief sought herein is not available pursuant to a petition seeking relief under California Code of Civil Procedure section 1085 and/or section 1088, then Plaintiffs alternatively requests that such

relief be granted, and a writ issue, to the extent necessary pursuant to California Code of Civil Procedure section 1094.5, or such other provisions of the California Code of Civil Procedure or California law as may be applicable.

164. Plaintiffs assert in the alternative that good cause exists for this Court to issue a writ of administrative mandate pursuant to California Code of Civil Procedure Section 1094.5 directing the Department to vacate and rescind the Emergency Regulations as detailed above.

165. Plaintiffs have a clear, present, and direct beneficial interest in, and right to, Defendants' performance of their legal duty to find legitimate means of addressing Hemp related legislation, which includes a duty not to exceed the authority delegated to the Department by the Legislature and the Health & Safety Code, and a duty to promulgate emergency regulations based only on satisfying the legal requirements for doing so.

166. Plaintiffs have no plain, speedy, and adequate remedy in the ordinary course of the law other than the writ sought herein. The adoption and enforcement of the Emergency Regulations against Plaintiff have caused, continue to cause, and will cause great and irreparable injury to Plaintiffs and their businesses.

167. At all times relevant to this action, Defendants have had the ability to perform the duties set forth herein and have failed and refused to do so. Defendants have acted without legal basis in refusing to carry out or discharge their mandatory duties as set forth herein.

168. Unless compelled by this Court to perform those acts and duties and to refrain from acts as required by law, Defendants will continue to refuse to perform said duties and continue to violate the law, and Plaintiffs and their members will be injured as a result.

FOURTH CAUSE OF ACTION

VIOLATION OF THE CALIFORNIA ADMINISTRATIVE PROCEDURE ACT

(Gov. Code § 11340 et seq.)

(Against All Defendants)

(Invalid Emergency Rulemaking)

169. Plaintiffs incorporate by reference and reallege each allegation set forth above.

170. "'Emergency' means a situation that calls for immediate action to avoid serious harm

to the public peace, health, safety, or general welfare." Gov. Code § 11342.545. This is a revised definition added in 2006 by Assembly Bill 1302. (Stats. 2006, ch. 713.) The prior definition allowed emergency adoption of regulations whenever the agency found that the regulations were "necessary for the immediate preservation of the public peace, health and safety or general welfare." Ibid.

171. Legislative history confirms that the amendment was intended to tighten the emergency standard. In an August 30, 2006, letter, Assembly Member Jerome E. Horton, lead author of the bill, stated: "AB 1302 modifies language that determines when a state agency may adopt emergency regulations. Because emergency regulations restrict public notice and participation, they should be permitted only in limited circumstances . . . . This standard clarifies and augments the demonstration that a state agency must make to justify the use of emergency regulations." (Assem. J. (2005-2006 Reg. Sess.) pp. 7634-7635 [emphasis added]; see also 1 Michael Asimow, et al., California Practice Guide: Administrative Law ¶ 26:155 (2020).

172. Case law prior to the revised definition recognized that, in the context of emergency regulations:

> [A]n emergency must have a substantial likelihood that serious harm will be experienced unless immediate action is taken. The anticipation that harm will occur if such action is not taken must have a basis firmer than simple speculation. Emergency is not synonymous with expediency, convenience, or best interests, and it imports more than merely a general public need. Emergency comprehends a situation of grave character and serious moment.

Sonoma County Organization of Public/Private Employees v. County of Sonoma (1991) 1 Cal.App.4th 267, 270, 277-78.

173. The APA imposes procedural requirements on agencies adopting emergency regulations.

174. The Finding of Emergency published with the proposed Emergency Regulations fails to satisfy the requirements of the APA. Gov. Code, § 11346.1(b)(2). The Finding of Emergency fails to provide any reasons for the urgency. Plaintiffs assert no emergency exits.

175. As detailed above, the Legislature has been attempting rule making concerning these provisions since at least 2021. Even the Department's justification for the Emergency Regulations

indicates legislative efforts on the Hemp issues have been ongoing since at least 2021.

176. The Finding of Emergency also failed to cite actual evidence, e.g., scientific data or research, demonstrating the need for the current Emergency Regulations on an expedited basis. Without any such evidence in support, the Finding of Emergency simply makes the claim that "an emergency exists and that the proposed emergency regulations are necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, and general welfare of Californians."

177. The Finding of Emergency failed to demonstrate that the existing guidance and regulations of the various federal and state agencies were inadequate to address the issues in the Emergency Regulations.

178. The Finding of Emergency does not explain the Department's delay in adopting the Emergency Regulations. It does not explain, as required by the APA (Gov. Code, § 11346.1(b)(2)), why the Department waited for three (3) years before doing anything, as well as why the Department could not enact such rulemaking through nonemergency regulations.

179. While Plaintiffs understand the seriousness of the issues at hand, the Department has failed to demonstrate, as it must, why its draconian prescriptions are necessary to address an emergency of its own making. The Department has been well aware of these issues for the past three years since AB 45, including with the most legislation (AB 2233) attempted a few months ago that failed to pass.

180. As a further proximate result of Defendants' actions and omissions, Plaintiffs have incurred and will incur fees and costs for attorneys and experts, said fees and costs being legally compensable under California law, in the course of enforcing Plaintiffs' rights under California law.

FIFTH CAUSE OF ACTION

REGULATORY TAKING

(Against All Defendants)

181. Plaintiffs incorporate by reference and reallege each allegation set forth above.

182. As set forth above, at all relevant times, Plaintiffs have been and are the owners of their businesses.

183. The Department has taken and/or damaged Plaintiffs' property by issuing the

Emergency Regulations and otherwise depriving Plaintiffs of all, or substantially all, economically viable uses of their businesses.

184. Plaintiffs have not been offered, or received, compensation from any source for taking and/or damaging their businesses.

185. As a proximate result of Defendants actions and omissions as described herein, Plaintiffs have suffered injury and damages, and are continuing to suffer injury and damages, including but not limited to that which has been described above, which damages are compensable pursuant to California Civil Code § 52.1(b) and the provisions of the United States and California constitutions, in an amount not less than $500 million, though such amount cannot now be ascertained with certainty, and shall be determined according to proof at trial, but which is within the jurisdiction of this Court.

SIXTH CAUSE OF ACTION

DECLARATORY RELIEF

Violation of the Commerce Clause

(Against All Defendants)

186. Plaintiffs incorporate by reference and reallege each allegation set forth above.

187. Need more As explained above, the Emergency Regulations criminalize final form food products that contain "any detectable amount of any THC," including all final form food products that are hemp-derived and contain 0.3% or less delta-9 THC on a dry weight basis.

188. Under California Health & Safety Code § 110611 et seq., hemp food products that contain 0.3% or less delta-9 THC on a dry weight basis are expressly legal, as are hemp products under the 2018 Farm Bill.

189. The Emergency Regulations' criminalization of final form food products that contain "any detectable amount of any THC" does not contain any exception for products that are manufactured in California but that are transported or shipped from California into interstate commerce to be sold exclusively in other states.

190. The Emergency Regulations' criminalization of final form food products that contain "any detectable amount of any THC," without excepting products that sold exclusively in other states, is a substantial burden on interstate commerce in violation of the Commerce Clause of the Constitution

of the United States. U.S. Const. art. I § 8, cl. 3.

191. The burden is especially severe because there is no federal license for transporting finished hemp products. Instead, the 2018 Farm Bill explicitly protects the transportation or shipment of hemp or hemp products in interstate commerce and preempts states like California from interfering with such.

192. Plaintiffs have been harmed, and will be further harmed, by the adoption of the Emergency Regulations because they are unable to manufacture final form food products that contain any detectable amount of any THC, even if such products are manufactured for exclusive sale outside California.

193. Additionally, Plaintiffs have been harmed, and will be further harmed, because they cannot transport in and through California final form food products that contain any detectable amount of THC, even though such products that do not exceed 0.3% of delta-9 THC on a dry weight basis have been declared expressly legal under the 2018 Farm Bill and California law.

SEVENTH CAUSE OF ACTION

VIOLATION OF THE DUE PROCESS CLAUSE OF THE FOURTEENTH AMENDMENT

(U.S. Const., Amend. XIV § 2)

(Against All Defendants)

194. Plaintiffs incorporate by reference and reallege each allegation set forth above.

195. Under the Due Process Clause of the Fourteenth Amendment, no State shall "deprive any person of life, liberty, or property, without due process of law."

196. Under *Birkenfeld v. City of Berkeley* (1976) 17 Cal.3d 129, 165, "a regulation may be invalid on its face when its terms will not permit those who administer it to avoid confiscatory results in its application to the complaining parties."

197. The Emergency Regulations threaten ruin for Plaintiffs. Some or all of the Plaintiffs may have to shut down their businesses entirely. The Emergency Regulations apply to all Plaintiffs and/or their members. The Emergency Regulations do not provide a means for obtaining variances or exceptions from strict compliance.

198. Plaintiffs request declaratory and injunctive relief to nullify the Emergency Regulations

and to enjoin Defendants from attempting to enforce them.

EIGHTH CAUSE OF ACTION

VOID FOR VAGUENESS

(U.S. Const., Amends. V, § XX, XIV § 2)

(Against All Defendants)

199. Plaintiffs incorporate by reference and reallege each allegation set forth above.

200. 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.

201. The Emergency Regulations are hopelessly and unconstitutionally vague.

202. 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."

203. The Emergency Regulations' definitions of "detectable" and "limit of detection" are of no help.

204. "Detectable" means "any amount of analyte, subject to the limit of detection," referring to the defined term of "limit of detection."

205. "Limit of detection" as "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.

206. In Article 3, Section 23100, which relates to "Serving and Package Requirements" for "Manufacture," they 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.

207. 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 (FDA) or the United States Environmental Protection Agency (USEPA).

208. 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.

209. 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.

210. Plaintiffs are therefore exposed to criminal prosecution for manufacturing, warehousing, distributing, offering, advertising, marketing, or selling their hemp products, yet it is impossible for Plaintiffs to know prior to conducting their activities whether their products are illegal under the Emergency Regulations.

211. The Emergency Regulations' "no detectable amount of THC" standard is therefore void as unconstitutionally vague.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray:

1. For a declaration that the Emergency Regulations is invalid because it violates the Department's statutory authority, the APA, the Health & Safety Code, the California Constitution, and/or the U.S. Constitution;

2. That a peremptory writ of mandate issue commanding Defendants to rescind and immediately cease all enforcement of the Emergency Regulations, or, in the alternative, at least the

provisions of the Emergency Regulations other than the age restrictions;

3. For a temporary and permanent injunction restraining Defendants from unconstitutionally enforcing the Emergency Regulations, or, in the alternative, at least the provisions at least the provisions of the Emergency Regulations other than the age restrictions;

4. For costs and attorney fees, under Code of Civil Procedure section 1021.5 and Government Code section 11120 et seq., incurred herein; and

5. For such other and further relief as this Court deems just and proper.

DATED: September 24, 2024

FROST BROWN TODD LLP

By: _____

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Verification

U.S. Hemp Roundtable, Inc. et al. v. California Department of Public Health et al.

I, Jonathan Miller, Esq., declare:

I am the in the General Counsel for Plaintiff U.S. Hemp Roundtable, Inc. ("USHRT") in the above-entitled matter.

I have read the foregoing Verified Petition and Complaint and know the contents thereof. The same is true of my own knowledge, except as to those matters which are therein stated on information and belief, and, as to those matters, I believe them to be true.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on September 22, 2024, at 3:50 PDT.

JONATHAN MILLER

FROST BROWN TODD LLP
LOS ANGELES

EXHIBIT A

State of California—Health and Human Services Agency
California Department of Public Health

TOMÁS J. ARAGÓN, MD, DrPH
Director and State Public Health Officer

GAVIN NEWSOM

NOTICE OF PROPOSED EMERGENCY REGULATORY ACTION
Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp
DPH-24-005E

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.

This notice is being provided at least five working days prior to the filing of the proposed emergency regulatory action with the Office of Administrative Law. A copy of the text of the proposed emergency regulations and finding of the emergency are enclosed and available for review on the Department's website at: Proposed Regulations (ca.gov).

After submission of the proposed emergency to OAL, OAL shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6 to the OAL Reference Attorney by mail to 300 Capitol Mall, Suite 1250, Sacramento, California 95814, by fax to (916) 323-6826, or by e-mail to staff@oal.ca.gov.

This notice is solely a notice of intent to file the proposed emergency regulations and should in no way be confused with the notice specified in Government Code sections 11346.4 and 11346.5. The Department shall provide separate notice of the subsequent 45-day public comment period, during which you may submit comments regarding the regulations.

To request a copy of the notice, and the regulation text in an alternate format, please email the Department at: Regulations@cdph.ca.gov. Please include the regulation title and control number (DPH-24-005E: Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp).

FINDING OF EMERGENCY
Regulations for Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp
DPH-24-005E

The director of the California Department of Public Health (Department) finds that an emergency exists and that the proposed emergency regulations are necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, and general welfare of Californians.

NOTICE AND INTRODUCTION

Notice is hereby given that the Department proposes to adopt the regulations described below. Government Code section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law (OAL), the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the OAL, the OAL shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.

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.

Age requirement

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.

List of intoxicating cannabinoids

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.

AUTHORITY AND REFERENCES

The Department is proposing to adopt the proposed rulemaking under the authority provided in sections 100275, 110065, 111921.3, 111921.7, 111922, 111925, and 131200 of the Health and Safety Code.

The Department is proposing to add sections 23000, 23005, 23010, 23015, and 23100 to Subchapter 2.6 of Chapter 5 of Division 1 of Title 17, California Code of Regulations in order to implement, interpret, or make specific sections 110045, 110085, 110095, 110100, 111920, 111921.3, 111921.7, 111921, 111922, 111925, 111925.2, 111926, 111926.2, 131095, and 131100 of the Health and Safety Code; and Part 101, Title 21 Code of Federal Regulations.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Purpose

These proposed regulations will specify the (1) serving and package size limits for total THC for industrial hemp final form food products intended for human consumption, (2) age requirement for offering or sale of industrial hemp extract in its final form or industrial hemp final form food products, and (3) intoxicating cannabinoids included in the definition of THC or "THC or comparable cannabinoid." The proposed regulations will protect public health and safety by protecting youth and reducing risk of illness, injury, or death.

Background

Existing state law

Assembly Bill (AB) 45 (Chapter 576, Statutes of 2021) was signed by the Governor on October 6, 2021. AB 45 requires the Department to implement statutory requirements, codified in Health and Safety Code sections 111920 et seq., to regulate industrial hemp in extracts, food, beverages, dietary supplements, processed pet food, cosmetics, and inhalable products. AB 45 established the Industrial Hemp Enrollment and Oversight Fund for the collection of fees to pay for the new regulatory work, including establishing and maintaining an industrial hemp enrollment and authorization, registration, and inspection program for industrial hemp manufacturers who produce raw hemp extract or who produce industrial hemp final form products.

AB 45 requires that all industrial hemp products that are sold or distributed in California shall conform with all applicable state laws and regulations. In current law, industrial hemp products cannot include total tetrahydrocannabinol (THC) of more than 0.3% (delta-8 THC, delta-9 THC, delta-10 THC) and THC acid. Industrial hemp products cannot include THC isolate as an added ingredient and cannabinoids produced through chemical synthesis. Manufacturers must include a certificate of analysis to confirm allowable total THC concentration and product content, and they must provide proof that the industrial hemp product in its final form or extract was from an approved industrial hemp growing program. The Department conducts licensure and compliance activities statewide to ensure these facilities and their products meet state and federal laws. To implement AB 45, the Department added industrial hemp firms into its existing registration structure, including licensing, inspecting, and conducting enforcement. The Department must separately license and evaluate the operations of firms that manufacture industrial hemp extracts out-of-state for import into California, as well as California firms that manufacture inhalable products for sales out-of-state. Inhalable products may be manufactured in California for the sole purpose of sale in other states; sale of inhalable products in California is prohibited until the Legislature establishes a tax on inhalable products.

The Department may investigate misbranding, adulteration, food manufacturing safety, unapproved drug products, and other issues to determine compliance with AB 45 or other laws. Enforcement may include:

- Regulatory warnings

- Public health advisories or warnings
- Administrative and civil penalties
- Recall of products
- Seizure and embargo of products
- Condemnation of embargoed products

Health and Safety Code sections 111922(a) and 111925(b) state that the Department "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," and may "regulate and restrict the cap on extract and may cap the amount of total THC concentration at the product level based on the product form, volume, number of servings, ratio of cannabinoids to THC in the product, or other factors, as needed."

Health and Safety Code section 111921.3 states that 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."

Health and Safety Code section 111921.7(b) states that the Department "may include any other cannabinoid, in addition to those expressly listed in subdivision (l) of Section 111920, in the definition of THC or 'THC or comparable cannabinoid' if the department determines, consistent with subdivisions (c) and (d), that the cannabinoid causes intoxication."

Federal law

Under the federal 2018 Farm Bill, industrial hemp is defined as the *Cannabis sativa Linnaeus* plant with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% (United States Code, Title 7, Section 5940(b)(2)). Industrial hemp regulation under AB 45 is stricter than federal law by limiting delta-8 THC, delta-9 THC, and delta-10 THC and any intoxicating cannabinoid as defined by the Department to 0.3% or less. In addition, industrial hemp cannot be synthetically derived or contain any THC isolates.

Current U.S. Food and Drug Administration (FDA) law is that cannabidiol (CBD) is an unapproved food additive, regardless of the source, and CBD in human food, dietary supplements and pet food are unapproved. Federally unapproved products are illegal to enter interstate commerce.

Policy Statement Overview

The proposed regulations focus on protecting our youth and public in general by identifying the serving size and package limits for total THC in final form food products intended for human consumption, setting age requirements, and prohibiting intoxicating cannabinoids in industrial hemp products.

The objective of these proposed regulations is to assure consumers that products sold as industrial hemp meet a consistent standard and that extractors, manufacturers, and retailers are following standards to ensure the quality and safety of their products, and

to protect the public health and safety through regulation of industrial hemp products that may pose a threat and to prevent injury, illness, or death.

Serving and package size limits

Since AB 45 was signed in late 2021, many food and beverage products are produced with intoxicating levels of total THC, and some have caused illness, injury, and death. The current law allows for up to 0.3% of total THC for extracts in industrial hemp final form products with no limits on the serving size of total THC. Depending on the size of the product, an individual could receive significantly more THC in an industrial hemp product compared to a cannabis product. The proposed regulations clarify that there shall be no detectable amount of total THC in each serving size and package of industrial hemp final form food products intended for human consumption including food, food additives, beverages, and dietary supplements. Such an amount is not psychoactive and significantly decreases the risks associated with the products.

Age requirement for extract and human food

At present, there is no minimum age requirement for the sale of industrial hemp products, which could contain high amounts of total THC. Thus, anyone can purchase with no restrictions. By setting a minimum age requirement of 21 years, it will be clear that 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, are not intended for sale to youth and may not be safe for youth to consume.

List of intoxicating cannabinoids

Under AB 45, only delta-8 THC, delta-9 THC, delta-10 THC, and THC acid (THCA) are explicitly identified in the definition of THC or “THC or comparable cannabinoid.” Adding additional intoxicating and potentially harmful cannabinoids to the definition of THC or “THC or comparable cannabinoid” will ensure that the presence of these cannabinoids in industrial hemp products is restricted to the limits of AB 45 and this regulation to ensure the safety of industrial hemp products.

EFFECT OF REGULATORY ACTION

This proposed action will add sections 23000, 23005, 23010, 23015, and 23100 to Subchapter 2.6 of Chapter 5 of Division 1 of Title 17 of the California Code of Regulations, as follows:

Add §23000. Definitions.

This section establishes definitions for Subchapter 2.6 as follows:

“Detectable” is defined as any amount of analyte, subject to the limit of detection. This definition is needed to further clarify provisions in the proposed regulations. By requiring no detectable amount of total THC, we establish a standard for what constitutes a level of THC or comparable cannabinoids that is below the threshold of detection, ensuring that any trace amounts present are not significant enough to cause impairment. This precision is crucial in maintaining safety standards and compliance with regulations related to intoxicating and harmful substances.

“Limit of detection” is defined as 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. This definition is needed to further clarify provisions in the proposed regulations. The limit of detection provides a foundation for determining the presence or absence of the intoxicating cannabinoids.

Add §23005. Age Requirement for Extract and Human Food.
This section requires that a person cannot offer or sell industrial hemp extract in its final form or industrial hemp final form food products intended for human food consumption including food, food additives, beverages, and dietary supplements, to a person under 21 years of age. The age aligns with other restricted use products in California, such as tobacco, cannabis, and alcohol products. This provision is necessary to ensure individuals with developing biological systems are protected from potential acute reactions and long-term impacts which have not been fully studied. There have been complaints regarding the use of industrial hemp products by children, with associated illness, injury, and deaths.

Add §23010. List of Intoxicating Cannabinoids.
This section lists intoxicating cannabinoids included in the definition of THC or “THC or comparable cannabinoids” that must be included in the 0.3% total THC limit in industrial hemp extract.

Delta-8 tetrahydrocannabinol (THC), delta-9 tetrahydrocannabinol (THC), delta-10 tetrahydrocannabinol (THC), and tetrahydrocannabinolic acid (THCA) are defined as THC or “THC or comparable cannabinoids” in the statutory definition at Section 111920(l) of the Health and Safety Code. This section lists cannabinoids added to the definition of THC or “THC or comparable cannabinoids.” The named cannabinoids were selected based upon scientific literature that the cannabinoids are intoxicating. This provision is needed because intoxicating cannabinoids, such as THC, forms of THC, and synthetic cannabinoids, can produce unpredictable and potentially dangerous side effects, including altered perception, loss of coordination, and increased heart rate. Unregulated use of these substances can lead to addiction, overdose, and long-term health consequences. This is particularly important for vulnerable populations, such as youth and individuals with pre-existing medical conditions, who may be more susceptible to the negative effects of intoxicating cannabinoids.

Regulators, retailers, and most importantly, consumers, can verify the content of intoxicating ingredients in industrial hemp products because manufacturers must provide lab testing results for extracts used in all industrial hemp products. Restricting the manufacture of intoxicating cannabinoids in industrial hemp products will reduce the adverse effects associated with consuming intoxicating cannabinoids. The Department has documented cases of injuries and illnesses within California caused by industrial hemp products with intoxicating cannabinoids, and there are known cases of the use of intoxicating cannabinoids causing death to persons located outside of California.

Add §23015. Severability.
This section provides that should a part of the regulation be challenged the Department's intent is that the remaining parts will remain in effect. This provision is needed to preserve the remaining, valid parts of the regulations to ensure the protection of public health and safety.

Add §23100. Serving and Package Size Limits.
Subsection (a): requires that an industrial hemp final form food product intended for human consumption including food, food additives, beverages, and dietary supplements shall have no detectable amount of total THC. This is needed to ensure products do not contain a scientifically detectable amount of total THC because of intoxicating effects and side effects on users. The Department has documented cases where high levels of total THC were found in food products that caused illness, injury, or death. Limiting the total THC in the serving sizes of products to a non-detectable amount reduces the risk of illness, injury, and death especially in children who may consume these products.

- Paragraph (1): requires each serving in a package to have no detectable amount of total THC. This is needed to ensure intoxicating cannabinoids are not included in final form food products. The identification of servings per package is a standard and common way of communicating to consumers the content in foods, beverages, and dietary supplements. Connecting total THC levels to this practice is necessary to further clarify provisions in the proposed regulations.
- Paragraph (2): requires each package to have no more than five servings. This is needed to ensure industrial hemp products are not packaged in a manner to provide high quantities of intoxicating cannabinoids to the consumer in a single package.
- Paragraph (3): requires that serving and package sizes must be determined using the same federal standards as non-industrial hemp food products. This is needed to clarify that industrial hemp food products must follow current established statutes for serving and package sizes for food, food additives, beverages, and dietary supplements. Using non-standardized serving and package sizes increases the potential for consumers to be exposed to high levels of total THC.

Subsection (b): provides that an independent testing laboratory must 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. This provision is necessary to ensure testing results are accurate and in accordance with current scientific methods. Variations in methodology may yield inaccurate testing results and could lead to unintended cannabinoid exposure to consumers.

Subsection (c): provides that manufacturers of final form food products must prove their products do not exceed the serving size limits established in this subchapter. This provision is necessary to prevent products with THC above the limits which produce intoxicating effects when consumed. Otherwise, it may not be clear that manufacturers must show their process to ensure their products meet the law. This provision is necessary to prevent the inclusion of intoxicating cannabinoids in products for human

use so the Department can fulfill its mandate to oversee food manufacturing activities and protect public health from the adverse effects, including injury, illness, or death of the use of THC or other intoxicating cannabinoids.

Subsection (d): provides that a person cannot 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. This provision is necessary to prevent the inclusion of intoxicating cannabinoids in products for human consumption so the Department can fulfill its mandate to oversee food manufacturing activities and protect public health from the adverse effects, including injury, illness, or death of the use THC or other intoxicating cannabinoids.

STATEMENTS OF DETERMINATIONS AND ECONOMIC IMPACT ASSESSMENT

The Department has determined that the proposed regulatory action would have a significant economic impact on California business enterprises and individuals.

EVALUATION AS TO WHETHER THE REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department has made a determination that these regulations are not inconsistent or incompatible with existing state regulations. As the oversight of industrial hemp activity is a newly created state responsibility, no other state regulations are already in existence that address the same topics. In addition, the Department has determined that its regulations do not conflict with the Food and Agriculture Code, Alcoholic Beverage Control Act, and division 9 (commencing with Section 23000) of the Business and Professions Code (see Health and Safety Code section 110040).

MANDATED BY FEDERAL LAW OR REGULATIONS

The Department has made a determination that this proposal is not mandated by federal law or regulations.

LOCAL MANDATE

The Department has determined that this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

FISCAL IMPACT ASSESSMENT

A. **Cost to Any Local Agency or School District:** None.
B. **Cost or Savings to Any State Agency:** None.
C. **Other Nondiscretionary Cost or Savings Imposed on Local Agencies:** None.
D. **Cost or Savings in Federal Funding to the State:** None.

DOCUMENTS RELIED UPON

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CONTACT PERSON

Inquiries regarding the proposed regulatory action can be directed to Michael Boutros, with the Office of Regulations at (279) 217-0866, or the designated backup contact, Dawn Basciano at (916) 440-7367.

CALIFORNIA CODE OF REGULATIONS
TITLE 17. PUBLIC HEALTH
DIVISION 1. STATE DEPARTMENT OF HEALTH SERVICES
CHAPTER 5. SANITATION (ENVIRONMENTAL)
SUBCHAPTER 2.6 INDUSTRIAL HEMP

ADOPT

Article 1. Definitions.

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.

Note: Authority cited: Sections 100275, 110065, 111921.7, 111922, 111925, and 131200, Health and Safety Code. Reference: Sections 111920, 111921.7, 111925, 111926, and 131100, Health and Safety Code.

Article 2. General Provisions

Section 23005. Age Requirement for Human Food.

A person shall not offer or sell 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.

Note: Authority cited: Sections 100275, 110065, 111921.3, and 131200, Health and Safety Code. Reference: Sections 111921, 111921.3, and 131095, Health and Safety Code.

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,7,10,10a-tetrahydro-6*H*-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-indole-3-carboxamide (XRL-11 &15);
(26) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3-carboxamide (UR-144);
(27) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3-carboxamide (FUB-144);
(28) N-(1-Amino-1-methyl-ethyl)-5-fluoropentyl-1-naphthalen-2-yl-1H-indole-3-carboxamide (AMB-FUBINACA);
(29) (3-[(1R,4R)-Isopropyl-2-methyl-1,3-benzodioxol-5-yl]-N-(2,4-dimethyl-3-methylbenzoyl)-N-methyl-1,2,3,4-tetrahydroisoquinolin-6-amine) (THJ-220); and
(30) (3-[(1R,4R)-Isopropyl-2-methyl-1,3-benzodioxol-5-yl]-N-(2,4-dimethyl-3-methylbenzoyl)-N-methyl-1,2,3,4-tetrahydroisoquinolin-6-amine) (RCS-4).

Note: Authority cited: Sections 100275, 110065, 111921.7, and 131200, Health and Safety Code. Reference: Sections 111920, 111921.7, 111925, 131095, and 131100, Health and Safety Code.

Section 23015. Severability.

In this subchapter, if any section, subsection, clause, sentence, or phrase of these regulations is for any reason held to be invalid or unconstitutional, or if any application of this subchapter to any person or circumstance is found to be invalid, the Department's intent is that the invalidity or unconstitutionality not affect any other section, subsection, clause, sentence, phrase or application which can be given effect without the invalid provision or application in this subchapter.

Note: Authority cited: Sections 100275, 110065, and 131200, Health and Safety Code. Reference: Sections 110045, 111921, and 131100, Health and Safety Code.

Article 3. Manufacture

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 pursuant to Health and Safety Code section 111926, 110085, and 110095, 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 (LOD) for chemical method analyses according to any of the following methods:

(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; or
(3) A method published by the United States Food and Drug Administration (USFDA) or the United States Environmental Protection Agency (USEPA).

(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.

Note: Authority cited: Sections 100275, 110065, 111922, 111925, and 131200, Health and Safety Code. Reference: Sections 110085, 110095, 110100, 111920, 111921, 111922, 111925, 111925.2, 111926, 111926.2, 131095, and 131100, Health and Safety Code; Part 101, Title 21 Code of Federal Regulations.

EXHIBIT B

2021 Cal. Legis. Serv. Ch. 576 (A.B. 45) (WEST)

CALIFORNIA 2021 LEGISLATIVE SERVICE

2021 Portion of 2021-2022 Regular Session

Additions are indicated by **Text**; deletions by * * * .
Vetoes are indicated by ~~Text~~ ;
stricken material by ~~**Text**~~ .

CHAPTER 576
A.B. No. 45

AN ACT to add and repeal Section 26013.2 of the Business and Professions Code, to amend Sections 11018.5, 100425, and 110065 of, to add Sections 110036, 110407, 110469, 110611, 111691, and 113091 to, to add Chapter 9 (commencing with Section 111920) to Part 5 of Division 104 of, and to repeal Section 111921.6 of, the Health and Safety Code, relating to industrial hemp, and declaring the urgency thereof, to take effect immediately.

[Filed with Secretary of State October 6, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

AB 45, Aguiar-Curry. Industrial hemp products.

(1) Existing law, the Sherman Food, Drug, and Cosmetic Law, prohibits the manufacture, sale, delivery, holding, or offer for sale of adulterated foods, beverages, or cosmetics. Existing law prescribes when a food or beverage is adulterated, including if it bears or contains any poisonous or deleterious substance that may render it injurious to the health of a person or other animal that may consume it. Existing law prescribes when a cosmetic is adulterated, including when it bears or contains a poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling or advertisement of the cosmetic, under customary or usual conditions.

The Sherman Food, Drug, and Cosmetic Law, among other things, regulates the labeling of food, beverages, and cosmetics and makes it a crime to distribute in commerce any food, drug, device, or cosmetic if its packaging or labeling does not conform to these provisions. Existing law also makes it unlawful for a person to disseminate any false advertisement of any food, drug, device, or cosmetic. Violation of the Sherman Food, Drug, and Cosmetic Law is a misdemeanor.

Existing law requires a person who manufactures pet food in California to obtain a license from the State Department of Public Health. Existing law also prohibits the manufacture, sale, or delivery of a pet food ingredient or processed pet food that is adulterated and defines “adulterated” for this purpose.

This bill would require a manufacturer of dietary supplements and food that includes industrial hemp to register with the State Department of Public Health and to be able to demonstrate that all parts of the plant used come from a state or country that has an established and approved industrial hemp program, as defined, that inspects or regulates hemp under a food safety program or equivalent criteria to ensure safety for human or animal consumption and that the industrial hemp cultivator or grower is in good standing and compliance with the governing laws of the state or country of origin.

This bill would state 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, and would prohibit 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.

The bill would also prohibit a manufacturer, distributor, or seller of an industrial hemp product from including on the label, or publishing or disseminating in advertising or marketing, a health-related statement, as defined, that is untrue in any particular manner as to the effects on health of consuming products containing industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp. By creating a new crime, this bill would impose a state-mandated local program.

This bill would create a registration process, under the State Department of Public Health, for hemp manufacturers who produce specified products that include industrial hemp or who produce raw hemp extract, as defined, including requirements for testing and labeling on products. The bill would define “THC” for these purposes and would authorize the department to include or exclude comparable compounds from the definition of THC for purposes of regulation as industrial hemp based on the compound's intoxicating effect, or lack thereof. The bill would authorize the department to collect specified fees, which would be used, upon appropriation, to implement the program. By creating a new crime, this bill would impose a state-mandated local program.

This bill, upon the enactment of a tax on inhalable products, would require the department to regulate those products, as specified, or enter into a memorandum of understanding or other interagency agreement with another state agency to do so. Until that tax is enacted, the bill would prohibit the manufacture and sale of inhalable products, except for the sole purpose of sale out of state.

This bill would require the Department of Cannabis Control to prepare a report to the Governor and the Legislature outlining the steps necessary for the incorporation of hemp products into the cannabis supply chain, as specified. The bill would also require the Department of Food and Agriculture and the State Department of Public Health, in consultation with the Department of Cannabis Control, if necessary, to develop a process to share license, registration, cultivar, and enforcement information to facilitate compliance and enforcement against unlicensed manufacturers or the sale of hemp that does not meet specified requirements. The bill would make communications shared between these agencies and local law enforcement for this purpose exempt from the California Public Records Act.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

Existing law provides that, except as otherwise provided by statute, all relevant evidence is admissible. The California Constitution provides for the Right to Truth-in-Evidence, which requires a $^{2}/_{3}$ vote of the Legislature to exclude any relevant evidence from any criminal proceeding, as specified.

This bill would make communications shared between agencies pursuant to the above provisions official information, which may be privileged and made inadmissible in an action or proceeding, thereby requiring a $^{2}/_{3}$ vote.

(2) Existing law, the Control, Regulate and Tax Adult Use of Marijuana Act (AUMA), added by Proposition 64 at the November 8, 2016, statewide general election, regulates the cultivation, distribution, transport, storage, manufacturing, testing, processing, sale, and use of marijuana for nonmedical purposes by people 21 years of age and older. The existing Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), among other things, consolidates the licensure and regulation of commercial medicinal and adult-use cannabis activities. Existing law, for purposes of commercial cannabis regulation, defines "cannabis" as derivatives of the cannabis plant, not including industrial hemp. Existing law defines industrial hemp, for this purpose, as cannabis plants having no more than 0.3% tetrahydrocannabinol (THC) contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin produced therefrom. Industrial hemp is exempt from the provisions of MAUCRSA.

AUMA authorizes the Legislature to amend the act to further the purposes and intent of the act with a $^{2}/_{3}$ vote of the membership of both houses of the Legislature, except as provided.

This bill would amend AUMA by changing the definition of "industrial hemp" to include cannabis plants 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% on a dry weight basis.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

(4) This bill would declare that it is to take effect immediately as an urgency statute.

The people of the State of California do enact as follows:

SECTION 1. Section 26013.2 is added to the Business and Professions Code, to read:

<< CA BUS & PROF § 26013.2 >>

26013.2. (a) On or before July 1, 2022, the department shall prepare a report to the Governor and the Legislature outlining the steps necessary to allow for the incorporation of hemp cannabinoids into the cannabis supply chain. The report shall include, but not be limited to, the incorporation of hemp cannabinoids into manufactured cannabis products and the sale of hemp products at cannabis retailers.

(b)(1) The report to be submitted pursuant to subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

(2) Pursuant to Section 10231.5 of the Government Code, this section is repealed on January 1, 2025.

(c) It is the intent of the Legislature to consider, in light of the report submitted pursuant to subdivision (a), whether and how to take legislative action concerning the incorporation of hemp into the cannabis supply chain no later than the 2023–24 legislative session.

SEC. 2. Section 11018.5 of the Health and Safety Code is amended to read:

<< CA HLTH & S § 11018.5 >>

11018.5. (a) "Industrial hemp" **or "hemp"** means ~~* * *~~ **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**.

(b) Industrial hemp shall not be subject to the provisions of this division or of Division 10 (commencing with Section 26000) of the Business and Professions Code, but instead shall be regulated by the Department of Food and Agriculture in accordance with the provisions of Division 24 (commencing with Section 81000) of the Food and Agricultural Code, inclusive.

SEC. 3. Section 100425 of the Health and Safety Code is amended to read:

<< CA HLTH & S § 100425 >>

100425. (a) The fees or charges for the issuance or renewal of any permit, license, registration, or document pursuant to Sections 1639.5, 1676, 1677, 2805, 11839.25, 103625, 106700, 106890, 106925, 107080, 107090, 107095, 107160, 110210, 110470, **110471,** 111130, 111140, 111630, **111923.5, 111923.6,** 112405, 112510, 112750, 112755, 113060, 113065, 114065, 115035, 115065, 115080, 117923, 117995, 118045, 118210, and 118245 shall be adjusted annually by the percentage change printed in the Budget Act for those items appropriating funds to the state department. After the first annual adjustment of fees or charges pursuant to this section, the fees or charges subject to subsequent adjustment shall be the fees or charges for the prior calendar year. The percentage change shall be determined by the Department of Finance, and shall include at least the total percentage change in salaries and operating expenses of the state department. However, the total increase in amounts collected under this section shall not exceed the total increased cost of the program or service provided.

(b) The state department shall publish annually a list of the actual numerical fee charges for each permit, license, certification, or registration governed by this section.

(c) This adjustment of fees and publication of the fee list shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) With respect to the fees or charges pursuant to Section 103625, the actual dollar fee or charge shall be rounded to the nearest whole dollar.

~~* * *~~

SEC. 4. Section 110036 is added to the Health and Safety Code, to read:

<< CA HLTH & S § 110036 >>

110036. All laws and regulations pertaining to industrial hemp products shall remain in effect until the adoption of regulations pursuant to the federal law that authorizes industrial hemp products. At that time, the department shall adopt new regulations either as necessary pursuant to the federal law or deemed necessary to protect consumers.

SEC. 5. Section 110065 of the Health and Safety Code is amended to read:

<< CA HLTH & S § 110065 >>

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.

SEC. 6. Section 110407 is added to the Health and Safety Code, to read:

<< CA HLTH & S § 110407 >>

110407. (a) A manufacturer, distributor, or seller of an industrial hemp product shall not include on the label of the product, or publish or disseminate in advertising or marketing, any health-related statement that is untrue in any particular manner as to the health effects of consuming products containing industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp in violation of this part.

(b) For purposes of this section, “health-related statement” means a statement related to health, and includes a statement of a curative or therapeutic nature that, expressly or impliedly, suggests a relationship between the consumption of industrial hemp or industrial hemp products and health benefits or effects on health. However, “health-related statement” does not include statements required to be made pursuant to federal Food and Drug Administration regulations for active ingredients in prescription drugs, nonprescription over-the-counter drugs containing inactive ingredients, or structure-function claims allowed for dietary supplements made in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 343(r)(6)).

SEC. 7. Section 110469 is added to the Health and Safety Code, to read:

<< CA HLTH & S § 110469 >>

110469. (a) A wholesale food manufacturing facility that manufactures products that contain industrial hemp shall be registered in accordance with Section 110460 and shall comply with good manufacturing practices as defined in Section 110105 and as determined by the department in regulation.

(b) Industrial hemp shall not be used in dietary supplements or food products unless the manufacturer demonstrates both of the following:

(1) All parts of the hemp plant used in dietary supplements or food products come from a state or country that has an established and approved industrial hemp program that inspects or regulates hemp under a food safety program or equivalent criteria to ensure safety for human or animal consumption.

(2) The industrial hemp cultivator or grower is in good standing and in compliance with the governing laws of the state or country of origin.

SEC. 8. Section 110611 is added to the Health and Safety Code, to read:

<< CA HLTH & S § 110611 >>

110611. Except as provided in Section 25621.5 of the Business and Professions Code, a dietary supplement, food, or beverage is not adulterated by the inclusion of industrial hemp, as defined in Section 11018.5, as long as the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920). The sale of a dietary supplement, food, or beverage that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp provided that the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements of Chapter 9 (commencing with Section 111920).

SEC. 9. Section 111691 is added to the Health and Safety Code, to read:

<< CA HLTH & S § 111691 >>

111691. A cosmetic is not adulterated because it includes industrial hemp, as defined in Section 11018.5, as long as the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920). The sale of a cosmetic that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp provided that the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920).

SEC. 10. Chapter 9 (commencing with Section 111920) is added to Part 5 of Division 104 of the Health and Safety Code, to read:

d. 104 pt. 5 ch. 9 pr. § 111920

Chapter 9. Industrial Hemp

d. 104 pt. 5 ch. 9 art. 1 pr. § 111920

ARTICLE 1. Definitions

<< CA HLTH & S § 111920 >>

111920. For purposes of this chapter, the following definitions apply:

(a) “Department” means the State Department of Public Health.

(b) “Established and approved industrial hemp program” means a program that meets any applicable requirements set forth in federal law regarding the lawful and safe cultivation of industrial hemp.

(c) “Final form product” is a product intended for consumer use to be sold at a retail premise.

(d) “Hemp manufacturer” means either of the following:

(1) A processor extracting cannabinoids from hemp biomass.

(2) A processor purchasing industrial hemp raw extract for the purpose of manufacturing a final form product.

(e) “Independent testing laboratory” means a laboratory that meets all of the following requirements:

(1) Does not have a direct or indirect interest in the entity for which testing is being done.

(2) Does not have a direct or indirect interest in a facility that cultivates, processes, distributes, dispenses, or sells raw hemp products in this state or in another jurisdiction.

(3) Does not have a license issued pursuant to Division 10 (commencing with Section 26000) of the Business and Professions Code, other than as a licensed testing laboratory.

(4) Is either of the following:

(A) A testing laboratory licensed pursuant to Division 10 (commencing with Section 26000) of the Business and Professions Code, if the licensed testing lab has notified the Department of Cannabis Control.

(B) Accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization for Standardization.

(f) “Industrial hemp” has the same meaning as in Section 11018.5. “Industrial hemp” does not include cannabinoids produced through chemical synthesis.

(g)(1) “Industrial hemp product” or “hemp product” means a finished product containing industrial hemp that meets all of the following conditions:

(A) 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) "Industrial hemp product" does not include industrial hemp or a hemp product 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. For purposes of nonfood applications, "industrial hemp product" does not include a hemp product that contains derivatives, substances, or compounds derived from the seed of industrial hemp.

(h)(1) "Manufacture" or "manufacturing" means to compound, blend, extract, infuse, or otherwise make or prepare an industrial hemp product.

(2) "Manufacturing" includes all aspects of the extraction process, infusion process, and packaging and labeling processes, including processing, preparing, holding, and storing of industrial hemp products.

(3) "Manufacturing" also includes processing, preparing, holding, or storing hemp components and ingredients.

(4) "Manufacturing" does not include planting, growing, harvesting, drying, curing, grading, or trimming a plant or part of a plant.

(i) "Raw extract" or "industrial hemp raw extract" means extract not intended for consumer use and that contains a THC concentration of not more than an amount determined by the department in regulation.

(j) "Raw hemp product" means a product that is derived from industrial hemp that is intended to be included in a food, beverage, dietary supplement, or cosmetic.

(k) "Retail" has the same meaning as in Section 113895.

(*l*) "THC" or "THC or comparable cannabinoid" means any of the following:

(1) Tetrahydrocannabinolic acid.

(2) Any tetrahydrocannabinol, including, but not limited to, Delta–8–tetrahydrocannabinol, Delta–9–tetrahydrocannabinol, and Delta–10–tetrahydrocannabinol, however derived, except that the department may exclude one or more isomers of tetrahydrocannabinol from this definition under subdivision (a) of Section 111921.7.

(3) Any other cannabinoid, except cannabidiol, that the department determines, under subdivision (b) of Section 111921.7, to cause intoxication.

(m) "THCA" means tetrahydrocannabinolic acid, CAS number 23978–85–0.

(n) "Total THC" means the sum of THC and THCA. Total THC shall be calculated using the following equation: total THC concentration (mg/g) +/- the measurement of uncertainty, as defined by the United States Department of Agriculture.

d. 104 pt. 5 ch. 9 art. 2 pr. § 111920

ARTICLE 2. General Provisions

<< CA HLTH & S § 111921 >>

111921. An industrial hemp product shall not be distributed or sold in the state except in conformity with all applicable state laws and regulations, including this chapter and any regulations promulgated thereunder, and with documentation that includes both of the following:

(a) A certificate of analysis from an independent testing laboratory that confirms both of the following:

(1) The industrial hemp raw extract, in its final form, does not exceed THC concentration of an amount determined allowable by the department in regulation, or the mass of the industrial hemp extract used in the final form product does not exceed a THC concentration of 0.3 percent.

(2) The industrial hemp product was tested for any hemp derivatives identified on the product label or in associated advertising in accordance with Section 111926.2.

(b) The industrial hemp product was produced from industrial hemp grown in compliance with Division 24 (commencing with Section 81000) of the Food and Agricultural Code if sourced from within California, or licensed in accordance with United States Department of Agriculture (USDA) requirements if sourced from outside the state.

<< CA HLTH & S § 111921.3 >>

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.

<< CA HLTH & S § 111921.5 >>

111921.5. (a) Unless explicitly approved by the federal Food and Drug Administration, industrial hemp shall not be included in products in any of the following categories:

(1) Medical devices.

(2) Prescription drugs.

(3) A product containing nicotine or tobacco.

(4) An alcoholic beverage.

(b) The department may prohibit the inclusion of industrial hemp in other products when it poses a risk to human or animal health through regulation.

(c) Cannabis and cannabis products are not subject to this section.

<< CA HLTH & S § 111921.6 >>

111921.6. (a) Manufacture or sale of inhalable products is prohibited. Manufacture of inhalable products for the sole purpose of sale in other states is not prohibited.

(b) This section shall become inoperative and is repealed on the effective date of a measure passed by the Legislature that establishes a tax on inhalable products and states the intent of the Legislature to fulfill the requirements of this section.

<< CA HLTH & S § 111921.7 >>

111921.7. (a) The department may exclude from the definition of "THC or Comparable Cannabinoid" one or more isomers of tetrahydrocannabinol if the department determines, consistent with subdivisions (c) and (d), that the tetrahydrocannabinol isomer does not cause intoxication.

(b) 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, consistent with subdivisions (c) and (d), that the cannabinoid causes intoxication.

(c) In making a determination under subdivision (a) or (b), the department shall consider scientific evidence concerning the pharmacological effects of the tetrahydrocannabinol or other cannabinoid in humans or other animals, if that evidence is available.

(d) Any initial determination under subdivision (a) or (b) shall not be subject to the administrative rulemaking requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, but the department, without being subject to those administrative rulemaking requirements, shall establish a process to receive public comment regarding those determinations, and shall publicly post all determinations on its internet website. However, any initial determination shall be confirmed subject to the administrative rulemaking requirements no later than 18 months following the date of the initial determination.

d. 104 pt. 5 ch. 9 art. 3 pr. § 111920

ARTICLE 3. Manufacture

<< CA HLTH & S § 111922 >>

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.

<< CA HLTH & S § 111922.3 >>

111922.3. (a) A hemp manufacturer who produces raw extract that will only be used for dietary supplements, foods, beverages, and cosmetics, or a hemp manufacturer who produces industrial hemp products shall comply with this chapter and, to the extent applicable, this part.

(b) A hemp manufacturer who produces processed pet food products shall comply with this chapter and Chapter 10 (commencing with Section 113025) of Part 6 and shall follow good manufacturing practices pursuant to those provisions.

d. 104 pt. 5 ch. 9 art. 4 pr. § 111920

ARTICLE 4. Registration and Fees

<< CA HLTH & S § 111923 >>

111923. The Industrial Hemp Enrollment and Oversight Fund is hereby established in the State Treasury. All money received by the department pursuant to Section 111923.5 shall be deposited into this fund and shall be expended by the department,

upon appropriation by the Legislature, to carry out and implement this chapter. Moneys in this fund shall not be redirected for any other purpose.

<< CA HLTH & S § 111923.3 >>

111923.3. (a)(1) A hemp manufacturer who produces an industrial hemp product that is a food or beverage shall register with the department pursuant to Article 2 (commencing with Section 110460) of Chapter 5.

(2) Sections 110473 and 110474 shall not apply to dietary supplements and food products that include industrial hemp.

(b) Notwithstanding the voluntary nature of registration provided in Section 111795, a hemp manufacturer who produces an industrial hemp product that is a cosmetic shall register pursuant to Article 4 (commencing with Section 111795) of Chapter 7.

(c) A hemp manufacturer who produces an industrial hemp product that is a processed pet food shall obtain a license pursuant to Article 2 (commencing with Section 113060) of Chapter 10 of Part 6.

(d)(1) An in-state hemp manufacturer who produces raw hemp extract and who does not produce an industrial hemp product, or an out-of-state hemp manufacturer who produces raw hemp extract with the intent to import that raw hemp extract into this state, shall register with the department pursuant to Article 2 (commencing with Section 110460) of Chapter 5.

(2) Sections 110473 and 110474 shall not apply to hemp manufacturers who register pursuant to this subdivision.

(e) All hemp manufacturers shall notify the department immediately of any change of information in their application for a license of registration.

<< CA HLTH & S § 111923.5 >>

111923.5. (a) In addition to licensing and registration requirements and fees required pursuant to other applicable laws, as specified in Section 111923.3, a hemp manufacturer shall obtain an industrial hemp enrollment and oversight authorization from the department. Authorization shall be renewed annually.

(b) The department shall assess an authorization fee and renewal fee to cover the actual reasonable costs of implementing the regulatory program in this chapter. Fees may be set at different amounts for different hemp manufacturer types, including food products, cosmetic products, and pet food products, based on the differing costs associated with regulatory requirements, including, but not limited to, the nature and scope of the authorization activities and oversight, inspection, and enforcement activities.

(c) The fee shall be adjusted pursuant to Section 100425.

(d) Fees may be prorated based upon the date of the renewal or issuance of the authorization.

<< CA HLTH & S § 111923.7 >>

111923.7. A hemp manufacturer located outside the state shall reimburse the department for travel and per diem required to perform necessary onsite inspections at the facility to ensure compliance with this chapter and related activities pursuant to this part.

<< CA HLTH & S § 111923.9 >>

111923.9. A hemp manufacturer or retailer who is operating in conformance with this part and in good faith compliance with their responsibilities under this chapter may manufacture or sell industrial hemp products or raw hemp extract without authorization for three months after the effective date of the act that added this chapter.

d. 104 pt. 5 ch. 9 art. 5 pr. § 111920

ARTICLE 5. Recordkeeping

<< CA HLTH & S § 111924 >>

111924. The department may adopt regulations for recordkeeping standards that shall apply to transporters, manufacturers, and retailers of industrial hemp product and raw extract.

d. 104 pt. 5 ch. 9 art. 6 pr. § 111920

ARTICLE 6. Testing Requirements

<< CA HLTH & S § 111925 >>

111925. (a) A hemp manufacturer shall meet all of the following testing requirements:

(1) Industrial hemp shall be tested in raw extract final form, to allow its use as an ingredient, prior to being incorporated into a product.

(2) Testing shall be completed by an independent testing laboratory.

(3) The manufacturer of the hemp extract in its final form or the final form industrial hemp product shall be able to prove total THC concentration does not exceed 0.3 percent. A manufacturer of raw extract shall be able to prove that the THC concentration meets department requirements set forth pursuant to subdivision (a) of Section 111921.

(b) The department may regulate and restrict the cap on extract and may cap the amount of total THC concentration at the product level based on the product form, volume, number of servings, ratio of cannabinoids to THC in the product, or other factors, as needed.

<< CA HLTH & S § 111925.2 >>

111925.2. A raw hemp product shall not be distributed or sold in this state without a certificate of analysis from an independent testing laboratory that confirms all of the following:

(a) The raw hemp product is the product of a batch of industrial hemp that was tested by the independent testing laboratory.

(b) A tested representative sample of the batch of industrial hemp contained a total THC concentration that did not exceed 0.3 percent on a dry-weight basis.

(c) The tested sample of the batch did not contain contaminants that are unsafe for human or animal consumption.

<< CA HLTH & S § 111925.4 >>

111925.4. (a) As of the effective date of the act adding this chapter, testing requirements for contaminant levels shall be the same as those for cannabis, as established in paragraph (2) of subdivision (d) of Section 26100 of the Business and Professions Code and regulations adopted pursuant thereto.

(b) The department may adjust the specific contaminant levels for industrial hemp by regulation to protect consumers.

<< CA HLTH & S § 111925.6 >>

111925.6. (a) A product batch may be reprocessed or remediated after failed testing, but the batch shall not be distributed or sold unless the reprocessed or remediated batch has been retested and successfully passed all the analyses required pursuant to this article.

(b) If the batch cannot be reprocessed or remediated, the product batch shall be destroyed.

(c) If a failed product batch is not reprocessed or remediated in any way, it shall not be retested. Subsequent certificates of analysis produced without reprocessing or remediation of the failed product batch shall not supersede the initial regulatory compliance testing certificate of analysis.

(d) This section shall not prevent a product batch from being retested when the certificate of analysis was obtained 12 months prior or more.

(e)(1) Reprocessing or remediation shall be an available remedy for failed product batches in all industrial hemp product categories and raw extract.

(2) Remediation is not allowed once a product enters the retail market.

(f) A failed product batch that cannot be reprocessed or remediated shall be destroyed, at the expense of the owner, on video surveillance, as authorized by the department, or under the supervision of an authorized agent of the department.

d. 104 pt. 5 ch. 9 art. 7 pr. § 111920

ARTICLE 7. Labeling and Advertisement

<< CA HLTH & S § 111926 >>

111926. (a) A manufacturer, distributor, or seller of an industrial hemp product shall follow packaging, labeling, and advertising laws, including, but not limited to, Chapter 4 (commencing with Section 110290), and federal laws incorporated or applicable in this state, including, but not limited to, Sections 110100, 110340, 110371, 110380, 110382, and 110407 and shall not violate this part.

(b) A hemp manufacturer shall not directly target advertising or marketing to children or to persons who are pregnant or breastfeeding.

(c) Advertising or marketing placed in broadcast, cable, radio, print, or digital communications shall only be displayed where at least 70 percent of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data.

<< CA HLTH & S § 111926.2 >>

111926.2. (a) An industrial hemp product that is a dietary supplement, food, or beverage shall not be distributed or sold in the state without packaging and labeling on the product that includes all of the following information:

(1) A label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the final form product batch by an independent testing laboratory that provides all of the following information:

(A) The product name.

(B) The name of the product's manufacturer, packer, or distributor, and their address and telephone number.

(C) The batch number, which matches the batch number on the product.

(D) The concentration of cannabinoids present in the product batch, including, at minimum, total THC and any marketed cannabinoids or ingredient, as required by the department in regulation.

(E) The levels within the product batch of contaminants, as required in subdivision (c) of Section 111925.2.

(2) The product expiration or best by date, if applicable.

(3) A statement indicating that children or those who are pregnant or breastfeeding should avoid using the product prior to consulting with a health care professional about its safety.

(4) A statement that products containing cannabinoids should be kept out of reach of children.

(5) The following statement, “THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY.”

(b) The requirements of this section shall apply to products manufactured 90 days or more after the enactment of this section.

<< CA HLTH & S § 111926.3 >>

111926.3. (a) An industrial hemp product that is a cosmetic shall not be distributed or sold in the state without packaging and labeling on the product that includes all of the following information:

(1) A label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the final form extract or the final form product batch by an independent testing laboratory that provides all of the following information:

(A) The product name.

(B) The name of the product's manufacturer, packer, or distributor, and their address and telephone number.

(C) The batch number, which matches the batch number on the product.

(D) The concentration of cannabinoids present in the product batch, including, at minimum, total THC and any marketed cannabinoids.

(E) The levels within the product batch of contaminants, as required in subdivision (c) of Section 111925.2.

(2) The product expiration or best by date, if applicable.

(3) The following statement, "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY."

(b) The requirements of this section shall apply to products manufactured 90 days or more after the enactment of this section.

d. 104 pt. 5 ch. 9 art. 8 pr. § 111920

ARTICLE 8. Enforcement

<< CA HLTH & S § 111927 >>

111927. (a) The department shall have the seizure and embargo powers provided for in Article 3 (commencing with Section 111860) of Chapter 7 with respect to industrial hemp products and raw extract.

(b) The department shall have the ability to recall industrial hemp products or raw extract that it determines to be dangerous to the public in the manner prescribed in Section 110806.

<< CA HLTH & S § 111927.2 >>

111927.2. (a) In addition to the inspection authority provided elsewhere in this part, the department may inspect financial data, sales data, and personnel data, as needed to enforce this chapter.

(b) State, local, or law enforcement officials may review paperwork from those handling or transporting industrial hemp plant material, raw extract, intermediary industrial hemp product, or final finished product and take samples at any point along the supply chain to test that sample for verification.

(c) Upon inspection, if the industrial hemp plant material, raw extract, intermediary industrial hemp product, or final finished product does not meet the definition of industrial hemp, the state, local, or law enforcement official shall notify the department.

(d)(1) State, local, and law enforcement officials shall immediately notify the department of an arrest made for a violation over which the department has jurisdiction that involves a person authorized pursuant to this chapter.

(2) The department shall promptly investigate whether grounds exist for suspension or revocation of the authorization or if other actions are warranted under this part.

<< CA HLTH & S § 111927.4 >>

111927.4. Violations of this chapter are subject to the fines and penalties established in Article 1 (commencing with Section 111825) of Chapter 8.

d. 104 pt. 5 ch. 9 art. 9 pr. § 111920

ARTICLE 9. Agency Coordination

<< CA HLTH & S § 111928 >>

111928. (a) The Department of Food and Agriculture and the State Department of Public Health, in consultation with the Department of Cannabis Control, if necessary, shall develop a process to share license, registration, cultivar, and enforcement information to facilitate compliance and enforcement against unlicensed manufacturers or the sale of industrial hemp that does not meet the requirements of this part.

(b) Communications shared between state agencies and local and law enforcement officials regarding license, registration, cultivar, and enforcement information of manufacturers and retailers of industrial hemp products and raw extract shall not be subject to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) and shall be considered "official information" pursuant to Section 1040 of the Evidence Code.

d. 104 pt. 5 ch. 9 art. 10 pr. § 111920

ARTICLE 10. Inhalable Products

<< CA HLTH & S § 111929 >>

111929. Inhalable products shall not be sold to consumers under 21 years of age.

<< CA HLTH & S § 111929.1 >>

111929.1. A hemp manufacturer who produces inhalable products shall comply with this chapter and, to the extent applicable, with the provisions of this part.

<< CA HLTH & S § 111929.2 >>

111929.2. An inhalable product shall not contain any of the following:

(a) Flavorings other than natural terpenes.

(b) Polyethylene glycol (PEG).

(c) Vitamin E acetate.

(d) Medium chain triglycerides (MCT oil).

(e) Squalene or squalane.

(f) Any other substance that the department finds to be a danger to public health.

<< CA HLTH & S § 111929.3 >>

111929.3. The department may enter into a memorandum of understanding or other interagency agreement with another state agency to administer and enforce provisions of this chapter as they relate to inhalable products, including, but not limited to, testing provisions, advertising and labeling provisions, and the provisions relating to the manufacture and sale of inhalable products.

<< CA HLTH & S § 111929.4 >>

111929.4. This article shall become operative upon the effective date of a measure passed by the Legislature that establishes a tax on inhalable products and states the intent of the Legislature to fulfill the requirements of this section.

SEC. 11. Section 113091 is added to the Health and Safety Code, to read:

<< CA HLTH & S § 113091 >>

113091. A processed pet food is not adulterated because it includes industrial hemp, as defined in Section 11018.5, or cannabinoids, extracts, or derivatives from industrial hemp, if the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920) of Part 5. The sale of processed pet food that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp, if the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in Chapter 9 (commencing with Section 111920) of Part 5.

SEC. 12. The Legislature finds and declares that Section 10 of this act, which adds Section 111928 to the Health and Safety Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

The Legislature finds that the information to be shared is proprietary business information.

SEC. 13. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 14. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the

meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are: In order to protect a rapidly expanding industry relating to derivatives from industrial hemp in California and to reduce inconsistency in implementation of state and federal law, it is necessary that this bill take effect immediately.

End of Document

EXHIBIT C

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. 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.

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. <u>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.</u>

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—
>
> (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

[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.