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BY ELECTRONIC FILING TO [DKT. NO. AMS-SC-19-0042-0001](#)

Bill Richmond
Chief, U.S. Domestic Hemp Production Program
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Dr. Patty Bennett
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Re: Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. 58,522 (Oct. 31, 2019)

Dear Mr. Richmond and Dr. Bennett:

Aimed Alliance is a 501(c)(3) not-for-profit health policy organization that protects and enhances the rights of health care consumers and professionals. We appreciate the opportunity to submit comments to the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) regarding the *Interim Final Rule, Establishment of a Domestic Hemp Production Program*, 84 Fed. Reg. 58,522 (Oct. 31, 2019) (the Rule).

Aimed Alliance strongly supports the Rule. As discussed below, we believe that AMS has set forth a reasonable framework for the content of State and Tribal plans that must be submitted to the agency for the domestic production of hemp.

1. Introduction

Our particular concerns with domestic hemp production arise from the presence in the plant of Δ^9 -tetrahydrocannabinol (THC), a psychoactive component of *Cannabis sativa L.* We believe that AMS has struck the right balance between controlling THC levels to protect public and consumer health while still encouraging the production and commercialization of hemp for legitimate purposes.

Aimed Alliance

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Cannabis sativa is one of the world's oldest cultivated plants.¹ More than 104 different cannabinoids have been identified in cannabis. The most commonly known compounds are THC and cannabidiol (CBD).² THC is psychoactive and produces the intoxicating effects; CBD alone is not demonstrated to cause impairment or intoxication.³ The National Academy of Sciences explains:

[THC is] responsible for the intoxicated state sought after by recreational cannabis users, owing to its ability to act as a partial agonist for type-1 cannabinoid (CB₁) receptors. Cannabinoids exist mainly in the plant as their carboxylic precursors (Δ^9 -tetrahydrocannabinolic acid [THCA] and cannabidiolic acid [CBDA]) and are decarboxylated by light or heat while in storage or when combusted. Δ^9 -THC is synthesized within the glandular trichomes present in the flowers, leaves, and bracts of the female plant.⁴

AMS addresses the practical importance of controlling THC content in hemp in the preamble to the Rule:

[A]s defined in the 2018 Farm Bill, the term “hemp” means the plant species *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. Delta-9 tetrahydrocannabinol, or THC, is the primary intoxicating component of cannabis. Cannabis with a THC level exceeding 0.3 percent is considered marijuana, which remains classified as a schedule I controlled substance regulated by the Drug Enforcement Administration (DEA) under the [Controlled Substances Act (CSA)].⁵

Consequently, any *Cannabis sativa* with THC above 0.3% is not legal hemp, but marijuana, and is illegal under the CSA. Entities growing or possessing marijuana rather than hemp are exposed to economic losses and specified penalties under the 2018 Farm Bill as well as other potential adverse

¹ National Academies of Sciences, Engineering, and Medicine. 2017. *The health effects of cannabis and cannabinoids: Current state of evidence and recommendations for research*. Washington, DC: The National Academies Press (hereinafter “NAS Cannabis Report”) at 43, available [here](#) (accessed Dec. 5, 2019). Unless otherwise indicated, internal citations and quotations within the NAS Cannabis Report are omitted.

² Food and Drug Administration (FDA) *Marijuana Questions and Answers* (hereinafter “FDA Q&A”), available [here](#) (accessed Dec. 5, 2019).

³ *Id.*

⁴ NAS Cannabis Report at 44.

⁵ 84 Fed. Reg. at 58523.

consequences.⁶ While not minimizing these legal repercussions for would-be hemp producers and downstream business interests who find themselves inadvertently trafficking in marijuana instead of hemp, Aired Alliance is especially concerned with the control of THC content to protect patient and consumer health. To that end, we commend AMS for envisioning and implementing a domestic hemp program where control of THC begins in the field.

Below, we elaborate upon the following:

- The overall importance of controlling THC levels to protect patients and consumers;
- The Rule’s testing and sampling provisions;
- Laboratory qualifications; and
- Additional issues for consideration.

2. THC and the Importance of Controlling It to Protect Public Health

Controlling THC levels in cannabis-derived consumer products is critical to consumer health. Cannabis-derived consumer products, particularly those marketed for their CBD content, are widely available in the marketplace in ingestible, topical, and inhalation formulations. Although CBD itself is not impairing, the THC that may be found in products containing CBD is. The Food and Drug Administration (FDA), researchers, and other stakeholders have well-documented that many CBD products (or products that purport to but do not contain CBD) have significant amounts of THC.⁷ One news organization reviewed the test results of over 200 CBD products; more than half of the products tested were inaccurately labeled, and more than 50 products falsely claimed that they were “THC-free.”⁸ The Associated Press has reported on products promoted as CBD-containing that are spiked with synthetic marijuana.⁹

THC lurking in otherwise innocuous-seeming consumer products is deeply concerning. These products are not approved by the FDA and consumers take them often because they are promoted to treat serious medical conditions, without the benefit of physician oversight and care. These products

⁶ Even states that have legalized marijuana for recreational and/or medical purposes will regulate facilities holding, processing, dispensing, or retailing marijuana. A producer, warehouse, trucker, distributor or retailer with *Cannabis sativa* with more than 0.3% THC is producing, holding, transporting or selling marijuana and could be in violation of state requirements applicable to marijuana establishments. *See, e.g.*, MD. Code, Health, §13-3306 Licenses Required for Medical Marijuana Growers to Operate in State; MD. Code, Health, §13-3307 Dispensary License Requirements; Colo. Revised State. § 44-12-201 State licensing authority for retail marijuana businesses); Colo. Revised Stat. § 44-12-306 Business and owner requirements for retail marijuana businesses). Additionally, commitments such as rental and lease agreements, banking, insurance, and other business obligations might all be jeopardized or be breached if an entity is accidentally dealing in marijuana rather than hemp.

⁷ Bonn-Miller M.O., et al., Labeling Accuracy of Cannabidiol Extracts Sold Online. *JAMA*. 2017;318(17):1708–1709 (finding nearly 70 percent of artisanal CBD products tested were mislabeled with respect to CBD content), available [here](#) (accessed Dec. 5, 2019); FDA, Warning Letters and Test Results for Cannabidiol-Related Products, available [here](#) (accessed Dec. 5, 2019).

⁸ WJLA, *Why consumers are claiming positive drug test results after using CBD oil* (Sept. 24, 2019), available [here](#) (accessed Dec. 5, 2019).

⁹ Associated Press, *How the Associated Press collected information on CBD vapes* (Sept. 16, 2019), available [here](#) (accessed Dec. 5, 2019).

have not demonstrated through adequate and well-controlled clinical investigations that they can safely and effectively treat any disease; they are not manufactured to standards that assure the product is consistent, potent, and not contaminated. The FDA has not determined whether the benefits of these products to a patient outweigh their risks under the conditions of use that the agency has reviewed and approved. Cannabis-containing consumer products are in contrast to, for instance, FDA-approved prescription drugs containing cannabis compounds, such as Marinol®, which contains synthetic THC, and Epidiolex®, which is a highly purified CBD oral solution. Marinol® and Epidiolex® are examples of FDA-approved products that are supported by substantial clinical evidence and manufactured to appropriate pharmaceutical standards, and the FDA has determined that their benefits outweigh their risks under the labeled conditions for use.

There is ample evidence of health consequences to marijuana use that are attributable to, or likely attributable to, its THC content. For example, the FDA and the U.S. Surgeon General strongly advise against the use of CBD, THC, and marijuana during pregnancy or while breastfeeding.¹⁰ The U.S. Surgeon General recently advised consumers that marijuana use during pregnancy may affect fetal brain development because THC can enter the fetal brain from the mother's bloodstream. The Surgeon General also advised that marijuana may increase the risk of a newborn with low birth weight. Research also suggests increased risk for premature birth and potentially stillbirth.¹¹

The Surgeon General also warned of the impacts of cannabis use on the developing, adolescent brain. The Surgeon General's Advisory noted data on changes in the areas of the adolescent brain involved in attention, memory, decision-making, and motivation as well as impaired learning in adolescents.¹²

The National Academy of Sciences conducted an in-depth overview of cannabis and identified numerous health consequences arising from the consumption of THC in marijuana.¹³ As also identified by the FDA and Surgeon General, cannabis use is associated prenatal, neonatal, and perinatal risks.¹⁴ Cannabis use is associated with motor vehicle accidents, substance use disorders, schizophrenia, and other psychoses.¹⁵ The National Academy of Sciences further determined that there was moderate evidence of increased risk of overdose injuries; impairment in the cognitive domains of learning, memory, and attention; and increased symptoms of other neuro-psychological conditions.¹⁶

The potential health consequences to consumption of cannabis-containing products are

¹⁰ FDA, *What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding*, available [here](#) (accessed Dec. 5, 2019); U.S. Surgeon General's Advisory: Marijuana Use and the Developing Brain (August 29, 2019), available [here](#) (accessed Dec. 5, 2019).

¹¹ U.S. Surgeon General's Advisory: Marijuana Use and the Developing Brain (Aug. 29, 2019), available [here](#) (accessed Dec. 5, 2019).

¹² *Id.*

¹³ NAS Cannabis Report at Part III, Other Health Effects.

¹⁴ U.S. Surgeon General's Advisory: Marijuana Use and the Developing Brain (Aug. 29, 2019), available [here](#) (accessed Dec. 5, 2019).

¹⁵ Hasin DS. US Epidemiology of Cannabis Use and Associated Problems. *Neuropsychopharmacology*. 2018;43(1):195–212, available [here](#) (accessed Dec. 30, 2019).

¹⁶ NAS Cannabis Report at 231, 267, 289.

particularly concerning because consumers are confused and misled. Users of recreational and medical marijuana know that the product they consume will have THC and state medical and recreational marijuana laws require disclosure of THC content on product labeling. In contrast, there is no such consensus understanding with regard to CBD products, and consumer uncertainty and ignorance abound. This consumer confusion is rooted in the fact that CBD products go to market without clear disclosure of THC content on product packaging or labeling. In fact, it is highly unlikely consumers will be able to ascertain the THC content in CBD products until after purchase, if at all.

Consumer confusion is evident in a recent survey published by the Grocery Manufacturers of America,

- 45% of respondents believe CBD is not intoxicating; and
- 51% of respondents believe it is intoxicating.¹⁷

For consumers who are lulled into believing that hemp-derived products may be consumed because they are not intoxicating or are THC-free, the consequences can be significant and serious. There are numerous news reports and lawsuits regarding consumers who used CBD products, tested positive for THC, and were fired from their jobs.¹⁸ The U.S. Air Force recently cautioned servicemembers to not use CBD because the THC content in the products could result in a positive drug test.¹⁹ There is also reporting concerning individuals who were believed to be in violation of the conditions of their parole or who lost custody of children as a result of positive drug tests that were due to confused testing methodologies or THC-tainted CBD.²⁰ Additionally, with CBD frequently, and falsely, marketed as a cure for addiction,²¹ we are very concerned that people in recovery may jeopardize their sobriety by using CBD products that purport to be free of THC when, in fact, they are not.²² Confectionery products, including gummies and chocolate, are popular vehicles for the delivery of CBD and THC and are very attractive to children, raising the risk of THC exposure in vulnerable pediatric populations.²³

¹⁷ Grocery Manufacturers of America, *The Urgent Need for CBD Clarity* (October 2019), available [here](#) (accessed Dec. 5, 2019).

¹⁸ See, e.g., WJLA, *Why consumers are claiming positive drug test results after using CBD oil* (Sept. 29, 2019), available [here](#) (accessed Dec. 5, 2019); *Horn v. Medical Marijuana, Inc., et al.*, No. 15-cv-701-FPG (W.D.N.Y.); *Darrow v. Just Brands USA, Inc.*, No. 1:19-cv-07079 (N.D. Ill).

¹⁹ Secretary of the Air Force Public Affairs, *Air Force says CBD products not ok to use, may cause positive drug test* (Nov. 19, 2019), available [here](#) (accessed Dec. 5, 2019).

²⁰ A.C. Lewis, *CBD or THC? Common Drug Test Can't Tell the Difference*, *New York Times* (Oct. 15, 2019), available [here](#).

²¹ See, e.g., November 22, 2019 FDA Warning Letter to Koi CBD LLC, available [here](#) (accessed Dec. 5, 2019).

²² See, e.g., HazeldenBettyFord Foundation, *CBD Oil: What you need to know*, available [here](#) (accessed Dec. 5, 2019).

²³ See, e.g., Wang GS, Le Lait M, Deakyne SJ, Bronstein AC, Bajaj L, Roosevelt G. Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015. *JAMA Pediatr.* 2016;170(9):e160971, available [here](#) (accessed Dec. 5, 2019); Whitehill JM, Harrington C, Lang CJ, Chary M, Bhutta WA, Burns MM. Incidence of Pediatric Cannabis Exposure Among Children and Teenagers Aged 0 to 19 Years Before and After Medical Marijuana Legalization in Massachusetts. *JAMA Netw Open.* 2019;2(8):e199456, available [here](#) (accessed Dec. 5, 2019); Michigan Poison Center spots increase in pediatric exposure to edible marijuana treats (Sept. 30, 2019), available [here](#) (accessed Dec. 5, 2019).

For all these reasons, Aimed Alliance strongly supports AMS’s careful approach to control of THC content in the cannabis plant to assure that only hemp is produced under the 2018 Farm Bill. If THC is controlled in the cultivation and production of hemp, THC will be better controlled in downstream processing of hemp into consumer products. Controlling and limiting THC content is critical to protecting patients and consumers, particularly pregnant and nursing women, children, consumers in recovery, and cannabis-naïve individuals, including those who must avoid Schedule I controlled substances as conditions of employment. Indeed, we are very much alarmed at those who argue that the 0.3% THC limit is too difficult to attain and should be adjusted upward to allow for more hemp production. Congress set out to encourage the production of hemp, not marijuana, and we support the continued maintenance of a firm demarcation at no more than 0.3% THC in the interest of public health and safety.

3. Aimed Alliance Supports the Rule’s Sampling and Testing Provisions

Given the above articulated public health concerns, we are especially appreciative of AMS’s efforts to control THC content that are reflected in the Rule’s sampling and testing provisions. Protecting patient health means controlling THC content in finished consumer products, and this means controlling THC content *throughout* the process by which a raw hemp product becomes a finished consumable. In our view, the best way to assure that finished hemp products do not contain excessive amounts of THC is to assure that the raw hemp ingredient is low in THC. Minimizing THC content begins in the field, with robust controls over hemp cultivation, production, sampling, and testing. We, therefore, support the Rule’s requirements that all state and tribal plans must provide:

- For sampling within 15 days prior to harvest;
- That samples for testing be cut just underneath the plant’s flowering material, located in the top one-third (1/3) of the plant; and
- For testing using a reliable analytical method where the total THC content accounts for the conversion of THCA into THC (the sum of THC and THCA).²⁴

Sampling 15 days prior to harvest and testing of flowering material are both scientifically sound and further public health. We concur with AMS’s conclusion that if producers delay harvest beyond 15 days, the plant will likely have a higher THC level at harvest than the sample that is tested.²⁵

Sampling of the flowers, buds, and bracts of *Cannabis sativa* is appropriate given that THC and other cannabinoids are distributed in these parts of the plant.²⁶ Permitting sampling to include more of the stalk and leaf material would dilute and obscure the total THC content given that these parts of the plant have lower THC content than the inflorescence.

These provisions regarding when and what to test are consistent with many state hemp

²⁴ See 84 Fed. Reg. at 58556-57, 58560; 7 C.F.R. § 990.3(a)(2)(i), 990.3(a)(3), § 990.25

²⁵ 84 Fed. Reg. at 58524.

²⁶ NAS Cannabis Report at 44.

production plans already in place.²⁷ Requiring state and tribal hemp production plans to include these elements in their sampling plans will help assure that only true hemp, with very low levels of THC, will ultimately be processed into consumer goods. Assuring THC content is low in the plant should result in lower THC content in hemp-containing finished products that consumers may ingest and inhale.

We understand that requiring total THC concentration to be no more than 0.3%, comprising both THC and THCA, is controversial. Aired Alliance supports AMS's decision to include THCA in the THC calculation as we believe it best reflects the total amount of THC that will ultimately be in the product and is most protective of consumer health. We also believe this total THC calculation aligns with the language of the Farm Bill. The Farm Bill specifies that state and tribal hemp production plans must include a "procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels."²⁸ While the language is opaque in that "post-decarboxylation" is not a test method, we agree with AMS that the most logical reading of this language, that gives effect to every word within this provision of the law, is that Congress intended for state and tribal plans to include a reliable procedure for testing THC where the sample is analyzed after decarboxylation.²⁹ Even high THC potency marijuana will have very little actual THC in the pre-decarboxylated plant because the plant expresses cannabinoids in the acid form. This calculation of total THC is well-established and used in numerous state hemp programs.³⁰

4. Laboratories should be qualified to conduct THC testing

The Rule provides that the laboratories testing hemp for THC content must be registered by the DEA to conduct chemical analysis of controlled substances because a failing sample would, by definition, be marijuana and a Schedule 1 controlled substance.³¹ USDA seeks comment on several aspects of the laboratory testing requirements. The agency is considering establishing a fee-for-service hemp laboratory approval process for laboratories that wish to offer THC testing services.³² These laboratories would be approved by the USDA, AMS, Laboratory Approval Service but also still have to be registered with DEA. USDA is also considering requiring all laboratories testing hemp to have ISO 17025 accreditation.³³

Timely, accurate, reliable laboratory testing is critical to the domestic hemp program. We believe laboratories participating in hemp production programs should be accredited, transparent, and

²⁷ See, e.g., [State of Nevada requires testing within 15 days prior to harvest](#) (accessed Dec. 5, 2019); [State of Kentucky requires testing within 15 days prior to harvest](#) (accessed Dec. 5, 2019); [State of Colorado samples the top 2 inches of plant](#) (accessed Dec. 5, 2019).

²⁸ 7 U.S.C. § 1639p(a)(2)(A)(ii).

²⁹ Generally, statutes should be construed to avoid rendering any statutory language superfluous with each word and clause of a statute operative effect, if possible. *Duncan v. Walker*, 533 U.S. 167, 174 (2001).

³⁰ [Oregon Administrative Rules 603-048: Industrial Hemp](#); (accessed Dec. 5, 2019); [Minnesota Industrial Hemp Program](#) (accessed Dec. 5, 2019); [Hemp in Massachusetts](#) (accessed Dec. 5, 2019); [Arkansas Industrial Hemp Program](#) (accessed Dec. 5, 2019); [Rhode Island Hemp Growth Act, § 2-26-3](#) (accessed Dec. 5, 2019); [Analytical Testing of Colorado Hemp Samples](#) (accessed Dec. 5, 2019).

³¹ 84 Fed. Reg. at 58525.

³² *Id.*

³³ *Id.*

regulated with vigorous oversight. Laboratories in the hemp program should follow uniform processes and procedures to minimize testing differences within the program. Regulators and producers – and the public – should be confident in obtaining a similar result regardless of the laboratory to which a sample is submitted. To that end, we strongly support mandatory DEA registration of testing labs, and encourage development of a USDA laboratory approval process and ISO accreditation to assure uniformity and oversight.

5. Aimed Alliance is concerned about total THC content in consumer products and gaps in regulatory oversight

Aimed Alliance is concerned with lack of regulatory oversight of hemp-derived consumer products in their finished and marketed form. We recognize AMS has promulgated a rule that is within the agency’s traditional agricultural cultivation and production expertise. Once a hemp crop is tested, harvested, and deemed to contain less than 0.3% THC on a dry weight basis, AMS will not follow the product as it is further processed, milled, extracted, and ultimately manufactured into finished consumer products to be sold at retail.

The definition of “hemp” in the Farm Bill, however, includes not just the plant but its extracts, derivatives, and isomers. It is presumed that products derived from hemp, such as CBD-containing foods, supplements, extracts, and tinctures, must not exceed 0.3% THC on a dry weight basis. Products that do have more than 0.3% THC would, presumably, be illegal marijuana under federal law. However, there are no further regulatory mechanisms for the testing or oversight of these finished products to assure they do not exceed this threshold.

This gap in regulatory oversight and uncertainty over the total THC content of finished cannabis-derived products is deeply concerning. While Aimed Alliance strongly supports rigorous control of THC from field to harvest, additional controls and limits are needed to assure that only finished products with very low levels of THC – as expressed in milligrams of total THC in the product as consumed, are available in the consumer market.

We thank AMS and USDA for your significant and thoughtful work to implement a domestic hemp program. We are pleased to support that effort. Should you have any questions, you may contact us at policy@aimedalliance.org or (202) 559-0380.

Sincerely,

Stacey L. Worthy
Counsel