U.S. Hemp Roundtable

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August 13, 2021

The Honorable Chuck Schumer
The Honorable Ron Wyden
The Honorable Cory Booker
U.S. Senate
Washington, DC 20510

Honorable Senators:

The U.S. Hemp Roundtable, the hemp industry's national advocacy organization, is deeply grateful to you for the inclusion of provisions in the draft Cannabis Administration and Opportunity Act ("CAOA") to ensure a regulatory pathway for the sale of hemp-derived cannabidiol ("CBD") as a dietary supplement. Current federal regulatory uncertainty has cast a cloud over the industry, depressing prices and markets, deeply impairing farmers and businesses, and offering no protections for consumer health and safety. The CAOA discussion draft offers a step forward toward realizing a hemp industry that provides economic opportunity to farmers and strong protections for consumers seeking hemp-based wellness options.

We also appreciate the formal process you have provided to encourage stakeholder feedback on the discussion draft, and in that spirit, we offer the following comments as a means to improve the bill and ensure a promising and prosperous future for hemp farmers, with critical protections for hemp and CBD product consumers.

You will notice one central theme throughout these comments: Hemp-derived CBD, as well as other hemp derivatives, have been sold in the consumer marketplace for years, and are non-intoxicating with a strong safety profile when subjected to the same regulatory regime as other dietary supplement and food and beverage ingredients. Accordingly, they should be regulated like any other botanical ingredient. By subjecting hemp-derived ingredients to a uniquely onerous regulatory regime, or continuing to treat them as illegal substances, the draft CAOA not only unfairly burdens hemp farmers, manufacturers and consumers, but it may also encourage black market sales of these products, some of which may be unregulated products that pose safety risks to the American public.

1. INCLUDE A PATHWAY FOR FOOD AND BEVERAGES:

We applaud the discussion draft's inclusion of language that creates a regulatory pathway for the marketing of CBD as a dietary supplement. However, unlike S. 1698, introduced earlier this year by Senators Ron Wyden, Rand Paul, and Jeff Merkley, the CAOA draft does not provide a pathway for the sale of CBD as a food and beverage ingredient. We believe this is a mistake.

First, a large CBD food and beverage market already exists and continues to grow: currently there are thousands of products available to consumers, across tens of thousands of retailers. Nearly two dozen states have stepped up to fill the federal regulatory void, explicitly legalizing the sale of hemp extracts in food and beverages – including large states such as New York, Texas and Florida. But a patchwork of inconsistent regulations has emerged, with varying mandates on labeling, testing and serving sizes, confusing consumers and burdening manufacturers. A consistent federal framework is needed in order to ensure health and safety compliance across all states.

Meanwhile, international organizations and U.S. states have evaluated the publicly-available safety evidence and determined that CBD products can be safely marketed. For example, the World Health Organization determined that pure CBD is "generally well tolerated with a good safety profile" and presents little risk of abuse or dependency potential, recreational use, or public health-related problems.[1] The United Kingdom's Food Standards Agency determined that CBD products can be regulated and marketed as novel foods, provided they meet standards for safety and content, recommending a 70mg daily limit for healthy adults.[2] New York State recently issued regulations that permit the sale of food and beverage products that contain up to 25 mg of CBD per serving.[3]

Finally, true economic opportunity for hemp farmers will only be realized when large food and beverage companies implement their plans to add CBD to their products. States with clear regulatory frameworks, like Colorado, have already seen large producers enter the market to sell products within their borders. The market for hemp biomass for dietary supplements is limited; allowing CBD in food and beverages would bring large, mainstream retailers on board, as well as more traditional consumer packaged goods companies. A new study by BDSA, a leading cannabinoid marketing research group, projects CBD sales to reach $19.5 billion by 2025, with mainstream retail exceeding $15 billion annually -- but that growth is only based on the assumption that FDA will regulate CBD as a food ingredient by 2022.[4]

Accordingly, we urge you to amend the CAOA by including the following language, found in S. 1698, which would permit the regulated sale of CBD and other hemp derivatives, as food and beverage ingredients:

> Section 301 (ll) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331 (ll)) is amended, in the matter preceding subparagraph (1), by inserting "(other than hemp, hemp-derived cannabidiol, or a substance containing any other ingredient derived from hemp)" after "made public."

2. EXPAND PROTECTIONS TO ALL HEMP DERIVATIVES:

The CAOA draft provides a regulatory pathway for the sale of hemp-derived CBD, but not for other derivatives. We strongly disagree with this approach. While CBD is currently the most popular hemp derivative, there is growing interest in others, such as CBN and CBG, and many others are being studied for potential use as a dietary supplement or food. The inclusion of additional hemp-derived compounds is the only way to avoid future regulatory uncertainty and the same dilemma we are currently facing with CBD, with respect to the Investigational New Drug ("IND") preclusion.

Their inclusion in the CAOA is also critical as a matter of consumer protection. By clarifying that these other hemp-derived compounds can also be used in dietary supplements, firms marketing these products as dietary supplements would be subject to all safety-related requirements applicable to dietary supplements, including the obligation to ensure ingredients are safe and not adulterated, good manufacturing practices are followed, products are labeled in accordance with FDA regulations, and the laws regarding adverse event reporting and recordkeeping are followed. Given the very low number of adverse events associated with dietary supplements since the passage of DSHEA, we believe the safety mandates imposed by this law as well as the food safety requirements under the Food Safety and Modernization Act provide ample protections for consumers – and sufficient authority for FDA to pursue enforcement against firms that violate these laws and put consumers at risk.

To the extent Congress is concerned about the impact on drug development, this issue is not unique to CBD or other hemp-derived compounds. FDA regulates products based on intended use, and for decades, ingredients such as fish oil and multi-vitamins have been sold as both dietary supplements and drugs without a negative impact on drug development. Provided hemp-derived compounds are promoted only for the intended uses permitted under the FD&C Act – which we believe the majority of mainstream products are already doing – then concerns regarding the impact on drug development are unfounded. Drug companies can continue to develop and market products to prevent, treat, mitigate, and cure disease, and supplement companies can continue to develop and market products to support health and wellness.

It is important to note that due to decades of prohibition before the 2018 Farm Bill, hemp derivatives could not be legally marketed as dietary supplements or food. FDA's current position with respect to CBD and the IND preclusion, coupled with the current language in the CAOA, will ultimately penalize hemp farmers and manufacturers, unfairly favor pharmaceutical companies, and block consumers from accessing popular, safe, and affordable general wellness products.

Accordingly, in addition to the amendment offered in Section 1 above, we urge you to amend the CAOA to align it with S. 1698 as follows:

> Section 201(ff)(3)(B) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(ff)(3)(B)) is amended in each of clauses (i) and (ii) by inserting "(other than hemp, hemp-derived cannabidiol, ***or a substance containing any other ingredient derived from hemp***)" after "an article".

3. ALLOW ALL FORMS OF SAFETY EVALUATION FOR CBD PRODUCTS:

The CAOA, as currently drafted holds CBD to a singular safety evaluation standard in stark contrast to all other dietary supplement ingredients. We strongly object to this limitation; as discussed above, hemp-derived CBD should be treated akin to any other botanical ingredient, subject to the same regulatory regimes.

Specifically, the discussion draft requires CBD manufacturers to provide a new dietary ingredient notification ("NDIN") for any supplement that contains CBD. We have no objection to the use of NDINs where appropriate, but as written, the current language in the discussion draft prevents CBD-containing supplements from utilizing the food supply exemption under Section 413(a)(1) of the FD&C Act.[5] Therefore, dietary supplements that contain CBD ingredients that have already undergone an extensive safety evaluation and have been introduced into the food supply, either through an independent conclusion of GRAS (often referred to as "self-affirmed GRAS") or through a successful GRAS notification, would also be required to be the subject of an NDI notification. That is also inconsistent with current law.

We see no reason why these legal pathways to market should not be available for hemp-derived CBD. Food ingredients are subject to a higher safety standard (reasonable certainty of no harm) than dietary supplement ingredients (reasonable expectation of no harm). Additionally, there are hundreds -- if not more -- ingredients used in food and dietary supplements that were introduced into the market through the GRAS process, and to date there has been no indication that any of these ingredients pose risks to consumers simply because they were not evaluated by FDA. Hemp-derived CBD (and other hemp-based ingredients) should not be singled out and prevented from utilizing the existing legal pathways available to all dietary supplements.

It is important to note that an NDIN-only pathway presents other significant challenges for the emerging hemp industry, FDA, and consumers alike. Requiring NDINs for each and every supplement that contains CBD poses unnecessary and costly burdens, especially on small hemp processors and manufacturers. We, along with many others in the industry, believe that when Congress enacted DSHEA, it did not intend to require a unique NDIN for every supplement that contains an NDI. Further, FDA itself acknowledges that multiple, product-based NDINs are not always required. The NDI Revised Draft Guidance (2016) expressly recognizes an "NDI master file" approach, which allows a single NDIN to cover conditions of use that encompass multiple products, noting that "[w]e accept notifications that cover multiple dietary supplements and include safety data for a range of doses, daily intake levels, and/or other variations in conditions of use."[6] NDIN Master files were also discussed during the May 2019 Public Meeting to Discuss Responsible Innovation in Dietary Supplements.[7] More importantly, it is unclear how FDA would have the resources to review and manage the vast number of NDINs contemplated under the current language in the CAOA, thereby creating an unfair disadvantage for CBD supplements that is not applied to any other botanical extract on the market. Finally, safety data for an NDIN often involves toxicity studies on animals, which forecloses the possibility of marketing such products as cruelty-free or in some cases obtaining vegan certification, thereby excluding an important and growing consumer base for CBD products.

The existential problem with an NDIN-only approach could not have been made clearer than with FDA's recent rejection of two NDINs for full spectrum hemp extracts.[8] The two companies that submitted these NDINs provided comprehensive and compelling safety data, and cooperated extensively with FDA's requests throughout the process. That the submissions of these two industry leaders were rejected is an unmistakable sign that the FDA is unlikely to approve any NDIN for a CBD supplement.

For these reasons, an NDIN-only approach is not feasible and would limit opportunity for consumer and diversity in offerings in marketplace, while also unfairly disadvantaging the CBD dietary supplement industry by imposing unique and unwarranted regulatory burdens on CBD.

4. PROVIDE A MORE COMPREHENSIVE PROCESS FOR ESTABLISHING DAILY CBD SERVING LIMITS:

Although we support the concept of a daily serving limit for CBD, we have serious concerns about the approach outlined in the CAOA draft. We strongly oppose the inclusion of language that would permit FDA to establish a daily serving limit through an Interim Final Rule. A crucial issue such as this must be subject to standard notice-and-comment rulemaking procedures to ensure there is ample opportunity for stakeholder input and scientific study. It is also important to note that Section

201(ff)(3)(B) of the FD&C Act already provides HHS and FDA with rulemaking authority as it pertains to articles subject to the IND preclusion. But addressing this through an Interim Final Rule as suggested by the draft is deeply problematic –it should be subject to standard notice-and-comment rulemaking procedures to ensure ample opportunity for stakeholder input and robust discussion of the science to support the daily serving limit.

We also must share our concerns about the overall impact of any daily serving limit. Setting such a limit, via regulation or otherwise, would be unprecedented for a dietary supplement ingredient – illustrating yet another example of the unique regulatory burdens placed on CBD when compared to other botanical dietary ingredients. Any such number proposed by FDA is likely to be understood by retailers, consumers, and others as the "de facto" limit, even if it is never formally adopted or finalized by FDA.

As discussed above, the United Kingdom's Food Standards Agency issued guidance recommending a maximum of 70 mg/day of CBD in food and supplements for healthy adults – demonstrating that there is sufficient safety data upon which a daily serving can be based. While we believe this limit is both reasonable and science-based, we are concerned that FDA likely to propose an arbitrary number that is significantly lower. A serving limit that is inappropriately low will cause significant disruption in the industry and impair opportunity for U.S. hemp growers. Worse, it could encourage unregulated black and gray markets for popular CBD products with serving levels that consumers currently depend on.

Accordingly, any potential daily serving limit should be the subject of robust and comprehensive discussion between the industry and FDA – prior to any public release – and be subject to the standard notice-and-comment process. Therefore, we urge you to remove current language in the CAOA discussion draft allowing FDA to set a daily serving limit for CBD in an expedited interim final rule fashion, in order for this issue to be fully vetted by industry, academia and scientists, in conjunction with FDA.

5. REFINING THE DEFINITION OF HEMP TO ENSURE TREATMENT OF INTOXICATING COMPOUNDS AS CANNABIS:

The CAOA offers an historic opportunity to refine the legal meaning of "hemp." When Congress passed the 2018 U.S. Farm Bill, the intention of the lead drafters of the hemp sections was to draw a clear line between non-intoxicating hemp and intoxicating cannabis, such as marijuana. At the time, this was addressed by developing a demarcation line of 0.3% delta-9 THC concentration on a dry weight basis.

In the intervening years, two important developments occurred. First, many farmers struggled to grow hemp that tested at or below this limit, and were forced to destroy their crops. In addition, many processors discovered that the THC levels in hemp temporarily spikes during the extraction process, which federal agencies consider a violation of the Controlled Substances Act. The hemp industry has joined leading national farm groups and state agriculture commissioners to urge federal policymakers to change the delta-9 THC concentration limit for hemp crops and in-process extracts to 1.0% on a dry weight basis.

However, at the same time, concern has arisen about the proliferation of intoxicating cannabinoids, particularly delta-8 THC, which are sold at retail stores under the guise of hemp with no appropriate consumer protections. We believe that these

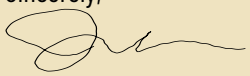
products should be regulated as adult-use cannabis to address necessary health concerns, while ensuring the safety of these products for adults who choose to purchase them.

We propose that the CAOA be amended to set two new limits for hemp and hemp products. All hemp tested in the field and in processing facilities would comply with a 1.0% delta-9 THC concentration limit. All hemp products intended for sale to consumers must have a total THC concentration (including delta-8, delta-9 and delta-10 THCs) that does not exceed 0.3%. The language to effectuate these changes is outlined below:

> The term "hemp" means 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 1 percent on a dry weight basis, except that a hemp product shall have a total THC concentration of not more than 0.3 percent on a dry weight basis.
>
> The term "Total tetrahydrocannabinol" or "total THC" means the sum of all tetrahydrocannabinols, including, but not limited to delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, and delta-10 tetrahydrocannabinol, and is calculated using the following formula: Total THC = (0.877 x tetrahydrocannabinolic acid) + the sum of all tetrahydrocannabinols, including, but not limited to delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, and delta-10 tetrahydrocannabinol, whether naturally occurring or produced through chemical conversion or synthesis.
>
> The term "hemp product" means a finished product derived from, or made by, processing hemp plants or a substance containing any other ingredient derived from hemp. The term "hemp product" does not include hemp extracts that are processed in any way for use in the manufacture of a hemp product, but have not yet been packaged as a finished products and are not intended for sale to consumers.

On a similar note, we are concerned about CAOA's Section 5906(a)2), which permits a tax drawback for cannabis extracts that contain no more than 0.3% delta-9 THC on a dry weight basis. This would seem to make murky the distinctions between hemp and marijuana and promote growing marijuana plants for the purpose of competing with the hemp industry. Such an outcome would be devastating to hemp farmers and pose enormous complications for regulators and law enforcement. Finished hemp products should only be derived from hemp plants.

Sincerely,



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[1] https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf<https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf>
[2] https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers;
[3] Cannabinoid Hemp_0.pdf (ny.gov)
[4] POLITICO Pro | Newsletter
[5] Under Section 413(a), a dietary supplement which contains an NDI is deemed adulterated unless: (1) the dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered, or (2) a NDI notification is submitted to FDA at least 75 days before the supplement containing the NDI is introduced or delivered for introduction into interstate commerce.
[6] https://www.fda.gov/media/99538/download
[7] https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-discuss-responsible-innovation-dietary-supplements
[8] FDA objects to CBD-related safety notifications (naturalproductsinsider.com)