Chairman Bernard Sanders
U.S. Senate Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

Ranking Member Dr. Bill Cassidy
U.S. Senate Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

Chairwoman Cathy McMorris Rodgers
U.S. House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Ranking Member Frank Pallone, Jr.
U.S. House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

August 18, 2023

Re: American Trade Association for Cannabis & Hemp's (ATACH) Response to: Congressional Request for Information on the Regulation of CBD

Thank you for the opportunity to respond to the committee's Request for Information (RFI).

The American Trade Association for Cannabis & Hemp ("ATACH") is a 501(c)(6) trade organization registered in Washington, DC, founded in 2014 to support and protect regulated cannabis businesses, promote consumer safety of marijuana and hemp products, and promote the expansion, protection, and preservation of businesses engaged in the state-legal trade of medical and recreational cannabis and hemp based products. We believe the United States should adopt a comprehensive regulatory system that involves both non-intoxicating and intoxicating substances derived from the cannabis plant.

ATACH's Cannabinoid Council consists of hemp and cannabinoid businesses, attorneys, analytical researchers, laboratories, and former regulators, each with extensive knowledge about the hemp-synthesized intoxicant phenomenon. ATACH has a historic Memorandum of Understanding with ASTM International which seeks to develop international standards for cannabis, its associated products, and its processes, and ATACH has participated in the National Conference on Weights and Measures (NCWM) in support of adoption of the first cannabis standard, which will appear in the National Institute for Science and Technology Handbook 130 Uniform Packaging and Labeling Regulation and Uniform Regulation for the Method of Sale of Commodities. ATACH recently published an in-depth analysis of hemp-synthesized intoxicants and a set of detailed recommendations for regulators in our paper, *Toward Normalized Cannabinoid Regulation*, which is available online and submitted along with this response.[1]

[1] https://atach.org/wp-content/uploads/2023/06/ATACH-Paper-Toward-Normalized-Cannabinoid-Regulation.pdf

ATACH's Key Positioning:

The regulation of cannabidiol ("CBD") should not permit intoxicating products under the guise of CBD or add to the proliferation of the massive unregulated gray market in hemp-synthesized intoxicants that has taken place due to the Farm Bill. Instead, non-intoxicating CBD products must be distinguished from intoxicants, and a real regulatory pathway must be provided federally for CBD products, just like other products in the US intended for human consumption. Cannabinoids produced from the cannabis plant should be regulated by the final product, with standardized considerations for dietary supplements and for food and beverage.

Fundamentally, a CBD product that is marketed, labeled and sold as such, should not be permitted to get a consumer intoxicated. In addition, it must also be accounted for, as a matter of law and regulation, that CBD products should not be chemically converted into synthetic intoxicating drugs and represented as "hemp" products, as it will cause confusion given that most consumers are often told that hemp products are not intoxicating.[2] Customer confusion can lead to involuntary consumption of intoxicants. We are very wary of those that seek to include products with intoxicating levels of THC within a CBD framework, and warn the committee that some trade organizations, such as the US Hemp Roundtable, have openly taken this untenable position advocating for THC levels that are equal to serving size recommendations in several marijuana legalization states.[3] Some organizations seek to minimize regulatory oversight for intoxicants by promoting a less regulated system than that which is already established in states.[4]

ATACH takes the position that non-intoxicating products that are intended for human consumption and are made from hemp — as well as products that include CBD — should be regulated through the Food and Drug Administration (FDA) and merit a federal pathway for commercialization of products and the promotion of public health and safety.

We also take the position that simply regulating non-intoxicating cannabinoids alone (such as CBD) is not sufficient when the plant they come from – the cannabis plant – is in urgent need of a federal regulatory solution. Its uses are too widespread, and carry too many broad social implications, such that the federal government should now play a role along with states in the regulation of one of the most widely used intoxicants and wellness products in the country. Any partial solution will fail to address the need for a

---

[2] Of 84 off-the-shelf CBD products tested, THC was found in 18 products. Katie Glenn, "As CBD Use Rises, Clinical Trials Needed to Determine Safety, Efficacy in Heart Disease Patients," *American College of Cardiology*, September 6, 2022, https://www.acc.org/About-ACC/Press-Releases/2022/09/06/14/48/As-CBD-Use-Rises-Clinical-Trials-Needed-to-Determine-Safety-Efficacy-in-Heart-Disease-Patients

[3] Vermont, Virginia, and Connecticut established adult serving sizes for THC at 5mg per serving. Massachusetts set it at 5.5mg per serving, which is the same as the Hemp Roundtable's recommended THC level for "low-THC" product recommendation. See *The Network for Public Health Law, Cannabis Regulation Fact Sheet*, THC Limits for Adult-Use Cannabis Products, October 10, 2022, https://www.networkforphl.org/wp-content/uploads/2022/11/THC-limits-for-Adult-Use-Cannabis-Products.pdf

[4] "The War on Hemp," US Hemp Roundtable, March 12, 2023, https://hempsupporter.com/news/the-war-on-hemp-we-need-your-help/, see also "What is delta-8 THC? What to know about the safety of 'diet weed' (and if it gets you high)", *USA Today*, April 15, 2023, https://www.usatoday.com/story/news/health/2023/04/15/what-is-delta-8/11521735002/

comprehensive reform that can account for the many important uses of the cannabis plant. ATACH is offering what we believe is the most appropriate regulatory solution for regulating cannabis.

When it comes to regulating cannabis products, we agree in part with the FDA's position as outlined in a memo issued to members of Congress in January of 2023. In its memorandum, the FDA argued that a new regulatory pathway is required, and we agree that may be the case when it comes to inhalable products. The FDA further called for a multi-agency regulatory framework to safely regulate cannabis-derived products in a manner that adequately addresses consumer protection risks and protects the public. Given the total number of cannabinoids in the plant and the number yet to be fully understood, it seems likely there will be additional non-intoxicating cannabinoids that will also be in need of evaluation and regulation similar to CBD.

However, while we support FDA's oversight of non-intoxicating cannabinoids, we do not believe that FDA should oversee regulation as the primary regulator of intoxicating cannabinoid products. The US already has a proven model for the regulation of intoxicants – alcohol – the lessons from which should be utilized in the case of the intoxicating products that contain cannabis, and regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB). We do not believe the FDA should create an entirely new regulatory regime along with a new regulatory body within the agency to regulate intoxicants, when the actual purpose of the agency is to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. Similarly, the FDA has existing pathways for food and dietary supplements, which are adequate to regulate cannabis when used in those forms and for those purposes, which we believe it can do given its standards for other products it currently regulates.

When it comes to intoxicants such as delta-9 THC, our organization's ethos is to "tax and regulate marijuana like alcohol." Consistent with the nation's regulatory model for alcohol, as well as the FDA's assertion that a cross-agency strategy is necessary to safely regulate cannabis-derived products, ATACH respectfully believes that the TTB should serve as the primary regulatory authority for intoxicating phytocannabinoid products in coordination with states. We detail this proposal below, so that intoxicants do not inadvertently fall outside the purview of regulation. We believe the FDA has a critical role setting serving sizes, assisting with labeling and testing standards, and it should regulate all non-intoxicating ingredients contained in any otherwise-intoxicating consumer product. We further take the position that fully synthetic analogs of THC are still controlled substances within the meaning of the Controlled Substances Act, and that the Farm Bill should not be used to skirt or weaken state level regulation, or the Analogue Act, such that fully synthetic products continue to proliferate.

Current Market Dynamics

1. What does the current market for CBD products look like? Please describe the types and forms of products available, manufacturing practices within the industry, market supply chain, how products are marketed and sold, the types of cannabinoids used in products, the marketed effects of CBD products, and the range of CBD doses currently found in the market.

Response:
Products containing CBD encompass a broad range, and terminology can be inconsistent. For our response, we consider CBD products to fall into three categories, based not on the presence of CBD, but rather the presence of other cannabinoids along with CBD.

CBD Isolate. A "CBD isolate" is the isolated compound containing CBD. It is typically produced through a process of extracting CBD from the cannabis plant, then purifying it to remove all other compounds. The result is a crystalline powder that is composed almost entirely of pure CBD. This formulation of CBD isolate is considered to be THC-free, because it doesn't contain any other cannabinoids or compounds. Proper processing can ensure removal of trace amounts of THC, which we define below. CBD isolate is often added to other products.

Broad Spectrum CBD. "Broad Spectrum CBD" is a type of CBD product that contains a range of naturally occurring compounds found in the cannabis plant, but which excludes THC.

Full Spectrum CBD. "Full Spectrum CBD" describes a type of CBD product that contains CBD and a wide variety of other naturally-occurring compounds found in the cannabis plant, including intoxicants, as well as terpenes and flavonoids.

Hemp Synthesized Intoxicants. Intoxicating cannabinoids that are chemically synthesized from a hemp-derived CBD molecule, including delta-8 THC, delta-9 THC, delta-10 THC and others. This is not a CBD product as such, but rather is produced from CBD.

ATACH believes that FDA should regulate CBD isolates, consumable products infused with CBD isolates, and broad spectrum CBD products when they meet minimum requirements limiting the presence of various THCs.

2. How has the market changed since the passage of the 2018 Farm Bill?

Response:
When the Farm Bill passed in 2018, many lawmakers expected that CBD would continue to be a popular product. A small industry sprang up, including hemp farmers, processors, and CBD-focused retail outlets, some of which marketed themselves as "dispensaries." Production increased in anticipation of a robust market, but sales slumped and producers found themselves with surplus CBD. Many in the former CBD industry began to convert CBD into intoxicants such as delta-8 THC and later delta-9 THC, which were more commercially viable and largely unregulated, and introduced them into retail channels and through interstate commerce.

Initially, those hemp-synthesized intoxicant products were not known in either the illicit or the state-regulated industries. Rather, they were introduced through the existing CBD farm-to-retail store infrastructure, and first appeared on store shelves in CBD retail shops. As interest quickly spread, those same products also began to appear in gas stations and convenience stores outside state marijuana regulatory systems. Unclear regulations and hemp's new status under federal law further enabled

interstate sales and web-based ordering of intoxicating products direct to consumers through common carriers such as the US Postal Service.

Four years later, we now see a new generation of producers with more sophisticated businesses moving into the market. This new wave of hemp-synthesized intoxicants producers includes those that still operate outside of a state regulated system, but also some state-licensed marijuana cultivators, and marijuana beverage and edible processors and brands that are now looking more closely at hemp-synthesized intoxicant ingredients or even launching new lines of intoxicating products.

In addition, where early interest in hemp-synthesized products began with delta-8 THC, the current market has embraced delta-9 THC, which is the primary intoxicant found in marijuana. Delta-9 THC in intoxicating quantities can arguably be produced from hemp without regulation, rendering delta-9 THC at the same time both uncontrolled under the Farm Bill and controlled by the Controlled Substances Act. At a recent cannabis conference, it was estimated that delta-9 THC (often referred to as D9 among hemp producers), accounts for 90% of intoxicants sales versus delta-8 THC in the hemp intoxicants space. Similarly, a recent study on Texas' hemp-derived products market found that in 2022, the market was valued at a staggering $8 billion dollars, 85-90% of which came from the sales of intoxicants, with CBD accounting for the remaining 10-15%.[5]

It is worth noting that part of the growth of the business community was fueled by the fact that companies are financially incentivized to favor hemp intoxicants over marijuana. The IRS published an FAQ[6] on hemp products that stated it would not apply the Internal Revenue Code's Section 280E tax penalty to hemp product producers.[7] By contrast, this same provision has been interpreted to prevent state-authorized marijuana businesses from taking ordinary and necessary business deductions on their income taxes, and poses an enormous burden for state-licensed marijuana businesses. Similarly, banks are not as limited with respect to hemp (a federally-recognized crop) in the same way they are with respect to marijuana (a Schedule I controlled substance), though banking problems continue to persist in the hemp industry due to the controlled status of marijuana.[8]

Additionally, producers of marijuana products are very limited in the number of retail outlets–dispensaries–which are accessed by a relatively small number of consumers compared with most retail industries. By contrast, hemp producers make their products available in many retail outlets, often where alcohol is sold, or online.

During this period, some states elected to establish consumer protection standards over hemp-synthesized intoxicants. Very generally, these state systems place minimum safeguards over hemp intoxicants such as minimum age requirements for purchase and possession, advertising, marketing, testing, or labeling

---

[5] "Texas Cannabusinesses Surpass $8B in Revenue, New Economic Report Says," *Yahoo! Finance*, August 10, 2023, https://finance.yahoo.com/news/texas-cannabusinesses-surpass-8b-revenue-112000233.html#:~:text=The%20Whitney%20Economics%20report%2C%20titled,employed%20more%20than%2050%2C000%20workers

[6] See "Cannabis Industry Frequently Asked," Internal Revenue Service, IRS.com, https://www.irs.gov/businesses/small-businesses-self-employed/cannabis-industry-frequently-asked-questions

[7] 26 U.S.C. §280E. Expenditures in Connection with the Illegal Sale of Drugs.

[8] Emily Flitter, "Hemp Industry Is Cleared to Do Business With Banks," *New York Times*, December 3, 2019, https://www.nytimes.com/2019/12/03/business/hemp-producers-banks.html

standards to prohibit hemp intoxicant products from appealing to minors. States that adopted some of these very basic safeguards, which essentially legalized and lightly regulated hemp synthesized intoxicating products, include Louisiana, Kentucky, Tennessee, Florida, and West Virginia.

Other states used their existing marijuana regulatory systems to provide a more comprehensive regulatory framework for hemp-based intoxicants, which ATACH favors and is in keeping with current legalization efforts. Some of these states moved to ban products pending further determinations by the agency, while others allowed them through the regulatory system for intoxicating marijuana products. These include Utah, California, New York, Washington, Connecticut, Maryland, Michigan, Nevada, Oregon, Vermont, Colorado, and Minnesota.

The market has changed dramatically since passage of the 2018 Farm Bill. The hemp consumer products market has transitioned from one driven by interest in non-intoxicating CBD as a wellness product appearing in food and supplements, to the discovery and rapid spread of intoxicating delta-8 THC and other synthetics as interest in CBD waned, and finally, to a shift to marijuana's primary psychoactive cannabinoid–delta-9 THC–as more businesses entered the market and popularity continued to spread. States have responded, many of which regulate or at least tolerate without regulation, hemp-synthesized intoxicants. Now, some companies are finding that hemp-derived products can offer better access to a wider market with a lighter financial burden imposed by federal tax law. Unfortunately in some cases the effect is to undermine state regulations in place for marijuana products, in that products that were limited to state adult-use marijuana regulatory systems are now sold outside that system. The result is a complicated mix of state legalization and regulation, while at the same time the federal government has effectively deregulated the products due to its lack of enforcement or regulatory structure. This creates significant consumer, regulatory, and enforcement confusion, with potential consequences for public health and safety.

3. How is the lack of national standards for CBD products affecting the market?

Response:

The fundamental problem that the hemp industry members of our organization face is the lack of effective, uniform regulation. This has led to several problems for consumers:

a. Without limiting or defining what a "derivative of hemp" is under the definition created in the 2018 Farm Bill, and otherwise removing "products derived from hemp" from the scope of the Controlled Substances Act, Congress appeared to open the door to commercial availability of non-intoxicants such as CBD. In doing so, Congress also inadvertently opened the door to the emergence of intoxicating cannabinoids such as delta-8 THC, delta-9 THC, delta-10 THC, and many others – all arguably "derived from hemp." FDA's statements that these substances have not been approved for consumption have not impacted the market of small businesses and marijuana companies that produce and sell them, and there has otherwise been no effort to create a framework for production, distribution, packaging, or labeling. Similarly, DEA's interim final rule and public statements that they deem products converted from hemp into various THC isomers, including Delta-9 THC, as "synthetically derived" Schedule I controlled

substances have not appeared to have any chilling effect on the national market for hemp intoxicants, and in any event, there has been no enforcement effort on the part of the DEA in the face of what is now a multi-billion dollar industry in hemp-synthesized intoxicants.[9]

b. The definition of hemp is that it contains less that .3% delta-9 THC on a dry weight basis, and because there has been no further regulatory effort to distinguish between wholesale production standards and those for finished retail products, that standard has been regularly misapplied to products such as edibles, beverages, tinctures, and vaporized products. These products are often measured in grams or ounces, while the presence of intoxicants like delta-9 THC is measured in *thousandths* of a gram, or milligrams. When manufacturers apply the 0.3% standard to the total weight of the consumer product, the product can include an enormous amount of THC, far exceeding potency limits even in regulated state marijuana programs. For instance, most marijuana programs in the US limit the intoxicating presence of delta-9 THC to either 5 or 10 mg per serving, with most at 10mg, including Colorado, Washington, California, Nevada, and others. However, if the limit were simply based on "less than 0.3% dry weight," without a physical limit on the amount of THC and no limit on serving sizes, the product can contain a very high amount of THC – far greater than the serving size of a regulated marijuana product. This has led to a wide array of intoxicating products that are sold online and in retail stores that advertise themselves to be "Farm Bill Compliant," with the implication being that the amount of THC they contain meets the requirements of federal law. Images showing a sample of these products are also submitted to the committee along with this response.

c. Finally, the lack of regulations have frustrated state efforts to manage the emergence and popularity of hemp-based intoxicants. The 2018 Farm Bill created a national market for the hemp trade, and states should have national guidance on testing standards, label contents, serving size recommendations, and other factors that can support their efforts to regulate.

Pathway

4. Please comment on the concerns FDA has raised with regard to regulating most CBD products through existing pathways (i.e., conventional foods, dietary supplements, and cosmetics), and FDA's view that there is a need for a new regulatory pathway for CBD products. If existing regulatory pathways are sufficient for regulating CBD products, please explain how these existing pathways can be used to address the concerns raised by FDA, as appropriate.

Response:

[9] "Texas Cannabusinesses Surpass $8B in Revenue, New Economic Report Says," *Yahoo!Finance*, August 10, 2023, https://finance.yahoo.com/news/texas-cannabusinesses-surpass-8b-revenue-112000233.html#:~:text=The%20Whitney%20Economics%20report%2C%20titled,employed%20more%20than%2050%2C000%20workers

ATACH does not believe a substance-specific framework is appropriate for all cannabis products. Cannabis products including naturally-derived cannabinoids should be generally regarded as safe (GRAS) when used as food, and treated as a supplement when used as a supplement. However, we believe the FDA should consider a new pathway for inhalants, since the regulatory considerations are so unique.

Cannabis products as GRAS. Marijuana and extracts containing cannabinoids have been in common use as traditional medicine in various cultures for the past 5,000 years of recorded human history. They appeared in the United States and were commonly available in the 19th century as a natural medicine. They were legalized under state laws beginning in 1996, and today are by far the most commonly used federally-illicit drug in the U.S. in an industry that generates multiple tens of billions of dollars each year in largely unregulated and untaxed activity. Three out of 4 states allow use for medical purposes, and approximately half allow adults to consume daily for intoxication. The purpose for taking cannabis products can be broad, but roughly fall into these two categories: medicinal and intoxicating (or "adult-use"). As such, use has been entirely unregulated at the federal level, yet marijuana and its extracts have shown a remarkable safety profile in both categories, especially compared with other licit and illicit drugs. When incidents are reported, it is often due to poor manufacturing practices or inaccurate labels, which are increasingly regulated by states. This ancient and natural substance should not be treated as a new drug - it is in fact one of the oldest drugs we have.

As a result, ATACH believes that when used in food, marijuana and extracts containing cannabinoids derived from the plant should be designated as GRAS through its common use and human experience. Manufacturers and distributors of dietary supplements containing more than trace amounts of cannabinoids or marijuana ingredients (explained in our response to #5, below) should be responsible for ensuring that their products are not adulterated or misbranded before marketing, in compliance with requirements found in the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by DSHEA and FDA regulations.

The FDA should further recognize certain non-intoxicating cannabis derivatives as dietary supplements under the Dietary Supplement Health and Education Act (DSHEA). As such, these products would have to adhere to specific labeling requirements and good manufacturing practices. We believe the FDA should regulate CBD similarly to other herbal products such as St. John's wort when used as a supplement.

FDA should not approve marijuana or naturally-derived cannabis food or supplement products before they enter the market. If a cannabis product contains a new dietary ingredient (NDI) not present in the food supply in its unaltered form and it is not a cannabis product, the manufacturer or distributor should be required to notify the FDA before introducing such a product into commerce. This notification should include information supporting the company's conclusion that the NDI-containing supplement can reasonably be expected to be safe.

Finally, it is worth pointing out that simply because cannabis would be considered GRAS when a food or when it is used as a supplement, the FDA would still play a significant role in areas of health and safety of products. While the FDA doesn't approve dietary supplements for safety or efficacy before they are available for sale to consumers, it does monitor them once they're for sale. If there are safety concerns, the FDA can take post-market action.

Scope

5. How should CBD and/or cannabinoid-containing hemp products be defined?

Response:

A CBD product or other cannabinoid-containing product is a "cannabis product" as the term is used by ASTM International, which we adopt here.[10] Such products should be considered to contain CBD or other cannabinoid if they contain more than a trace amount of CBD or other cannabinoid. FDA should not regulate products that contain more than trace amounts of THC or other intoxicating compound derived from the cannabis plant.

ATACH believes the "trace amount" should be determined by research that can examine daily intake and identify a safe threshold for consumption. "Trace amount" should mean that it is below the threshold for misuse, overdose, accidental overconsumption, inaccurate dosage, or other risk to the public. Until research can be conducted to meet the requirements for FDA in establishing a different standard needed to meet these goals, we suggest no more than 0.5 mg per individual package of delta-9 THC or its equivalent total THC concentration, in order to be deemed a non-intoxicating cannabinoid product regulated by FDA.[11] A comprehensive approach to calculating a total THC concentration, or "Total Intoxicating Cannabis Content" ("TICC") amount is discussed below and further throughout our response. Any product containing more than 0.5 mg per individual package of delta-9 THC or its equivalent TICC should be deemed an intoxicating or potentially intoxicating cannabis product, and regulated by the TTB in coordination with state regulators.

Unfortunately there is no published research based in the US that identifies a threshold amount of THC needed for impairment in every case. We base our recommendation of 0.5 mg delta-9 THC (or its equivalent) per individual package based on member deliberation, an understanding of the production of intoxicating products, and this figure was further corroborated by four studies based in the EU and Australia that examined both the lowest observed "adverse" effect level, and the dosage level that led to no "adverse" effect level based on daily consumption.[12] These studies showed a great deal of consistency,

---

[10] ASTM D8441/D8441M-22, *Standard Specification for International Symbol for Identifying Consumer Products Containing Intoxicating Cannabinoids*, https://www.astm.org/d8441_d8441m-22.html

[11] It is important to note that there are several different types of THC, each intoxicating at different levels, where most cannabis consumers are familiar with the potency of delta-9 THC, which is the primary intoxicant in marijuana. These various levels of potency based on THC type should be accounted for in any regulatory system. ATACH has proposed a labeling standard for intoxicating cannabis-containing products. The standard requires that all intoxicants in the final product should be included to result in a "Total Intoxicating Cannabis Content" ("TICC") figure. That figure is then compared with a standard serving size of delta-9 THC (similar to how medical practitioners compare relative potency of different types of opioids), to result in a "delta-9 equivalency" or "DNE." For example, a product might contain delta-8, delta-9, and delta-10 THC in a packet of gummies. The total amount of all three (including a conversion from THCa where appropriate) results in the TICC for the product. That potency is compared with a 10mg dose of delta-9 THC, which is the primary intoxicant in the marijuana plant and familiar to nearly all intoxicating cannabis consumers. This could be refined through affinity studies in conjunction with consumer feedback. We chose 10mg delta-9 THC because it is a fairly standardized serving size in state-regulated medical marijuana and adult use legalization programs, and familiar to consumers.

[12] Croatian Food Agency, HAH 2011, determined to be .5mg/day, European Industrial Hemp Association (EIHA 2021), equivalent to 0.56mg, Food Standards Australia New Zealand (FSANZ 2002, FSANZ 2012) equivalent to .48

each at or near 0.5mg THC as remaining below detectable levels for an adult. We believe this is a good starting point for regulators, but should be modified if results from further studies become available and indicate a different level is optimal.

What compounds should be included and excluded from a regulatory framework?

Response:
FDA should have direct regulatory authority over all non-intoxicating cannabinoids including CBD (inclusive of CBD isolate and broad spectrum CBD products). TTB should be responsible for intoxicants derived from the cannabis plant when present in more than trace amounts. This likely includes "full spectrum" CBD products, which currently do not have a consistent federal definition and are sometimes used as intoxicants. Fully synthetic intoxicating cannabinoids should remain controlled substances and within the jurisdiction of the DEA until a comprehensive framework for federal cannabis legalization is contemplated.

> *a. Should Congress or FDA limit the amount of intoxicating or potentially intoxicating substances produced by Cannabis sativa L. in food and dietary supplements?*
>
> **Response:**
> Yes. They should not be allowed in food and dietary supplements except in trace amounts, unless they are produced and marketed for that purpose, and are regulated by TTB with FDA's assistance pursuant to an MOU, similar to the MOU related to alcohol.
>
> *What products, if any, should not be allowed on the market?*
>
> **Response:**
> ATACH believes there is room in the marketplace for both non-intoxicating and intoxicating cannabinoids, and consumers strongly support their availability – but sensible regulation is needed.
>
> As stated, food, beverages, and dietary supplements should not be intoxicating unless they are specifically intended for that purpose. Products that are not intended to be intoxicating should not contain more than trace amounts of any intoxicating cannabinoid. Products that are considered to be intoxicating should be regulated by TTB in coordination with states, similar to alcohol.
>
> ATACH believes that fully synthetic intoxicants and other THC analogs derived from hemp should remain controlled substances. Like designer drugs in the 1990's, there are many possible variations of these drugs creating significant regulatory and law enforcement challenges, their potency and safety profiles can be a danger to consumers, and their likelihood of harm is far greater than their potential benefit when compared with a narrower set of better-understood phytocannabinoid alternatives, delta-8, delta-9, delta-10, and CBN.

---

mg/day, and Leson Environmental Consulting found .5mg/day commissioned by the North American Industrial Hemp Council (Grotenhermen et al. 2001).

How should these substances of concern be addressed?

Response:
They should remain controlled substances unless it can be shown they can qualify as intoxicants similar to established phytocannabinoids, and then moved from DEA to TTB for oversight.

Which substances, if any, warrant greater concern?

Response:
Analogs of THC that are created using semi-synthetically produced intoxicants and transformed into fully synthetic compounds warrant the most concern, and should remain controlled substances and merit further study.

b. How should Congress or FDA identify appropriate limits for THC and other cannabinoids in finished products? Relatedly, how should a framework account for "total THC," including tetrahydrocannabinol acid (THCA), in FDA's regulation of intermediate and finished products?

Response:
We support an approach that identifies when a "trace amount" of any cannabinoid is present, as discussed above, and intoxicating cannabinoids should be regulated by TTB.

The term "total THC" is defined by both the USDA and various state regulations as the sum of delta-9 THC and THCa, which aims to capture the total amount of intoxicating and potentially intoxicating cannabinoids present. While the concept of "total THC" is effective in determining the total amount of THC in living plants and raw cannabis plant material following harvest, it is insufficient for accounting for the total aggregate amount of potentially intoxicating cannabinoids in finished final form products, especially those which are manufactured.

Cannabis products may contain multiple forms of THC as well as other forms of intoxicants including CBN and HHC. To provide consumers with the most accurate information regarding the potential potency of finished final form products, we recommend adopting a comprehensive standard called "Total Intoxicating Cannabinoids Concentration" (TICC) which aims to include all potentially intoxicating compounds. The TICC number should be used as a unifying symbol on all cannabis products that contain intoxicants in order to clearly indicate their presence. The ASTM D37 Committee on Cannabis and Hemp is currently working on a standard "Specification for Determining What is an Intoxicating Cannabinoid." This standard, along with the current ASTM D844 International standard defining the International Intoxicating Cannabinoid Product Symbol (IICPS), will contribute to the development of the TICC and a meaningful framework for consumers, since it can be widely applied to all potential intoxicating cannabinoids, including delta-8, delta-9, delta-10, THC-V, CBN, and others.

We further anticipate that under a Memorandum of Understanding between TTB and FDA, which should also include USDA, the FDA would likely be tasked with assisting regulators by

determining what amount of cannabinoid intoxicant constitutes a "serving," much like the current Alcohol by Volume (ABV) available worldwide for alcohol. Similar to "trace amount," this figure should be determined through study by identifying the threshold level of intoxicants that can be present in an individual's system before it can be said to impact the individual. That threshold should be measured in DNE, or delta-9 equivalency, so that consumers with experience with marijuana products can anticipate the relative potency of the product, even when it contains a combination of minor intoxicating cannabinoids.

ATACH believes it is likely that serving sizes in state medical marijuana or adult-use legalization states are set at levels likely to intoxicate, with most set at 10mg, and others at 5mg of delta-9 THC per serving. It is not unusual for a consumer to be advised to consume some fraction of a single gummy candy in order to avoid overdose. We believe this unit of measure is too high to be practical for many consumers and suggest that serving sizes closer to 2.5mg are a more appropriate level. That level of delta-9 THC or its equivalent is unlikely to get most consumers intoxicated (much like a single beer will have a limited effect on an adult consumer), but can serve as a useful benchmark for consumers as they decide on their their own consumption level to suit their personal taste - as with alcoholic beverages.

c. Should FDA regulate the manufacture and sale of "semisynthetic derivatives," or "biosynthetic cannabinoids," which are still scheduled under the CSA?

Response:
No, not if they are intoxicants. There should be a well-defined set of intoxicating cannabinoids that fall within TTB's jurisdiction, similar to alcohol. FDA should regulate anything that is non-intoxicating. If it is intoxicating and it is not within TTB's list of intoxicating cannabinoids, it should be treated as a controlled substance. As new cannabinoids are discovered, there should be a way to evaluate and consider the most appropriate place for regulation, including as a new potential intoxicant for TTB and states to regulate.

6. Other non-cannabinoid products are available on the market that have raised safety concerns among some individuals, which FDA has regulated without a substance-specific regulatory framework (e.g. kratom, caffeine, etc.). How has FDA dealt with products containing those substances? How might these products be implicated by a CBD-specific product framework?

Response:
As mentioned above in our response to #4, ATACH does not believe a substance-specific framework is appropriate for cannabis products because we believe cannabis products can largely fall into existing pathways, except for inhalants, and defer to the agency on whether or not a pathway is needed for that. We believe that when used as a food, raw cannabis and naturally occurring extracts should be generally regarded as safe (GRAS), and should be treated like a supplement when created, used and dosed (via serving size recommendations) for that purpose.

7. How has the absence of federal regulation over CBD created a market for intoxicating,

synthetically-produced compounds, such as Delta-8 THC, THC-O, THC-B, HHC-P, and Others?

Response:
See response to #3, above.

a. What is the public health impact of these novel compounds?

Response:
These products may present public health risks, especially if ingested by children or pets. ATACH is particularly concerned about the presence of contaminants or harmful residual chemicals, labeling discrepancies, wide variability in dosage and intoxicating effect for any consumer.

A summary of key news stories on health incidents in different parts of the country is submitted along with this response, entitled Intoxicating Hemp-Derived Cannabinoid (IHDC) Bibliographical Resources.

Between December 1, 2020, and February 28, 2022, the FDA received 104 reports of adverse events from delta-8 THC products consumed. These adverse events included hallucinations, vomiting, tremors, anxiety, dizziness, confusion, and loss of consciousness. In the same period, national poison control centers reported 2,362 exposure cases to delta-8 THC products, with a significant percentage involving pediatric patients. One pediatric case even resulted in death.[13]

As of June 30, 2021, there were 183 cases in the FDA Adverse Event Reporting System (FAERS) database that listed D8-THC as a suspect. The most common adverse effects in these cases were dyspnea, respiratory disorders, and seizures. The FAERS database indicates a potential safety signal regarding D8-THC, evidenced by a 2-fold increase in the reporting odds ratios from 2019 to 2021.[14]

The market is flooded with delta-8 THC and other D9-THC isomer products with confusing label information. These products often resemble commercially available food items and are labeled as hemp-derived products. There are concerns about greater chances of contamination or adulteration in hemp-derived products containing D8-THC due to synthetic processing and an absence of regulatory requirements compared to state-licensed cannabis products. It is not known how many of the incidents reported were caused by contaminants versus the cannabinoids themselves.

b. How have FDA and state regulators enforced against products containing these compounds?

[13] See: 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC, Federal Food and Drug Administration, May 4, 2022, https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc
[14] Teresa A Simon et al, Delta-8, a Cannabis-Derived Tetrahydrocannabinol Isomer: Evaluating Case Report Data in the Food and Drug Administration Adverse Event Reporting System (FAERS) Database, *Drug, Healthcare, and Patient Safety*, January 29, 2023, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9894081/

Response:
The FDA and state regulators have attempted to address these products in various ways:

1. The FDA established a Cannabis Product Committee (CPC) to develop and implement a strategy and policy for the regulation of cannabis products.[15]

2. It also issued several sets of warning letters to companies illegally marketing or selling products containing either CBD or delta-8 THC.[16] In May 2022, the FDA issued warning letters specifically for products containing delta-8 THC for the first time.[17]

3. In September 2021, the FDA issued an advisory highlighting safety concerns related to delta-8 products and emphasized that no delta-8 THC products have been approved by the FDA.[18]

4. The 2018 Farm Bill provided a federal definition of hemp and removed it from the list of Schedule I controlled substances. The act specifically outlined that hemp-derived products with less than 0.3% delta-9-tetrahydrocannabinol (THC) on a dry weight basis are legal. This has allowed the influx of products, including delta-8 THC products, that meet this definition into consumer markets.[19] The USDA issued a policy statement and guidelines based on that amendment.[20]

5. Numerous states have enacted their own legislation to regulate or prohibit access to hemp intoxicants, as discussed elsewhere in this response.

c. How should Congress consider the inclusion of these products in a regulatory Framework for cannabinoid hemp products, if at all?

Response:
Congress should establish a regulatory system for all cannabis and naturally-derived cannabinoids derived from cannabis, and utilize the successful model for alcohol, including involvement of both TTB and FDA, and here also includes USDA and other appropriate agencies. As discussed elsewhere in this response, when naturally-derived intoxicating cannabinoids are present in

[15] https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd)
[16] *Id*, and
(https://www.healthlawadvisor.com/2022/05/19/recent-fda-enforcement-action-colors-regulatory-landscape-for-delta-8-thc-products/
[17] https://www.healthlawadvisor.com/2022/05/19/recent-fda-enforcement-action-colors-regulatory-landscape-for-delta-8-thc-products/
[18] https://www.healthlawadvisor.com/2022/05/19/recent-fda-enforcement-action-colors-regulatory-landscape-for-delta-8-thc-products/
[19] https://www.healthlawadvisor.com/2022/05/19/recent-fda-enforcement-action-colors-regulatory-landscape-for-delta-8-thc-products/
[20] https://www.usda.gov/farmbill

greater than trace amounts in a cannabis product, they should be regulated by TTB with assistance from FDA in areas of health and safety. FDA should regulate products that contain cannabinoids that are non-intoxicating such as CBD, along with ingredients in intoxicating food that are not intoxicating. Accordingly, the following steps should be taken in such a Congressional effort:

a. Non-hemp cannabis and intoxicating phytocannabinoids naturally derived from the cannabis plant should be removed from the Controlled Substances Act so that they may be regulated.

b. A tax should be imposed for the sale of intoxicating cannabinoids, and TTB granted primary regulatory authority over products and businesses that produce and sell them. TTB should work with states to register licensed businesses.

c. FDA should be required to regulate non-intoxicating cannabis products. Cannabis and naturally-derived phytocannabinoids should be designated as GRAS as a matter of law when used as a food and in appropriate amounts, and should be treated as a supplement when produced, used, and dosed through serving size recommendations in a manner consistent with a wellness product.

d. The Food, Drug, and Cosmetics Act should be amended to clearly establish protections for intoxicating cannabinoids, similar to the Tobacco Control Act.

e. A Memorandum of Understanding should be created among TTB, FDA, and the USDA to establish areas of cooperation and coordination in business registration, health and safety standards, and cultivation.

f. The Fair Packaging and Labeling Act (FPLA) should be amended to establish a framework for government warnings related to cannabinoids.

g. Congress should establish protections for state marijuana programs so that FDA cannot prohibit the production or sale of state-licensed cannabis products to qualified consumers.

h. Congress should create a provision addressing the expungement of past marijuana-related offenses which would ensure justice and reduce undue burdens on many citizens.

i. A portion of the taxes generated from marijuana sales should be reinvested into public health campaigns educating the public about responsible use, similar to campaigns for alcohol and tobacco.

j. Congress and the FDA should encourage and fund research on the medical benefits and potential risks of cannabis use, ensuring that the public and medical professionals are well-informed.

k. Congress, TTB and the FDA, should look to organizations like ASTM International to help establish a federal framework for standardizing cannabis products and production, ensuring that they are free from harmful contaminants and are of a consistent quality.

8. CBD products are not limited to just ingestible routes of administration—some are interested in products with alternative routes of administration (e.g., inhalable, topical, ophthalmic drops, etc.).

a. For which non-ingestible routes of administration are consumers interested in consuming CBD products?

Response:
In addition to food, capsules, pills, and beverages/liquids, routes include patches, sublinguals, cosmetic (topical), and inhalants including both combustion and vaporization ("vaping"). It is worth noting that all of these forms of products other than food and inhalants are forms the FDA currently recognizes as delivery methods for dietary supplements.

b. How should a regulatory framework for cannabinoid products account for non-ingestible routes of administration?

Response:
FDA does not currently regulate inhalants, but does regulate food, supplements, supplement patches, sublingual supplements, and cosmetic products. FDA may need a new pathway and framework for inhalable products.

Federal-State Interaction
9. In the absence of federal regulation or enforcement over CBD products, many states have established state regulatory programs to safeguard public health and create market certainty for industry participants.

a. Which product standards relating to warning labels, minimum age of sale, manufacturing and testing, ingredient prohibitions, adverse event reporting, and others, have states adopted to protect consumer safety?

b. Which such standards, if any, should Congress look to as models?

Response:
States have only begun to adopt and implement robust regulations, and because this is a new area of regulation, it is likely all state efforts should be taken into consideration at least to some extent when identifying the "perfect" model. States that have begun the process of creating a regulatory framework (beyond simply creating an age limit) include Minnesota, California, New York, Connecticut, Maryland, Michigan, Nevada, Oregon, Vermont, Kentucky, Tennessee, Florida, Louisiana, South Dakota, and Virginia. Oregon's regulatory agency also engaged in robust analysis on the topic of setting limits for hemp products, which it published in the course of adopting regulations.[21] The most common areas of regulation include age restrictions, imposition

[21] Oregon Liquor & Cannabis Commission, Considerations in Establishing Cannabinoid Limits for Hemp Products; Rationale for Rulemakeing," December 27, 2021.

of licensing regimes, testing requirements and standards, labeling requirements, serving sizes (potency), and limitations on product type. In addition, ATACH has recommended measures we believe states should adopt. These include:

1. Modify the definition of "hemp" to regulate by finished product and delineate intoxicating from non-intoxicating products.
2. Add a definition for "work in process hemp extract" that is not intended for sale to consumers to facilitate reasonable safeguards for hemp farming and allowing the threshold level of delta-9 THC for work in process extract only to be 1% rather than 0.3% on a dry weight basis, and adopt regulations for finished products to separate intoxicating from non intoxicating products.
3. If not already provided for under state law, the state should establish a regulatory framework to ensure that intoxicating cannabis products are taxed, tested, and regulated, including the following:
    a. Impose age limit of 21 or over for retail sales, with strict criminal penalties for knowingly selling or providing to minors.
    b. Testing methods should be developed and mandated. Labs should be required to participate in proficiency testing in a program that is designed to look for HSI known contaminants.
    c. Require licensing for any business who manufactures regulated intoxicating products intended for consumption, and registration with TTB
    d. Require licensees meet GMP,
    e. Manufacturers should be responsible for meeting all testing standards before products may be made available for retail sale,
    f. Penalties should apply for unlicensed manufacturing, which we believe should reflect the penalties that apply for the unlicensed manufacture of alcohol for sale in the same jurisdiction. In addition, health and safety threats caused by unknown ingredients or contaminated products should be a separate cause of action.
    g. Include reasonable licensing requirements to fit into existing structures for retail outlets authorized to sell intoxicating products, or where there are none have state law adopt law to do so.
    h. Keep fees and taxes low to encourage participation and reduce the illicit market.
    i. Adopt the uniform delta-9 THC equivalent standard for all HSI products and their labels.
    j. Testing standards should be as comprehensive and normalized as possible, including:
        i. Standards that apply to marijuana product testing—including those for residual solvents or heavy metals which could be present due to the cultivation process, and,
        ii. Additional standards that account for the array of authorized manufacturing methods and the residual chemicals that can appear using conversion methods, and which should be identified and removed prior to sale or distribution.
    k. Accurate labeling. Consumers must be informed on contents and potential risks. Accordingly, we recommend that labels contain the following information:

https://www.oregon.gov/olcc/Docs/commission_minutes/2021/Considerations-In-Establishing-Cannabinoid-Limits-Hemp-Whitepaper.pdf

i. Contains an intoxicating cannabinoid and associated warnings related to impairment
ii. TICC, calculated through a delta-9 THC equivalency, so that consumers can understand product potency, along with serving size to delineate intoxicating from non intoxicating products.
iii. In the case of intoxicating cannabinoids, "Not FDA approved"
iv. An estimate of the length of time it typically takes for the product to take effect;
v. A disclosure of ingredients:
    1. Possible allergens,
    2. Every compound that is intoxicating, and
    3. Whether or not the product contains unknown compounds (if allowed by state law);
    4. A nutritional fact panel where applicable;
vi. Requiring that edible intoxicating hemp products be clearly identifiable, when practicable, with a standard symbol indicating that it contains and intoxicant;

l. Packaging for child-friendly products should require opaque, child-resistant packaging, which must be designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by 16 C.F.R. 1700.20 (1995);
m. Engage in public education
    i. HSI's can contain a dangerous mix of chemicals if not regulated;
    ii. State licensed businesses are the best option currently for consumers because they are subject to oversight
n. Establish clear causes of action based on hazardous consumer products. The potential harm that could be caused by poorly manufactured products is significant, and false statements, misleading labels, or dangerous ingredients place individual consumers directly in harm's way. The state Attorney General should be empowered to bring legal actions against manufacturers that manufacture or vendors who sell products that are shown to be harmful, including those that contain contaminants beyond trace amounts, or which are otherwise sold illegally in the state.
o. Support state law enforcement. The state should allocate funding for proper analytical equipment, staffing for it, and law enforcement training related to HSI's and applicable law. Enforcement should reorient from criminal drug laws to those centered on business practices and product health and safety concerns.

10. How should Congress consider federal preemption as it works towards a regulatory pathway? Should states be able to continue to build upon federal regulation of CBD products?

Response:
As stated in our opening comments in this response, we believe that both the benefits and challenges related to the cannabis plant require a comprehensive regulatory solution that includes both states and federal agencies. Comprehensive regulations should encompass all the uses of the plant, including

intoxication, wellness, and others. Our concern is that just like the Farm Bill, a new federal law that partially regulates cannabis products would invoke state participation in a new regulatory regime before that system is fully considered and the uses of cannabis are accounted for. The direct result from the 2018 Farm Bill change is a multi-billion dollar gray market in hemp-synthesized intoxicants that are entirely unregulated by the federal government. We cannot afford mismanagement of intoxicants made from cannabis including marijuana, or the same problems we have faced for generations will simply continue in some new form, while the underground persists. At the federal level, it is possible that no solution is better than the wrong solution, given state involvement and the fact that three out of four states already have regulatory systems in place.

Since states began moving away from prohibition policies in 1996, they have been the only regulatory authority for marijuana and intoxicating cannabinoids, and those programs are considered broadly successful and uncontroversial. Federal law should not undermine the control systems that states have adopted – many of which were adopted through voter initiatives that amended their state constitutions and could be a challenge for state lawmakers to change. These programs should not be preempted. State systems should instead be recognized as partners with TTB, the FDA, the USDA, and not undermined.

Safety

11. What is currently known about the safety and risk-benefit profile of CBD and other hemp derived cannabinoids? What safety and toxicity data are available to support this knowledge. Please include in your answer any relevant information about safety with regard to specific populations, such as children and pregnant individuals.

The FDA has approved Epidiolex for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome. This approval provided evidence of CBD's efficacy and safety with respect to specific medical conditions. As discussed elsewhere, the approval process raised concerns about CBD's effect on liver function and interference with other drugs, particularly in high doses.[22] It also identified side effects such as fatigue and digestive upset.[23]

In 2018, the World Health Organization indicated that CBD was "generally well tolerated, with a good safety profile," and that it was found to be non-addictive.[24] A study published in 2018 found that chronic CBD exposure in mice promotes functional impairment of the reproductive system of male mice.[25]

---

[22] Stephen M. Hahn, M.D., Commissioner of Food and Drugs and Amy Abernethy, M.D., Ph.D., Principal Deputy Commissioner, "Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products," Food and Drug Administration (FDA) January, 8 2021, https://www.fda.gov/news-events/fda-voices/better-data-better-understanding-use-and-safety-profile-cannabidiol-cbd-products

[23] Safety of CBD in Humans – A Literature Review, Food and Drug Administration, December 12, 2019, https://www.fda.gov/media/152317/download

[24] Cannabidiol (CBD) Critical Review Report, Expert Committee on Drug Dependence, Fortieth Meeting, June 2018, https://www.sciencedirect.com/science/article/abs/pii/S0890623818301357#:~:text=Mice%20exposed%20to%2030%20mg,decreased%20in%20both%20treated%20groups.

[25] Renata K. Carvalho, et al., "Chronic cannabidiol exposure promotes functional impairment in sexual behavior and fertility of male mice, *Reproductive Toxicology*, October 2018.

Unfortunately, little is currently known about its effect on specific populations such as pregnant women or elderly people.[26]

12. What actions, if any, should the Federal government take to better understand the potential benefits or harms of CBD products and other cannabinoids?

Response:
FDA, TTB, Agriculture, and other assigned regulatory agencies should work with states and engage in establishing testing standards for hemp-synthesized intoxicant products, making recommendations to states, and working with TTB to identify best manufacturing standards that can be effectively used to produce products, but which can also simplify testing by limiting the ways products can be manufactured (greatly complicating testing standards). It should also engage in testing to better identify the threshold for detectable amounts of THC in products.

13. How should a new framework for CBD products balance consumer safety with consumer Access?

Response:
As discussed elsewhere, when taken as a food, CBD should be considered GRAS, and when used as a supplement, it should be regulated as a supplement. When it appears in other regulatory pathways such as in patches, it should be regulated on that basis, no differently than other supplements that use patches or appear in cosmetics.

In terms of balancing access with consumer safety, the FDA plays a pivotal role in ensuring the health and safety of consumers even when products like food with GRAS status or dietary supplements. This includes oversight and review of GRAS determinations, setting manufacturing standards, labeling and marketing oversight, adverse event monitoring, post-market surveillance, research and data collection, and ensuring consumers get accurate information and educational material. As research continues, FDA continues to review research and adjusts guidelines accordingly so that standards can remain current and appropriate.

14. Some stakeholders have raised concerns that CBD products have inherent risks. What are those inherent risks, and at what levels of CBD do those risks present themselves? What data and other evidence support the existence of such risks, and from which products are such data and evidence derived?

Response:
At the outset, it should be noted that there are several supplements that are widely available on the market today that have well known, inherent risks, including St. John's wort. St. John's wort (Hupericum perforatum) is recognized by FDA as a supplement, and while many people take St. John's wort as an herbal remedy for depression and other conditions, it can have significant side effects and interactions, including interactions with antidepressants, birth control pills, blood thinners, HIV/AIDS medication, and

[26] Statcy Weiner, "CBD: Does it work? Is it safe? Is it legal? AAMC News, July 20, 2023, https://www.aamc.org/news/cbd-does-it-work-it-safe-it-legal

cancer medications. It can lead to serious drug interactions including serotonin syndrome. It has side effects including dizziness, diarrhea nausea, fatigue, and increased sensitivity to light.

There are indications that CBD can have inherent risks as well. These can include injury to the liver, adverse reactions caused by CBD and other medication.[27] These indications came as result of the FDA's evaluation of Epidiolex, a drug that contains a highly-purified form of CBD.

The FDA has expressed disapproval for almost all CBD products, with a particular concern about the potential side effects such as liver damage and drug preclusion. Despite these reservations, there hasn't been a notable influx of cases of healthy adults taking retail products and subsequently experiencing acute liver toxicity. Overall, CBD as a chemical compound is deemed relatively safe, especially for liver function, by researchers like Ryan Vandrey, a professor of psychiatry at Johns Hopkins.[28]

In humans, a study showed that self-medication of CBD doesn't damage the liver. This research involved approximately 800 people taking CBD, and after approximately 30 days of consumption, liver tests revealed no abnormalities.[29] This may be because common therapeutic CBD dosage recommendations generally range from 0.5 mg/kg/day to 20 mg/kg per day. Studies that raised concern about liver damage took place with mice, and used significantly higher doses than what humans typically consume for therapeutic benefits. We believe that in therapeutic ranges, CBD should be considered safe, but high doses may be a concern and should remain a pharmaceutical medication and use should be overseen by a physician.

15. FDA approved Epidiolex, a drug containing CBD, based in part on a data package that included preclinical data from rodent safety models, as well as clinical trials. FDA has received safety data on CBD products from several manufacturers also based on rodent models. How should FDA consider data submitted for a CBD-containing drug as evidence to support that CBD is safe for human consumption in non-drug products, recognizing the inherent differences in the intended uses of such products?

Response:
As discussed earlier, ATACH does not believe that naturally-derived CBD should be treated as a drug when it is used as a general wellness product and it is taken in relatively small amounts.[30] When used as a food, it should be considered GRAS. When it is used as a supplement such as St. John's wort, it should be treated as a supplement. When used as a cosmetic, it should be allowed in any amount as long as it does

[27] Stephen M. Hahn, M.D., Commissioner of Food and Drugs and Amy Abernethy, M.D., Ph.D., Principal Deputy Commissioner, "Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products," Food and Drug Administration (FDA) January, 8 2021, https://www.fda.gov/news-events/fda-voices/better-data-better-understanding-use-and-safety-profile-cannabidiol-cbd-products.
[28] Niranjana Rajalakshmi, Why the FDA Wants to Stop Companies from Putting CBD in Everything," Slate, October 5, 2022, https://slate.com/technology/2022/10/cbd-fda-cannabidiol-seltzers-liver-damage.html
[29] *Id.*
[30] The current dosage recommendations for Epidiolex is 2.5 mg/kg taken twice daily, which would amount to 5 mg/kg per day. Depending on the response and tolerance, the dose can be increased to a maximum recommended dose of 10 mg/kg per day. A 175lb adult would receive approximately 400mg of CBD on a daily basis with the recommended starting dose.

not make therapeutic claims. FDA may want to create a new regulatory pathway for non-intoxicating inhalables. Finally, patches (categorized as medical devices) should be regulated similar to cosmetics, and manufacturers should also avoid therapeutic claims.

16. Should there be limits on the amount of CBD in foods, dietary supplements, tobacco, or cosmetics? If so:

Response:
When CBD is used in food or a dietary supplement, CBD should be used for general wellness (not for the purpose of treating specific medical conditions) and should be provided in therapeutic CBD dosage amounts – far lower than pharmaceutical dosage recommendations when used to treat seizures.

a. Should Congress or FDA set such limits, recognizing the time it can take to complete the legislative process and the regulatory process at FDA?
Yes. Congress should recognize that most CBD products are not sold in dosage amounts greater than 20mg, and limit CBD serving sizes to that amount until FDA determines that a different amount is more appropriate.

b. How should that amount be determined? What should the amount be?
See above.

c. Should such limits be applied on the amount per serving, and/or per package?
In the case of supplements, 20mg per serving, with daily allowance recommendations not to exceed 100mg (¼ of the starting daily dosage recommendation for Epidiolex).

d. Could FDA set such limits under its current statutory regulatory authorities for foods and dietary supplements to potentially address safety concerns, notwithstanding exclusionary clause issues?
Yes.

e. How should the experience of states inform the setting of limits on amounts of CBD in products?
FDA should be informed by state experience regulating these products.

17. How should a regulatory framework account for CBD products marketed in combination with other substances that may alter or enhance the effects of CBD (e.g., caffeine, melatonin, etc.)?

Response:
As with all supplements, FDA should set manufacturing standards, establish regulations for labeling and marketing, utilize its systems for monitoring and investigating adverse events related to foods and supplements, monitor the market for products that might pose a risk to public health, and engage in product recalls, public warnings or other enforcement actions. It should conduct and support research to understand safety and nutritional aspects and to understand consumption patterns and the exposure and potential health risks. FDA can offer industry and consumers with accurate information, and engage in ongoing review of its own guidelines and standards as science evolves.

18. What precedent is there for FDA restricting certain otherwise allowable ingredients in legally marketed products? What amount and type of evidence has been

required/demonstrated to support any such restrictions?

Response:
Over the years, the FDA has restricted or banned certain ingredients that were initially legally marketed products due to safety concerns.

- Phenylpropanolamine (PPA) was once a common ingredient in over-the-counter (OTC) cold and cough medications and weight loss products, PPA was linked to an increased risk of hemorrhagic stroke. Based on these concerns, in 2000, the FDA requested that manufacturers remove PPA from their products and that it no longer be considered safe for OTC use.

- Ephedra was used in dietary supplements for weight loss and to enhance athletic performance, however the FDA banned ephedra in 2004 after it was linked to serious side effects, including heart attack, stroke, and death.

- Trans Fats (Partially Hydrogenated Oils) were : In 2015, the FDA determined that Trans Fats (Partially Hydrogenated Oils), the primary dietary source of artificial trans fat in processed foods, are not "generally recognized as safe" (GRAS) for use in human food. Companies were given three years to remove PHOs from products.

- In 2010, the FDA warned four companies that the caffeine added to their malt alcoholic beverages was an "unsafe food additive" and could lead to health issues, including increased risk of binge drinking.

In order for the FDA to impose restrictions or bans, they typically rely on a combination of scientific studies, adverse event reports, expert panels, and public comments to determine if an ingredient is unsafe. The type of evidence required varies based on the product and its intended use.

19. What functional ingredients combined with cannabinoids raise safety concerns?

Response:
Research into the interactions between cannabinoids (like CBD and THC) and other functional ingredients is still evolving. However, there are some concerns that have been raised regarding potential interactions of cannabinoids with other substances:

Combining alcohol with cannabinoids, especially THC, can exacerbate the effects of both. This can lead to increased intoxication, impaired judgment, and a higher risk of crashes. Organizations such as Responsibility.org have raised concerns about poly-drug impairment and its effect on driving.[31] Additionally, excessive consumption could magnify the depressive effects on the central nervous system, making activities like driving even more dangerous.

[31] See "Marijuana and Other Drug-Impaired Driving," Foundation for Advancing Alcohol Responsibility, https://www.responsibility.org/wp-content/uploads/2015/03/Marijuana-and-Other-Drug-Impaired-Driving1.pdf

Cannabinoids can interact with a wide range of prescription medications by either inhibiting or inducing an important enzyme used in proper liver function. This can increase or decrease the effects of certain drugs, potentially leading to side effects or decreased efficacy. Some examples of affected drugs include antiretrovirals, antihistamines, antiepileptics, and some cardiovascular drugs.

Some individuals have reported amplified anxiety or restlessness when combining significant amounts of caffeine with THC. CBD, on the other hand, has sometimes been suggested to counteract some of the anxious side effects of caffeine, though more research is needed.

As already mentioned, St. John's wort can have negative side effects and drug interactions. This herbal supplement, often used for depression, can interact with many medications due to its effects on the liver enzyme system.[32] When combined with cannabinoids, there is potential for interactions, although specific outcomes remain under-researched.

There is evidence that CBD can enhance the anticoagulant effect of warfarin, which may increase the risk of bleeding. Regular monitoring and serving size adjustments might be necessary if combining these.[33] As CBD has been shown to raise levels of liver enzymes in some studies, there's concern about combining it with other supplements or medications that also have potential liver effects. This includes but isn't limited to certain herbal supplements, acetaminophen, and statins.

Quality

20. How should Congress create an FDA-implemented framework to ensure that manufacturers provide appropriate consumer protections and quality controls?

Response:

FDA can create a framework to ensure appropriate consumer protections and quality controls for CBD in food and as used as a supplement. The FDA has already initiated an internal working group to explore potential regulatory pathways for CBD products. This could include a new regulatory pathway, particularly for inhalation.

Part of its role could be to establish labeling requirements to create clear and informative information, establishing quality control standards (looking to groups like ASTM International which has already begun this work), setting serving sizes, establishing standards for production for use in animal feed, working with state regulatory partners to continually monitor the marketplace, and take actions when products do not adhere to regulations or they pose a risk to the public. The FDA can cross-coordinate with TTB, with USDA in areas of health and public safety, engage in public awareness and education, and support and engage in ongoing research.

> *a. How should such a framework compare to the current Good Manufacturing Practice (GMP) requirements that apply to food, dietary supplements, and*

[32] Peter Doohan, et al., "Cannabinoid Interactions with Cytochrome P450 Drug Metabolism: a Full-Spectrum Characterization, The AAPS Journal, June 28, 2021, https://pubmed.ncbi.nlm.nih.gov/34181150/
[33] Jessica Greger, et al., A Review of Cannabis Interactions With Anticoagulant and Antiplatelet Agents, J Clin Pharmacol, April 2020, https://pubmed.ncbi.nlm.nih.gov/31724188/

Cosmetics?

Response:
The establishment of a framework for CBD in food and as a supplement by the FDA should take into account the existing Good Manufacturing Practice (GMP) requirements, but it is essential to recognize unique aspects and challenges associated with CBD products that might require additional considerations. Current GMPs apply broadly to food, dietary supplements, and cosmetics. The CBD-specific framework should be tailored to different product categories (e.g., edibles, tinctures, inhalables, topicals) considering their distinct risk profiles.

GMPs emphasize consistency, cleanliness, and quality control throughout the manufacturing process. For CBD, additional quality controls might be necessary to ensure minimal THC presence (below the allowable threshold), and the absence of contaminants such as pesticides or heavy metals related to cultivation.

While GMPs have standards for labeling, CBD products should have additional specifics on their labels, such as source (naturally-derived vs. synthetic), whether or not they are considered broad spectrum or an isolate, CBD concentration, and a clear indication if the product contains THC. There should be provisions in place for CBD products to inform consumers about potential interactions with medications, side effects, or how CBD can affect individuals differently.

Otherwise, GMP requirements can ensure that facilities will be clean and maintained, that employees will be trained, and there is product traceability in the case of potentially mislabeled or contaminated products.

b. Are those food, dietary supplement, and cosmetics GMP frameworks adequate for regulating quality in CBD? Why or why not?

Response:
See response above for particular areas in which the framework for CBD might be tailored to unique characteristics of CBD.

21. What are alternative quality approaches that Congress should consider for CBD products? For example, how should third parties be leveraged for the creation and auditing of manufacturing and testing requirements?

Response:
ATACH believes Congress should look to ASTM International, recognized as a global leader in the development and delivery of voluntary consensus standards. The D37 Committee specifically addresses issues related to cannabis products.

The D37 Committee consists of experts from various disciplines who focus specifically on cannabis and its derivatives, and its over 100 years in standards development is being utilized to produce cannabis product standards. Its transparent, consensus-based approach takes into consideration the perspective of

all stakeholders, from producers to consumers. ATACH believes this comprehensive approach with interdisciplinary input and engagement with stakeholders is essential, and ASTM International is already taking a leading role in the development of sensible standards.

Form, Packaging, Accessibility, and Labeling

22. What types of claims should product manufacturers be permitted to make about CBD products? Please reference how such permitted claims compare to the types of claims that may be made about drugs, foods, dietary supplements, and cosmetics.

Response:

Manufacturers should limit claims about CBD in food or in supplements in a way that is consistent with all manufacturer claims about food and supplements. Specifically, they should refrain from making any specific health or medical claims that are not backed by substantial scientific evidence or approved by the FDA. Instead, they could focus on general wellness attributes, without implying the treatment or mitigation of specific diseases or conditions. For example, by emphasizing the natural origins of the product or suggesting that it may promote relaxation without specifically implying a treatment for anxiety. Similarly, claims about cosmetics containing CBD should not be any different than other wellness products that appear in topical products.

23. What is the evidence regarding the potential benefits of including a symbol or other marking on product labeling to provide clarity for consumers who would purchase products that contain CBD?

Response:

Standardized marks are essential for consumer clarity, product standardization, educating consumers, and facilitating regulation. ATACH supports ASTM International's D37 Committees mark that denotes that a product is a cannabis product.

There is not a substantial body of research specifically focused on the issue of the use of a mark or universal symbol with CBD products in particular. However, there are related labeling requirements that are well understood to be a benefit to the consumer, including nutrition labeling, fair trade, and organic labeling. Research has shown that label contents can influence consumer behavior.[34]

24. What are the potential benefits or drawbacks of an additional or substitute standardized label panel for CBD products, compared to the current Nutrition Facts Label and Supplements Label?

Response:

A substitute standard for labels that are specific to CBD or cannabinoid-containing products would include both benefits and drawbacks. The clearest benefit is targeting information that provides specific

[34] Erin Hobin, et al., Effects of strengthening alcohol labels on attention, message processing, and perceived effectiveness: A quasi-experimental study in Yukon, Canada, Int J Drug Policy, March 12, 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7224201/#:~:text=Strengthening%20health%20messages%20on%20alcohol%20container%20labels%20significantly%20increased%20consumer,CI%3A2.0%2C7.0)

details about all the cannabinoids present, their relative concentrations or volume, the type of CBD (isolate, or broad spectrum). A standardized label would offer the industry consistency, and would be a benefit to consumers.

Drawbacks might include overly-complicated labels, additional costs for manufacturers if labeling requirements are excessive, or a stigma associated with marijuana for products that are non-intoxicating.

25. What precedent exists in foods, dietary supplements, tobacco, and cosmetics for requirements of labeling to present risks to special populations in labeling (e.g., children, pregnant and lactating women, consumers taking certain drugs, etc.)? What amount and type of evidence has been required to support such requirements?

Response:
The FDA regulates the labeling requirements for foods under the FDCA. This labeling is mandatory for most prepared foods like breads, cereals, canned and frozen foods, snacks, desserts, drinks, etc. Nutrition labeling for raw produce (fruits and vegetables) and fish is voluntary.

Dietary supplements come with their own set of labeling requirements. The Dietary Supplement Health and Education Act of 1994 (DSHEA) was established to amend the Federal Food, Drug, and Cosmetic Act with regards to standards pertaining to dietary supplements. The DSHEA includes provisions on safety, claims, statements of nutritional support, ingredient labeling, new dietary ingredients, and more.

The FDA requires warning labels on foods in certain circumstances based on potential risks to health, which is determined through monitoring, reporting, testing requirements, and surveys.

For instance, the FDA monitors food allergic reactions and other related hypersensitivity reports through their Consumer Complaint System. Depending on the potential safety concern raised by these complaints, the FDA can take regulatory actions such as issuing safety communication or even removing the product from the market. In addition, the industry reports undeclared allergens through the Reportable Food Registry (RFR).

The FDA also periodically conducts surveys and sample tests to gather information about specific foods, particularly those with undeclared allergens. For instance, they conducted surveys in 2013 and 2014, as well as in 2018 and 2019, to study the presence of undeclared milk allergens in dark chocolate products. They use techniques like the enzyme-linked immunosorbent assay (ELISA) and other advanced methods to test for allergens in foods.

The decision to require a warning label typically arises from scientific evidence showing potential harm. The level of risk that warrants a warning can vary, but the FDA usually acts based on evidence indicating that consuming the food or ingredient in question could cause adverse health effects in a significant portion of the population or a vulnerable subgroup.

In terms of types of labels, one common type of label requirement, along with categories like allergens or nutrition labels, is related to specific ingredients with known risks. If a food contains an ingredient that

poses a health risk to certain populations, it may need a warning. For example, products containing phenylalanine, which can be harmful to individuals with phenylketonuria (PKU), must include a warning about the presence of this ingredient. In addition alcoholic beverages include a warning label indicating the risks associated with excessive alcohol consumption, especially during pregnancy.

26. Some suggest requiring labels for CBD products to include "potential THC content." Would THC content be unknown in a particular product? Is there precedent for such a labeling requirement?

Response:
We are not aware of any. ATACH believes it is reasonable for producers of products containing cannabinoids to know whether or not their products contain intoxicants. It may be possible for CBD to naturally convert into THC to a limited extent, but there are no studies to suggest it could happen to such a degree that it would result in more than trace amounts.

27. How should access to CBD products by children be regulated? For example, would it be appropriate to have an age restriction on the purchase of CBD products? If so, what is an appropriate age limit?

Response:
There is no known research into the effect CBD can have on developing brains, and CBD is commonly taken by minors within the context of state-regulated medical marijuana programs with no known adverse effects. Given that CBD products regulated by FDA would not have more than trace amounts of any intoxicating cannabinoid in the regulatory scheme we are advocating, the only limitation should be dosage requirements that might take weight into account. Until there are indications that CBD could be harmful for children, they should not be otherwise limited.

28. What specific additional restrictions should apply to CBD products regarding their appeal to or use by children with regard to marketing, packaging, and labeling? Is there precedent in the food, dietary supplement, tobacco, or cosmetics space for restricting certain product features that would make products appealing to children? Please describe.

Response:
Intoxicating consumer items made from cannabinoids should be clearly labeled and sales should be limited to adults 21 or over. These products should not be marketed in a manner as to appeal to minors, such as with cartoon character mascots, or candy shapes that appeal to children, or in packaging that is intended to appeal to children. ATACH does not believe that child-proof packaging for every type of intoxicating product is effective and instead generates waste. For certain products that might have unique appeal for children such as infused candy, we would support a requirement that such products require child-proof packaging. But we would oppose a blanket requirement that all products be packaged in this manner, just as alcohol products do not have unique childproof packaging.

29. Some suggest requiring packages with multiple servings to be easily divisible into single servings. Does a framework like this exist today for any other product or substance?

Response:
ATACH believes that intoxicating confectionary items such as candy should contain a single serving per individual package. By contrast, beverages, flower products, and food items can be divisible into single servings so long as they are clearly labeled and the packing or marketing material is not directed at minors. This is akin to a bottle of bourbon that contains multiple servings. However, owing to the nature of candy and the potential risk to minors, we believe it is dangerous to vulnerable populations to have individual pieces of candy that are equal to an intoxicating serving size, with multiple serving sizes in an individual package. For these products, regulators should consider the total amount of intoxicant contained in the entire individual package, rather than individual pieces, since minors are unlikely to stop at one piece of candy, and the presence of intoxicants is not obvious.

***

Thank you for the opportunity to respond to the RFI. The US will continue to face challenges in the regulatory space around cannabis until it adopts a comprehensive solution which accounts for all of the uses of the cannabis plant, which we have presented here. CBD should be regulated, but that regulation should take place within a broader framework, or unintended consequences will continue to create significant challenges for regulators and law enforcement.

Further inquiries, clarifications or additional follow up should be directed to Chris Lindsey, Director of State Advocacy and Public Policy, 712 H Street, NE, Unit#518, Washington, D.C. 20002 chris@atach.org.

Sincerely,

Michael Bronstein
President
American Trade Association for Cannabis and Hemp

Attachments:

1. Toward Normalized Cannabinoid Regulation, ATACH's white paper on hemp-synthesized intoxicants.
2. Hemp-Synthesized Products, a listing of intoxicating hemp products.
3. Hemp-Derived Cannabinoid (IHDC) Bibliographical Resources.