AIMED ALLIANCE

August 18, 2023

The Honorable Bernard Sanders
Chair
Health, Education, Labor and Pensions Committee
United States Senate
Washington, DC 20510

The Honorable Bill Cassidy, M.D.
Ranking Member
Health, Education, Labor and Pensions Committee
United States Senate Washington, DC 20510

The Honorable Cathy McMorris Rodgers
Chair
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Re: July 29th Request for Information on Topics Related to the Regulation of CBD

Via Electronic Communication to CBD@mail.house.gov and CBD@help.senate.gov

Dear Chair Sanders, Ranking Member Cassidy, Chair McMorris Rodgers, and Ranking Member Pallone:

On behalf of Aimed Alliance, a 501(c)(3) not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers, we appreciate the opportunity to contribute to the request for information concerning the regulation of cannabidiol (CBD) products. As a non-profit entity committed to prioritizing consumer safety and access to healthcare, we recognize the significance of this issue in relation to public health and consumer well-being.

We extend our appreciation for your leadership in strengthening consumer protections within the U.S. CBD market and for proactively seeking input from stakeholders when assessing the potential for a regulatory pathway for hemp-derived CBD products. Aimed Alliance is eager to collaborate with Congress and the Food and Drug Administration (FDA) in pursuing a legislative approach to the regulation of CBD products that equips FDA with the necessary tools to effectively manage while also placing a high priority on ensuring consumer access and safety.

Attached you will find our responses to the requested information, along with the corresponding attached materials. Should any inquiries arise or if you require additional information from Aimed Alliance, please do not hesitate to contact us at policy@aimedalliance.org.

Thank you again for considering our insights and input. We are enthusiastic about the potential positive impact of collaborative efforts in establishing a robust regulatory framework for CBD products.

Sincerely,

Olivia Backhaus
Counsel to Aimed Alliance

Aimed Alliance CBD RFI Questions and Answers

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.**

The market for CBD products is rapidly expanding. CBD products come in various types and forms, including: CBD oil/tinctures, which are liquid extracts with CBD concentrations that could be taken sublingually;[1] edibles, which are CBD-infused food products, like gummies, chocolates, and beverages;[2] topical products, which are creams, lotions, and balms infused with CBD;[3] capsules, which are measured doses of CBD in pill form;[4] vape products, which are inhalable CBD products like vape pens and e-liquids;[5] isolates and concentrates, which are pure CBD or high-concentration extracts used in various applications;[6] and pet products, which are CBD-infused products for pets, like treats and oils.[7]

CBD products are often marketed as natural remedies for various health concerns, including stress, anxiety, pain, and sleep issues.[8] These products span a wide spectrum of concentrations, ranging from minimal amounts (e.g., 20 mg in soft drinks) to potentially excessive doses that surpass the FDA-approved levels for treating seizure disorders (e.g., gummies containing 1500 mg of CBD).[9] Manufacturers use websites, social media, and influencer marketing to reach

[1] Victoria Stokes, *CBD Oil vs. Tincture: What's the Difference?,* HEALTHLINE, https://www.healthline.com/health/cbd-oil-vs-tincture (May 16, 2023).
[2] Suyog Shinde, *CBD Edibles Market Flourishes as Consumers Embrace the Benefits of Cannabidiol in Food Products* (Jun. 28, 2023), https://www.linkedin.com/pulse/cbd-edibles-market-flourishes-consumers-embrace-benefits-shinde-/.
[3] *CBD Skin Cream: How to Use and Best Options*, MEDICAL NEWS TODAY, https://www.medicalnewstoday.com/articles/cbd-skin-cream.
[4] Lauren Silva*, 10 Best CBD Capsules and Capsules of 2023*, FORBES HEALTH (Aug. 1, 2023), https://www.forbes.com/health/body/best-cbd-capsules/.
[5] What to know about vaping CBD, *Medical News Today*, https://www.medicalnewstoday.com/articles/vaping-cbd.
[6] *CBD Isolate: 5 CBD Products That Provide Great Health Benefits*, https://www.dallasnews.com/branded-content/2023/08/03/cbd-isolate-5-cbd-products-that-provide-great-health-benefits/.
[7] *Best CBD for Dogs: 5 CBD Oil Products to Give Your Dog Relief From Chronic Pain, Anxiety, and More*, WASHINGTONIAN, https://www.washingtonian.com/2023/07/17/best-cbd-for-dogs-5-cbd-oil-products-to-give-your-dog-relief-from-chronic-pain-anxiety-and-more/.
[8] Dawn MacKeen, *What Are the Benefits of CBD?* (Oct. 27, 2021), https://www.nytimes.com/2019/10/16/style/self-care/cbd-oil-benefits.html#:~:text=%E2%80%9CCBD%20is%20not%20a%20scam,cycle%20people%20back%20into%20using.
[9] Joshua Brown and Almut Winterstein, *Potential Adverse Drug Events and Drug–Drug Interactions with Medical and Consumer Cannabidiol (CBD) Use*, 8 JOURNAL OF CLINICAL MEDICINE 989 (2019).

consumers,[10] and retailers include grocery stores, gas stations, health spas, retail pharmacies, bakeries, and coffee shops.[11]

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

The passage of the 2018 Farm Bill, and the subsequent legalization of hemp, facilitated the growth of the CBD industry. The removal of legal barriers led to increased investment, research, and product innovation. The market saw a proliferation of various CBD-infused products, including oil/tinctures, edibles, topical products, capsules, vape products, isolates and concentrates, and pet products.[12]

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

The lack of national standards for CBD consumer products has created several challenges within the market. Without consistent regulations and guidelines, the CBD consumer product industry has experienced a range of issues that impact consumers, manufacturers, and the overall market, including quality control, mislabeling, safety concerns, and legal uncertainty.

- Quality control: Due to the lack of national standards, CBD consumer products can contain harmful substances. They have been found to contain illegal levels of THC and harmful metals, toxins, and mold. One study found illegal substances that cause impairment, such as "spice" or "K2", in one third of CBD vape oils analyzed.[13]

- Mislabeling: The lack of federal regulatory standards and supervision has resulted in mislabeling and inaccuracies in product information, amplifying the chance of consumers inadvertently using substances containing undisclosed or unintended ingredients. A study indicated that, among 89 tested products, 16 (18%) contained less CBD than advertised, 52 (58 percent) had more CBD than stated, and 21 (24) were accurately labeled.[14]

- Safety concerns: The FDA has approved one CBD medication, Epidiolex, for the treatment of seizures associated with three rare conditions,[15] but has not determined other

[10] Mohammed Soleymanpour, *Therapeutic Claims in Cannabidiol (CBD) Marketing Messages on Twitter Proceedings*, 22021 IEEE INTERNATIONAL CONFERENCE ON BIOINFORMATICS 3083-88 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8794048.
[11] Joshua Brown and Almut Winterstein, *Potential Adverse Drug Events and Drug–Drug Interactions with Medical and Consumer Cannabidiol (CBD) Use*, 8 JOURNAL OF CLINICAL MEDICINE 989 (2019).
[12] Joshua Brown and Almut Winterstein, *Potential Adverse Drug Events and Drug–Drug Interactions with Medical and Consumer Cannabidiol (CBD) Use*, 8 JOURNAL OF CLINICAL MEDICINE 989 (2019).
[13] Holbrook Mohr*, The AP Tested 30 Kinds of CBD Oil: More than a third contain synthetic marijuana, or no CBD at all*, CHICAGO TRIBUNE (Sept. 17, 2019), https://www.chicagotribune.com/nation-world/ct-nw-vaping-cbd-bad-drugs-20190917-77fx47fb2jey7okmk223drbrlq-story.html.
[14] *Study Shows Widespread Mislabeling of CBD Content Occurs for Over-the-Counter Products* (Jul. 20, 2023), https://www.hopkinsmedicine.org/news/newsroom/news-releases/study-shows-widespread-mislabeling-of-cbd-content-occurs-for-over-the-counter-products.
[15] *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy*, U.S. FOOD & DRUG ADMIN. (Jun. 28, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

CBD products to be safe as drugs, dietary supplements, or food additives.[16] Studies of CBD have identified potential risks that require additional research.[17] For example, the impacts of long-term CBD use, dosing levels that trigger known risks, and effects of CBD on children and brain development remain unknown.[18]

Without federal standards for CBD consumer products, combined with proper oversight and enforcement, consumers might use CBD consumer products in amounts or ways that could interact negatively with other medications, or trigger or exacerbate health conditions. Moreover, misleading marketing claims could lead consumers to replace proven medical treatments with unverified CBD products.

The absence of federal industry-wide production standards leaves CBD product consumers exposed to contaminants, such as heavy metals, pesticides, and solvents, which may be present in improperly sourced or processed CBD.[19]

- Consumer misconceptions: The unregulated CBD market inadvertently fosters a false sense of security among consumers. Many believe that because these products are widely available, they must be safe and effective. However, without standardized testing, quality control, and accurate labeling requirements, consumers lack crucial information about the products they are using. This misinformation poses risks to vulnerable populations, such as individuals seeking relief from medical conditions.[20]

- Legal uncertainty: In the absence of clear federal regulations, CBD products of varying levels of quality have flooded the market, ranging from oils and edibles to skincare items and pet products. This regulatory gap exposes consumers to potential health, safety, and employment risks. The lack of regulatory clarity makes it challenging for manufacturers to ensure product safety; label products in a consistent, clear, and adequately informative way; and maintain transparent business practices. It can expose manufacturers to litigation and potential liability for consumer harm.

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[16] *FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol*, *Will Work with Congress on a New Way Forward*, U.S. FOOD & DRUG ADMIN. (Jan. 26, 2023), https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol.

[17] *Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products*, U.S. FOOD & DRUG ADMIN. (Jan. 8, 2021), https://www.fda.gov/news-events/fda-voices/better-data-better-understanding-use-and-safety-profile-cannabidiol-cbd-products.

[18] *Consumer Updates*, U.S. FOOD & DRUG ADMIN. (Aug. 8, 2023), https://www.fda.gov/consumers/consumer-updates.

[19] Jenny Wiley et al., *Cannabidiol: Science, Marketing, and Legal Perspectives, Research Triangle Park* (Apr. 2020), https://www.ncbi.nlm.nih.gov/books/NBK565434/.

[20] *Cannabidiol (CBD) – Potential Harms, Side Effects, and Unknowns*, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN. (Feb. 2023), https://store.samhsa.gov/sites/default/files/pep22-06-04-003.pdf

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.**

We support the concerns raised by The Food and Drug Administration regarding the safety of consumer products containing CBD. We also agree with FDA's position that the current safety standards for foods and dietary supplements are not adequate for CBD consumer products. For example, the Federal Food, Drug and Cosmetic Act (FD&C Act) dietary supplement regulations do not require manufacturers to provide the FDA with evidence substantiating a supplement's safety, and notification requirements solely focus on reporting new ingredients. This approach places the burden on the FDA to rely heavily on post-marketing surveillance efforts yet does not require manufacturers to report non-serious adverse events. Further, current law does not enable the FDA to efficiently remove unsafe products from the market.

Given that existing federal laws are inadequate for regulating CBD consumer products, it is crucial for Congress either to create new protections under the current regulatory frameworks for food, dietary supplements, and tobacco products, or to establish a dedicated regulatory framework for CBD-containing consumer products intended for human consumption (both by ingestion and by inhalation). Either regulatory approach should also encompass consumer products containing other cannabinoids, such as delta-8 tetrahydrocannabinol (THC) and delta-10 THC. Appropriate regulation of CBD consumer products will require a hybrid approach that draws from the regulations governing foods, dietary supplements, tobacco products, and over-the-counter (OTC) drugs.

For more information, read the attached fact sheet, Aimed Alliance's "Essential Elements of a Regulatory Framework for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion."

Scope

5. a. **Should Congress or FDA limit the amount of intoxicating or potentially intoxicating substances produced by Cannabis sativa L. in food and dietary supplements? Which substances, if any, warrant greater concern? How should these substances of concern be addressed? What products, if any, should not be allowed on the market?**

The existing landscape lacks legal provisions or guidelines that empower the FDA to establish restrictions on serving sizes for dietary supplements or to stipulate the permissible quantity of dietary ingredients within a single serving of such supplements. In contrast, the FDA has already

proposed a rulemaking to impose a maximum nicotine level to reduce the addictiveness of cigarettes.[21]

Similar to the FDA's proposed nicotine limit, FDA should establish specific limits per serving for CBD, THC, and other psychoactive cannabinoids within consumer products incorporating cannabis-derived components. Examples include delta-8-, delta-9- and delta-10-THC. Delta-8-THC is a form of THC found in low concentrations in marijuana and hemp plants. Delta-8-THC is created in higher concentrations by chemically converting CBD extracts. This process yields intoxicating and impairing effects in delta-8-THC that are similar to, but slightly milder than, those products by the delta-9-THC in marijuana. Delta-9-THC is the primary psychoactive cannabinoid that produces marijuana's intoxicating and impairing effects.[22] Products with more than .3 percent delta-9 THC are deemed marijuana, which is a Schedule I (illegal) controlled substance under federal law. Delta-10-THC is another form of THC found in low concentrations in marijuana and hemp plants. Delta-10-THC is created in concentrated amounts chemically converting CBD extracts. The concentrated product reportedly yields euphoric effects when consumed.[23]

Additionally, to prevent the consumption of hazardous levels of CBD, THC, or other psychoactive cannabinoids resulting from the ingestion of multiple servings, Congress should instruct the FDA to implement a cap on the cannabinoid content per package. This per-pack limit is crucial to minimize potential risks associated with these substances.[24]

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?

CBD occupies a unique place in federal law because it is different from other FDA-regulated products, like fish oil, which is available as a prescription medication, supplement, and food additive. CBD is naturally derived from the cannabis plant, which also contains psychoactive delta-9 THC. When cannabis has a concentration of more than .3 percent THC, it is considered marijuana and is illegal under federal law. When cannabis contains no more than .3 percent THC, it is considered hemp. In 2018, Congress changed federal law to make hemp legal. Currently, the

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[21] *FDA Announces Plans for Proposed Rule to Reduce Addictiveness of Cigarettes and Other Combusted Tobacco Products*, U.S. FOOD & DRUG ADMIN. (Jun. 21, 2022), https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco#:~:text=Today,%20the%20BidenHarris%20Administration,and%20certain%20other%20combusted%20tobacco.

[22] Aimed Alliance, *Cannabinoids: A Fact Sheet for Consumers*, (Aug. 31, 2022), https://aimedalliance.org/wp-content/uploads/2022/08/Aimed-Alliance-Cannabinoids-Fact-Sheet-8.31.2022.pdf.

[23] Aimed Alliance, *Cannabinoids: A Fact Sheet for Consumers*, (Aug. 31, 2022), https://aimedalliance.org/wp-content/uploads/2022/08/Aimed-Alliance-Cannabinoids-Fact-Sheet-8.31.2022.pdf.

[24] Aimed Alliance, *Essential Elements of a Regulatory Framework for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion* (Jul. 26, 2023), https://aimedalliance.org/wp-content/uploads/2023/08/AA-Essential-RegFramework-CanabisProducts-June2023_v7.pdf.

only product containing CBD that may be marketed legally in the U.S. is Epidiolex, an FDA-approved CBD medication. Unlike supplements and foods containing fish oil, those containing CBD may not be marketed legally because CBD consumer products came to the market after the FDA approved Epidiolex. Congress should prioritize addressing the unique situation of CBD and other hemp-derived cannabinoid products as a discrete matter that needs immediate attention and action.

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?

The absence of federal CBD and other cannabinoid regulations has led to unclear rules, exploitation of the legal gray area, deceptive marketing, safety concerns, and inadequate oversight and enforcement.

The absence of federal standards or effective oversight allows novel products to enter the market without undergoing the rigorous safety research and manufacturing quality control measures mandated for other regulated products. For example, delta-10-THC was reportedly discovered in 2020 when cannabis plants were exposed to a fire retardant, causing a chemical reaction that yielded delta-10-THC.[25] Credible research into delta-10-THC's safety does not yet exist. Furthermore, it is likely that some manufacturers use unsafe chemicals to convert CBD extracts into delta-10-THC. The lack of federal oversight increases the risk of products containing unsafe contaminants and chemical residues making their way into circulation.

Misleading marketing is another issue. Novel cannabinoid compounds are marketed as legal and safe, despite inadequate evidence to support these claims. Some manufacturers market these products as cures for medical conditions, discouraging consumers from seeking proper medical treatment.[26]

Lastly, the lack of regulations makes it relatively easy to bring CBD products to the consumer market and can also foster market growth as manufacturers seize the opportunity to profit at low cost from the high demand for CBD and THC products (much of which stems resulting from unsubstantiated marketing).

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

These compounds are still relatively new, and their impact on human health remains insufficiently understood. Limited research has explored their safety profile and potential health effects and the absence of comprehensive studies leaves both short-term and long-term health risks unclear.[27] Listed below are the safety considerations linked with various cannabinoids:

[25] Aimed Alliance, *Cannabinoids: A Fact Sheet for Consumers* (Aug. 31, 2022), https://aimedalliance.org/wp-content/uploads/2022/08/Aimed-Alliance-Cannabinoids-Fact-Sheet-8.31.2022.pdf.
[26] Aimed Alliance, *Cannabinoids: A Fact Sheet for Consumers* (Aug. 31, 2022), https://aimedalliance.org/wp-content/uploads/2022/08/Aimed-Alliance-Cannabinoids-Fact-Sheet-8.31.2022.pdf.
[27] Aimed Alliance, *Essential Elements of a Regulatory Framework for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion* (Jul. 26, 2023), https://aimedalliance.org/wp-content/uploads/2023/08/AA-Essential-RegFramework-CanabisProducts-June2023_v7.pdf.

Delta-8-THC products lack FDA approval for safe use in any context. National poison control centers received 2,362 exposure calls related to delta-8-THC between January 1, 2021, and February 2, 2022. Certain consumer product manufacturers may employ unsafe household chemicals in delta-8-THC production. As with non-FDA-approved CBD products, manufacturing might occur in unsanitary conditions, leading to unsafe contaminants.[28]

Beyond the specific safety concerns, delta-8-THC has prompted worries about mislabeling, susceptibility among adolescent groups, and potential drug interactions.

- Mislabeling: The lack of regulatory supervision has resulted in mislabeling and inaccuracies in product information, increasing the chance of consumers inadvertently using substances containing undisclosed or unintended ingredients.

- Adolescents: The promotion and availability of these compounds raises alarm about their attractiveness to youth and vulnerable populations. The potential for misuse or unforeseen consequences within these groups poses a public health concern. The FDA has cautioned against the consumption of THC-containing foods by children, as it may lead to severe adverse events. These products often appeal to children and could be mistaken for well-known, commonly consumed foods. In fact, between January 1, 2021, and May 31, 2022, poison control centers reported 10,448 cases of single-substance exposure involving only THC-containing edible products. A significant 77 percent of these cases concerned patients aged 19 or below, with 65 percent being unintentional exposures. Moreover, 91 percent of these unintentional exposures affected pediatric patients.[29]

- Interactions and conflicts: These emerging compounds might interact with other substances, medications, or existing health conditions in ways yet to be fully understood, potentially jeopardizing individuals with latent or active health problems. THC, akin to prescription drugs, is metabolized by liver enzymes and could disrupt concentrations, toxicity levels, and efficacy of other medications.[30]

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

[28] Aimed Alliance, *Cannabinoids: A Fact Sheet for Consumers*, (Aug. 31, 2022), https://aimedalliance.org/wp-content/uploads/2022/08/Aimed-Alliance-Cannabinoids-Fact-Sheet-8.31.2022.pdf.
[29] *FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC*, U.S. FOOD & DRUG ADMIN. (Jun. 16, 2022), https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc.
[30] *FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC*, U.S. FOOD & DRUG ADMIN. (Jun. 16, 2022), https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc.

The U.S. Food and Drug Administration has issued warning letters to entities for their unlawful sale of food items that contain THC.[31]

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

The FDA should establish a dedicated regulatory framework for CBD-containing consumer products that also encompasses consumer products containing other potentially intoxicating cannabinoids. Congress should adopt a hybrid approach that draws from the regulations governing foods, dietary supplements, tobacco products, and over-the-counter (OTC) drugs.

For more information, please refer to the attached fact sheet, Aimed Alliance's "Essential Labeling Requirements for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion."[32]

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?

Consumers are interested in various non-ingestible routes of administration for CBD products. Some of these routes include inhalable CBD products, such as vaporizers or inhalers, and CBD-infused creams, lotions, balms, and patches that are applied directly to the skin.[33]

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

Congress should authorize a regulatory framework addressing all cannabinoid consumer products, including vape products. For each route of administration, there must be labeling requirements, per-serving and per-package cannabinoid limits, health and safety warnings, dosage recommendations, and quality control measures to ensure that consumers receive adequate, accurate information and have a clear understanding of the products they are using, regardless of the chosen administration method.

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[31] *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, U.S. FOOD & DRUG ADMIN. (Jul. 5, 2023), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

[32] Aimed Alliance, *Essential Labeling Requirements for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion* (Jul. 26, 2023), https://aimedalliance.org/wp-content/uploads/2023/08/AA-Essential-LabelReq-CanabisProducts-June2023_v4.pdf.

[33] Caroline Igo, 7 *Natural Remedies for Insomnia*, CNET (Aug. 10, 2023), https://www.cnet.com/health/sleep/7-natural-remedies-for-insomnia/.

Federal-State Interaction

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

When considering a new framework for CBD and other cannabinoid consumer products, the balance between consumer safety and consumer access can be achieved through a hybrid approach that draws from existing regulations governing foods, dietary supplements, tobacco products, and OTC drugs.

For more information, please refer to the attached fact sheet, Aimed Alliance's "Essential Labeling Requirements for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion."[34]

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?

The federal government oversees interstate commerce, which encompasses the regulation of drugs, which are defined as articles (and components thereof) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (and their components, but not food) intended to affect the structure or any function of the body of man or other animals.[35] An objective of the FD&C Act is to ensure that safe and effective drugs are available to the public. State laws that prevent the accomplishment of the FD&C Act's objective that safe and effective drugs be available to the public should be preempted by federal law.[36]

To the extent that Congress desires to ensure that safe CBD-containing consumer products are available to the public, then Congress should expressly state such intent in federal law and expressly preempt state laws that prevent the accomplishment of Congress's objective.

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

[34] Aimed Alliance, *Essential Labeling Requirements for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion* (Jul. 26, 2023), https://aimedalliance.org/wp-content/uploads/2023/08/AA-Essential-LabelReq-CanabisProducts-June2023_v4.pdf.
[35] 21 U.S. Code § 321(g)(1), https://www.law.cornell.edu/uscode/text/21/321.
[36] *Zogenix, Inc. v. Patrick*, Civ. Action No. 14-11689-RWZ (Mass. 2015), https://docs.justia.com/cases/federal/district-courts/massachusetts/madce/1:2014cv11689/159783/94

about safety with regard to specific populations, such as children and pregnant individuals.

We defer to the FDA's expertise on the current understanding of the safety and risk-benefit profile of CBD and other hemp-derived cannabinoids.

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

When considering a new framework for CBD products, the balance between consumer safety and consumer access can be achieved through a hybrid approach that draws from existing regulations governing foods, dietary supplements, tobacco products, and over-the-counter (OTC) drugs. Congress should enact legislation that effectively regulates consumer products containing cannabis-derived ingredients for human consumption, ensuring comprehensive protection of public health and safety.

For more information, read the attached fact sheet, "Aimed Alliance's Essential Elements of a Regulatory Framework for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion."

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?

Assessing the data submitted for a CBD-containing drug as evidence of its safety for human consumption in non-drug products requires an understanding of inherent differences in manufacturing processes and usage. When assessing CBD manufactured for non-drug products, it is important to consider the potential for contamination. Epidiolex is produced in facilities operating under FDA's strict regulations for manufacturing processes. In contrast, non-drug CBD products are manufactured by thousands of companies across the country, increasing the likelihood of contamination due to the higher number of manufacturers involved. Additionally, Epidiolex was approved for use in a small population with specific health conditions and is available only with a prescription. CBD consumer products are widely available to a broad range of consumers without a prescription. Many of these consumers have health conditions that were not assessed in Epidiolex studies. Similarly, consumers of non-prescription CBD-containing products might take medications or consume substances that were not assessed in Epidiolex studies. Therefore, the Epidiolex data is inadequate to support broad consumer use of CBD without medical guidance.

Congress should require the manufacturers or distributors of consumer products containing cannabis-derived ingredients and intended for human consumption to submit a premarket notification to the FDA at least 75 days before introducing the product into interstate commerce.

The premarket notification should include adequate, credible evidence that the new product is safe under the conditions of its intended use, namely in a broad population of consumers with varying health statuses, prescription regimens, and substance exposure.

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

c. Should such limits be applied on the amount per serving, and/or per package?

Yes. Congress should require the FDA to set per-serving limits on the amount of CBD, THC, and other potentially psychoactive cannabinoids in consumer products containing cannabis-derived ingredients and intended for human consumption. Additionally, to prevent exposure to unsafe amounts of CBD, THC, or other psychoactive cannabinoids by ingesting multiple servings, Congress should require the FDA to limit the total amount of each cannabinoid per package.

For more information, read the attached fact sheet, Aimed Alliance's "Essential Elements of a Regulatory Framework for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion."

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?

There are no current laws or regulations that allow the FDA to impose limits on the serving size of a dietary supplement or the amount of a dietary ingredient that can be in a serving of a dietary supplement.[37] However, the FDA has proposed a maximum nicotine limit for approach for cigarettes and other tobacco products in effort to reduce nicotine use, addiction, and death.[38] Congress should authorize FDA to impose per-serving and per-package limits on CBD and other potentially psychoactive cannabinoids in consumer products.

Quality

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

Congress should adopt a hybrid approach to consumer protection and quality control by incorporating elements from the regulations currently imposed on foods, dietary supplements, tobacco products, and over-the-counter (OTC) drugs. For example, restrictions on advertising and flavoring tobacco products to appeal to minors should be applied similarly to cannabinoid-containing vaping products.

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[37] *Questions and Answers on Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Oct. 26, 2022), https://www.fda.gov/food/ information-consumers-using-dietary-supplements/ questions-and-answers-dietary-supplements.

[38] *FDA Announces Plans for Proposed Rule to Reduce Addictiveness of Cigarettes and Other Combusted Tobacco Products*, U.S. FOOD & DRUG ADMIN. (Jun. 21, 2022), https:// www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness- cigarettes-and-other-combusted-tobacco.

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

Congress should require the producers of consumer products containing cannabis-derived ingredients and intended for human consumption to follow CGMPs like those applicable to foods, dietary supplements, and cosmetics. The respective standards should be to cannabinoid-containing consumer products based on their method of administration.

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?

New regulatory standards for consumer products containing cannabis-derived ingredients and intended for human consumption should ensure labeling accuracy by limiting variances between labeled content and actual product content.

Under the Food Safety Modernization Act, the FDA oversees the Laboratory Accreditation for Analyses of Foods (LAAF) program. The LAAF program ensures the accuracy and reliability of certain food testing through laboratory uniformity of standards and enhanced FDA oversight of participating laboratories.[39] To ensure the accuracy and reliability of the testing of consumer products containing cannabis derived ingredients and intended for human ingestion, Congress should require the manufacturers of such products to use laboratories approved under LAAF or a similar FDA-regulated program.

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?

The FDA currently regulates the labeling of most foods and dietary supplements.[40] Consumers are familiar with these products' labels and know where to look for information of interest to them. Labels for consumer products containing cannabis-derived ingredients should be as identical as possible to the labels consumers are accustomed to seeing on products with similar methods of administration (such as foods, dietary supplements, and tobacco products).

Consumer products containing cannabinoids should also be subject to additional labeling requirements. For example, the FDA requires that calorie counts be displayed in a large and bold font on foods' Nutrition Facts labels and that calorie declarations be clear and prominently

[39] FMSA Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF), U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma- final-rule-laboratory-accreditation-analyses-foods-laaf (Oct. 19, 2022); 21 C.F.R. § 1160 (2019).
[40] *Food Labeling & Nutrition*, U.S. FOOD & DRUG ADMIN. (Jun. 5, 2023), https://www.fda.gov/food/food-labeling-nutrition.

placed on food items sold in vending machines.[41] Similarly, Congress should require that labels of consumer products containing cannabis-derived ingredients and intended for human consumption prominently display the per-serving intake values of CBD, THC, and other psychoactive ingredients.

For more information, read the attached fact sheet, "Essential Labeling Requirements for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion."[42]

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?

The FDA requires health warnings on cigarette packages to improve public understanding of the negative health consequences of cigarette smoking.[43] Labeling of consumer products containing cannabis-derived ingredients should include warnings that alert consumers of evidence-based health and safety risks. For example:

- Pregnancy: FDA strongly advises against the use of CBD and THC (and marijuana) in any form during pregnancy or while breastfeeding due to potential serious health consequences.[44]

- Child ingestion: The FDA has warned that children's ingestion of foods containing THC may cause serious adverse events.[45]

The 2022 Medical Marijuana and Cannabidiol Research Expansion Act requires the federal government to report the impacts of marijuana on adolescent brains and the ability to operate motor vehicles. Congress should expand that research to include additional cannabinoids. Known harms or risks associated with cannabinoids in consumer products should be described on the labels of such products.

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[41] *Food & Nutrition Serv. Memorandum SP 28 – 2016, CACFP 09 – 2016, SFSP 11 - 2016, FDA Requirements for Vending Machines*, U.S. DEP. AGRIC. (Mar. 2, 2016), https://www.fns.usda.gov/cn/fda-requirements-vending-machines; *Calories on the New Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/food/new-nutrition-facts- label/calories-new-nutrition-facts-

[42] Aimed Alliance, *Essential Labeling Requirements for Consumer Products Containing Cannabis-Derived Ingredients and Intended for Human Ingestion* (Jul. 26, 2023), https://aimedalliance.org/wp-content/uploads/2023/08/AA-Essential-LabelReq-CanabisProducts-June2023_v4.pdf.

[43] Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide (Revised), U.S. FOOD & DRUG ADMIN. (July 2021), https://www. fda.gov/regulatory-information/search-fda-guidance-documents/required-warnings-cigarette-packages-and- advertisements-small-entity-compliance-guide-revised.

[44] *What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/ consumer-updates/what-you-should-know-about-using- cannabis-including-cbd-when-pregnant-or-breastfeeding (Oct. 16, 2019).

[45] *FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC*, U.S. FOOD & DRUG ADMIN. (June 16, 2022), https://www.fda.gov/ food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food- products-containing-thc.

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?

Regulating children's access to CBD products is crucial to ensure their safety and prevent unintended consumption. Implementing age restrictions on the purchase of CBD products is an appropriate approach to achieve this goal. Similar to age restrictions on other products with potential health risks, such as tobacco and alcohol, age limits for CBD products can help strike a balance between adult access and safeguarding minors.

Determining an appropriate age limit requires careful consideration of factors such as cognitive development and potential health risks. While there is not a one-size-fits-all answer, setting an age limit of 18 or 21 years could be considered, similar to the legal purchasing ages for tobacco and alcohol in most states.

When implementing age restrictions, regulations should ensure effective enforcement mechanisms are in place to prevent underage access. For example, retailers should be trained to check identification and refuse sales to individuals below the legal age limit. Additionally, online sales of cannabinoid-containing consumer products should incorporate stringent age verification processes to prevent underage purchases. Lastly, restrictions could be placed on where and how CBD products are displayed in retail environments to help limit their appeal to children.

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.

The Tobacco Control Act not only prohibited flavored cigarettes but also established a minimum legal sales age, restricted vending machine sales, prohibited tobacco-brand sponsorships of various sports and entertainment events, and put an end to free distribution of sample cigarettes and non-tobacco promotional items. This framework offers valuable insights for the development of regulatory measures for CBD products.[46] The following measures are particularly important in safeguarding against the appeal and use of CBD products by children.

- Packaging and labeling restrictions: CBD products should be packaged and labeled in a way that minimizes appeal to children. This might include limitations on the use of vibrant colors, cartoon characters, or imagery that could attract a younger audience. Clear and informative labeling, including the potential risks, should be mandatory to discourage misuse.

[46] *Family Smoking Prevention and Tobacco Control Act - An Overview*, U.S. FOOD & DRUG ADMIN. (June 3, 2020), https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview.

- Flavor restrictions: Similar to the ban on mint and fruit-flavored e-cigarettes,[47] limiting the use of certain flavors in CBD products can deter their appeal to children. Flavorings that mimic popular sweets or sugary treats should be restricted to prevent associations with child-friendly products.

- Marketing restrictions: Marketing tactics that might appeal to children, such as the use of animated characters, celebrities, or imagery related to children's interests, should be banned. This could include restrictions on advertisements in the media and sports and entertainment events.

[47] *FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint*, U.S. FOOD & DRUG ADMIN. (Jan. 2, 2020), https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children.