AIMED ALLIANCE

September 1, 2021

Via Electronic Communication
Cannabis_Reform@finance.senate.gov

U.S. Senator Chuck Schumer
Senate Majority Leader
322 Hart Senate Office Building
Washington, D.C. 20510

U.S. Senator Ron Wyden
Senate Finance Committee Chair
221 Dirksen Senate Office Bldg.
Washington, D.C., 20510

U.S. Senator Cory Booker
717 Hart Senate Office Building
Washington, DC 20510

Re: Cannabis Administration and Opportunity Act

Dear Senators Schumer, Wyden, and Booker:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on the Cannabis Administration and Opportunity Act ("CAOA") discussion bill. **In particular, we support (1) ensuring racial justice through cannabis regulation; (2) the creation of a regulatory pathway for cannabidiol (CBD) products; (3) FDA jurisdiction over cannabis products; (4) implementing strong safety requirements; and (5) preventing misleading marketing activities.**

I. Racial Justice and Cannabis Regulation

Cannabis legalization and regulation is a matter of racial justice. Historically, in the United States, the criminalization and prosecution of cannabis disproportionately impacts communities of color.[1] For example, despite cannabis use being equivalent between Black and White communities, Black individuals are 3.5 times more likely to be arrested for cannabis use than White individuals.[2] Even in states that have legalized cannabis, such as Colorado, Black individuals are still 1.5 times more likely to be arrested for having cannabis than White individuals.[3] These arrests can have substantial repercussions, including loss of child custody, employment, public housing, and public benefits, such as health care coverage.[4] Aimed Alliance supports Congress's efforts to regulate cannabis in a manner that addresses racial disparities and the long-term impacts that disproportionate arrests have on minority communities.

[1] https://www.aclu.org/news/criminal-law-reform/a-tale-of-two-countries-racially-targeted-arrests-in-the-era-of-marijuana-reform/
[2] *Id.*
[3] *Id.*
[4] *Id.*

While supporting this initiative, we also urge Congress to take steps to ensure consumers are protected from unknown and potentially dangerous chemicals in cannabis products, false and misleading advertising, and improper self-dosing.

II. Regulatory Pathway for CBD Products

Aimed Alliance supports the creation of a regulatory pathway for CBD products as dietary supplements provided that the pathway includes proper protections to ensure such products are safe and effective. According to the discussion draft, the CAOA may remove the prohibition on marketing CBD products as dietary supplements but would deem such products to be adulterated if they contain more than an HHS-determined level of CBD per recommended daily serving.[5] The CAOA may also provide the FDA with the ability to require safety-related labeling or packaging requirements and give the FDA the ability to take enforcement action against any noncompliant CBD-containing products that are not properly labeled as dietary supplements.[6] It would also give the FDA more comprehensive enforcement tools over products marketed as dietary supplements that contain substances that are excluded from the definition of dietary supplement, such as synthetic (i.e., non-hemp-derived) CBD.[7]

The CAOA should include provisions allowing the FDA to require additional safety and efficacy requirements, such as quality and potency testing, in order for CBD products to be marketed as dietary supplements. Many recent studies have shown that non-prescription CBD products are either adulterated or mislabeled. One 2019 study found that one-third of tested CBD products contained forms of synthetic marijuana while others did not contain any CBD at all.[8] A separate 2019 study found that nearly 70 percent of all products tested contained high levels of pesticides and heavy metals.[9] While the states have a patchwork of laws aimed at addressing these harms, a clear regulatory pathway is needed to ensure products are safe nationwide. Therefore, proper potency and quality testing is necessary to ensure products do not contain inaccurate amounts of CBD or contaminants, such as heavy metals, pesticides, and THC. Safety-related labeling and packaging alone is insufficient.

We also support providing the FDA with more comprehensive enforcement tools. While the FDA has issued approximately 80 warning letters since 2015 to marketers of non-prescription CBD products, companies continue to make unproved and misleading claims.[10] Despite lack of clinical evidence or FDA-approval, they have falsely stated that non-prescription CBD products can be used to prevent, cure, mitigate, and treat medical conditions, such as anxiety, depression, joint issues, digestive issues, chronic pain, ADHD, Alzheimer's disease, cancer, heart disease, and most recently, COVID-19.[11] More aggressive enforcement actions may be necessary to deter such companies.

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[5] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf at p. 27.
[6] *Id.* at p. 27.
[7] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf at p. 27.
[8] https://apnews.com/article/ut-state-wire-tx-state-wire-fl-state-wire-cbd-marijuana-7b452f4af90b4620ab0ff0eb2cca62cc
[9] https://wjla.com/features/i-team/the-risk-of-contaminants-and-false-labeling-in-the-exploding-cbd-industry
[10] https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products
[11] https://www.pbwt.com/misbranded/cbd-the-next-cure-all-and-the-next-frontier-for-false-advertising-litigation

III. FDA Jurisdiction

According to the discussion draft, the CAOA would transfer jurisdiction of cannabis products from the Drug Enforcement Agency ("DEA") to the Bureau of Alcohol, Tobacco, Firearms, and Explosives ("ATF"), the Alcohol and Tobacco Tax and Trade Bureau ("TTB"), and the U.S. Food and Drug Administration ("FDA").[12] The CAOA would provide discretion to these agencies to determine by a Memorandum of Understanding ("MOU") each agency's responsibilities.[13] Aimed Alliance recommends that the FDA have sole regulatory authority over cannabis products' labeling, packing, and advertising. The FDA is the appropriate regulatory authority to oversee these functions, and it is consistent with the FDA's current authority over dietary supplements and food products.

Additionally, providing dual responsibilities over these matters to the FDA, the TTB, and ATF, and giving the agencies discretion to formalize the responsibilities, could lead to years of confusion or duplication of efforts as witnessed by the regulation of certain alcohol products. For example, in 1974, the FDA and ATF (which had dual jurisdiction over labeling) entered an MOU designating ATF as "the primary agency responsible for the promulgation and enforcement of labeling regulations of distilled spirits, wine and malt beverages."[14] ATF agreed that its regulations would be consistent with the FDA's labeling requirements.[15] However, in 1975, "ATF yielded to pressure from the alcohol industry and decided not to require alcoholic beverage ingredient labeling, citing factors such as costs to the industry, international trade implications, the extensiveness of existing regulations, and the uniqueness of the alcoholic beverage manufacturing process."[16] As such, one stakeholder noted that the "FDA's primary constituency was the consuming public, while [ATF's] main constituency was the liquor industry, so it is not surprising that FDA wanted to require ingredient labeling on alcoholic beverages, while [ATF] did not."[17] Soon after, the FDA revoked the initial MOU and announced it would enforce liquor industry compliance with its labeling requirements.[18] This led to another

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[12] https://www.democrats.senate.gov/imo/media/doc/Cannabis%20Administration%20and%20Opportunity%20Act.pdf at p. 17.

[13] The draft discussion bill states "FDA would be recognized as the primary federal regulatory authority with respect to the manufacture and marketing of cannabis products, including requirements related to minimum national good manufacturing practice, product standards, registration and listing, and labeling information related to ingredients and directions for use. TTB would be recognized as the primary federal regulatory authority with respect to the taxation of cannabis products and trade practices of cannabis enterprises including the collection of federal excise taxes and enforcement of tax laws; tracking and tracing of cannabis products; and prohibitions on unfair competition and commercial bribery. The agencies would have dual jurisdiction related to certain aspects of cannabis product labeling and packaging, advertising, and other consumer information; however, the Discussion Draft would instruct agencies to coordinate and reduce duplication to the greatest extent practicable." https://www.democrats.senate.gov/imo/media/doc/Cannabis%20Administration%20and%20Opportunity%20Act.pdf

[14] https://dash.harvard.edu/bitstream/handle/1/8592152/mayberger.foodanddruglawpaper.caffeinatedalcoholicbeverages.pdf?sequence=1

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

MOU between the agencies, followed by a lawsuit, and several follow-up MOUs that continue to this day.[19]

Just as with alcohol, it could take several years and multiple MOUs to sort out the responsibilities between the agencies, leading to confusion and potential proliferation of bad actors who take advantage of the gap in the authorities. Therefore, to avoid similar situations in the future with cannabis regulation, the FDA should be given sole authority over product labeling, packing, and advertising.

IV. Implementing Safety Requirements

The CAOA would require the FDA to develop standards for cannabis products to protect the public health.[20] These would include standards on (1) the ingredients of the cannabis product; (2) the testing of the cannabis product; and (3) requiring the results of cannabis testing to show that the cannabis product conforms with applicable standards.[21] Additionally, the CAOA would establish the Center for Cannabis Products within the FDA, which would develop regulations for cannabis registration, listing, manufacturing, product standards, labeling, distribution, and recall.[22] The CAOA would also require that products not meeting the Center for Cannabis Products' requirements to be considered adulterated or misbranded, and any distribution of these adulterated products would be a violation of federal law.[23]

These provisions are necessary to mitigate the risk of non-FDA-approved cannabis products. Given that non-FDA-approved CBD products do not have to go through the rigorous safety and efficacy protocols or meet standards for quality, purity, and dosage, products may be adulterated with harmful substances, including high levels of THC, heavy metals, toxins, and mold.[24] For example, according to *the New England Journal of Medicine*, between March and April 2018, over 150 people presented to hospitals in Illinois with uncontrollable bleeding after using synthetic cannabis-based products that contained brodifacoum (i.e., rat poison).[25] Additionally, they may have more of, less of, or lack the active ingredient altogether.[26] Therefore, standards are needed to reduce the risk that such products will be unsafe.

V. Preventing Misleading Advertising

According to the discussion draft, the CAOA would prohibit misleading labeling and advertising practices.[27] It also would require cannabis manufacturers to submit consumer information, other labeling, and a representative sampling of advertisements for cannabis products to the FDA to ensure such materials are not misleading. Additionally, while the CAOA would not permit cannabis products to be regulated as dietary supplements, it would authorize

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[19] *Id.*
[20] https://www.politico.com/f/?id=0000017a-a490-dc3c-a57e-b4d8e25b0000
[21] https://www.politico.com/f/?id=0000017a-a490-dc3c-a57e-b4d8e25b0000
[22] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf at p. 25.
[23] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf
[24] https://wjla.com/features/i-team/the-risk-of-contaminants-and-false-labeling-in-the-exploding-cbd-industry
[25] https://www.nejm.org/doi/10.1056/NEJMoa1807652
[26] https://www.medicalnewstoday.com/articles/fda-report-evaluates-cbd-product-labeling-accuracy
[27] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf

manufacturers to make claims about the benefits of their products in the same manner as dietary supplements.[28] However, to prevent confusing and misleading statements, labeling would need to contain a warning that "these statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[29] Furthermore, states would be permitted to take more stringent measures regarding advertising and promotion of cannabis products.[30]

Aimed Alliance supports these consumer protections. As mentioned above, marketers of non-FDA-approved cannabis products regularly make unfounded claims that their products can treat medical conditions, such as anxiety, depression, joint issues, digestive issues, chronic pain, ADHD, Alzheimer's disease, cancer, and heart disease since 2015.[31] These claims violate the Federal Food, Drug and Cosmetics Act's provisions on unapproved new drugs and misbranded drugs.[32] However, while the FDA has issued warning letters, harsher penalties are required to serve as a more meaningful deterrent.

VI. Conclusion

In conclusion, Aimed Alliance supports the CAOA's efforts to address the racial justice of cannabis legalization, while also ensuring that the consumer protections that apply to typical drugs and dietary supplements also apply to cannabis and CBD products.

Sincerely,

Stacey Worthy
Aimed Alliance

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[28] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf
[29] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf; https://www.chpa.org/public-policy-regulatory/regulation/regulation-dietary-supplements/marketing-and-advertising
[30] https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf
[31] https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products
[32] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mb-solutions-llcbiospectrum-cbd-610649-07222021