

American Association of
Child & Adolescent
Psychiatry

August 18, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy & Commerce
U.S. House
Washington, D.C. 20515

The Honorable Bernard Sanders
Chair
Committee on Health, Education, Labor
and Pensions
U.S. Senate
Washington, D.C. 20510

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy & Commerce
U.S. House
Washington, D.C. 20515

The Honorable Bill Cassidy, MD
Ranking Member
Committee on Health, Education, Labor
and Pensions
U.S. Senate
Washington, D.C. 20510

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

On behalf of the American Association of Child and Adolescent Psychiatry (AACAP) and the over 10,000 child and adolescent psychiatrists, fellows, residents, and medical students that we represent, I am writing in response to your request for information (RFI) on the Food and Drug Administration's (FDA) regulation of cannabidiol (CBD), particularly to share the perspectives of child and adolescent psychiatrists. AACAP applauds your Committees prioritization of consumer safety as you look to find a regulatory pathway for hemp-derived CBD products.

Hemp is a cannabis plant that contains less than .3 percent of tetrahydrocannabinol (THC), an intoxicating cannabinoid compound found in marijuana cannabis plants. Cannabidiol (CBD) is a cannabinoid compound that can be derived from marijuana or hemp plants. Regardless of the origin of the CBD, it does not act as an intoxicant. Rather, CBD may have medicinal effects for certain conditions including seizure, pain, and wasting commonly associated with cancer and HIV. There is currently insufficient clinical evidence to support most of the purported health benefits of CBD. Moreover, more research is necessary to gauge the long-term effects of cannabinoids like CBD and THC on youth, pregnant women, and other vulnerable populations.

To properly ensure that consumer safety is prioritized when crafting legislation on the FDA regulation of CBD products, AACAP urges your Committees to consider the following recommendations: (1) clarify that hemp-derived products are broad-spectrum products, (2) restrict tetrahydrocannabinol compounds as a class of compounds per the Controlled Substances Act and (3) require age restrictions and other warning labels for hemp-derived broad-spectrum products.

Additionally, as your Committees look to craft legislation focused on consumer safety, AACAP also calls on you to (1) increase investments in research on effects of CBD on children and adolescents and (2) fund education for youth, families, and providers on CBD products.

Hemp-derived CBD Products are Broad-spectrum Products

Cannabidiol derived from the hemp plant is inherently a broad-spectrum product in that plant-derived products are not considered “pure.” Hemp-derived products may contain other cannabinoid compounds including terpenes, flavonoids, and even small amounts of THC. Only pharmaceutical grade CBD should be considered “pure.” AACAP suggests that the regulations under consideration define hemp-derived products as broad-spectrum products and pure CBD products as pharmaceutical grade CBD.

Tetrahydrocannabinol and THC-derivates are a Class of Compounds

Hemp-derived CBD can be converted into synthetic tetrahydrocannabinols like Delta-8 THC that are chemically similar to Delta-9 THC and can induce psychoactive responses similar to Delta-9 THC. AACAP recommends that all tetrahydrocannabinols be classified as Schedule 1 substances so that manufacturers are required to prove their medical utility and safety before being reclassified. AACAP also recommends that funding be provided for consumer awareness education regarding Delta-9 derivatives as they can be assumed to be less harmful than Delta-9 THC.

Hemp-derived CBD Products Should be Age-restricted and Have Warning Labels

Hemp-derived cannabinoids have not been approved by the FDA as medical or healthcare-related products and, as such, are not subject to the efficacy and safety standards that guide pharmaceutical products. Because hemp-derived products are broad-spectrum products and liable to contain non-CBD cannabinoids, the products should be clearly labeled as such, including that they may contain THC. Warning labels should advise consumers that CBD and other cannabinoid dosing cannot be guaranteed and may not be uniform throughout the product.

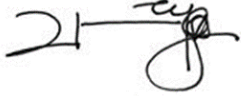
Recent research shows that 3.0% of the general U.S. population of 12-17-year-olds reported that they vaped CBD, with 21.3% of current e-cigarette user aged 12-17-years report current CBD vaping.¹ Given the known adverse health outcomes of adolescent cannabis users including depression, increased suicide ideation, and the associated risk of long-term cannabis exposure and adolescent and adult cannabis use disorder, hemp-derived CBD products should be age restricted and include warnings regarding the potential negative developmental impacts on children, pregnant women, and breastfeeding mothers. AACAP recommends that hemp-derived broad-spectrum CBD be restricted to adults aged 18 and over. Similarly, AACAP recommends continued research in the effects of cannabinoid exposure on children and adolescents as well as research on the impact of price elasticity on youth consumption of marijuana and hemp-related product consumption.

AACAP is grateful for the opportunity to provide comments on this important matter. As child and adolescent psychiatrists who treat patients across the lifespan, we are acutely aware of the short and long-term impacts of pediatric exposure to unregulated “medical” and “healthcare”

¹ [Prevalence and Factors Associated With Vaping Cannabidiol Among US Adolescents | Tobacco and e-Cigarettes | JAMA Network Open | JAMA Network](#)

products. Every effort should be made to require product transparency by the manufacturers and consumer awareness of the known and unknown risks of using unregulated products that are subject to little or no quality control. Please contact AACAP's Chief of Advocacy and Practice Transformation, Alexis Geier Horan at ahoran@aacap.org, should you seek additional information from AACAP or for any other follow-up.

Respectfully,

A handwritten signature in black ink, appearing to read 'W. Ng', with a stylized flourish at the end.

Warren Y. K. Ng, MD, MPH

President