THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 2800
Philadelphia, PA 19103-7077
P 215.575.9050
F 215.575.4939

901 E Street NW, 10th Floor
Washington, DC 20004
P 202.552.2000
F 202.552.2299

pewtrusts.org

August 23, 2021

The Honorable Chuck Schumer
Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Ron Wyden
Chairman, Committee on Finance
United States Senate
Washington, D.C. 20510

The Honorable Cory Booker
United States Senate
Washington, D.C. 20510

Re: ''Cannabis Administration and Opportunity Act''

Dear Leader Schumer, Chairman Wyden, and Senator Booker,

The Pew Charitable Trusts (Pew) thanks you for your leadership on the release of the "Cannabis Administration & Opportunities Act" (CAOA) discussion draft and appreciates the opportunity to provide our comments. Pew is an independent, nonpartisan research and policy organization with a longstanding focus on public health, which includes assuring the safety and quality of dietary supplements. The release of the discussion draft is an important step towards regulating the growing cannabidiol (CBD) industry, which includes a substantial number of CBD-containing products sold as dietary supplements. As you consider next steps in the legislative process, we strongly urge you to include an important product listing requirement that would allow the U.S. Food and Drug Administration (FDA)—the agency with primary responsibility over dietary supplements—to better protect consumers from potentially unsafe dietary supplements, including those that contain CBD.

The growth of the dietary supplement industry has outpaced federal oversight

Since the enactment of the Dietary Supplement Health and Education Act (DSHEA) more than 25 years ago, the dietary supplement industry has grown exponentially—from around 4,000 products in 1994, to as many as 80,000 today.[1] The COVID-19 pandemic further exacerbated this growth, as an increasing number of consumers turned to dietary supplements throughout the past year to support their health and wellness.[2] If section 505 of CAOA—which establishes CBD products as dietary supplements—were to be implemented, the number of products under FDA Office of Dietary Supplement's jurisdiction would only increase as the CBD market—which already includes a substantial number of products sold as supplements—is expected to reach $16 billion by 2025.[3]

[1] https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2021/04/congress-should-prioritize-dietary-supplement-reform-as-part-of-efforts-to-strengthen-public-health
[2] https://www.naturalproductsinsider.com/business-resources/how-covid-19-has-sparked-new-normal-health-and-wellness-industry
[3] https://www.cowen.com/insights/cowen-collective-view-of-cbd/

Currently, the FDA lacks the ability to know with certainty what dietary supplement products are reaching consumers and what is in them. This is especially dangerous because not all dietary supplements are safe. Between 2004 and 2013, FDA received more than 15,000 reports of health problems linked to supplements, including 339 deaths and nearly 4,000 hospitalizations. In a recent Pew survey of American adults, 1 in 8 (12%) said they or an immediate family member had experienced a severe side effect, such as a heart, kidney, or liver problem, from a supplement. Furthermore, between 2007 and 2019, the agency found that 965 products marketed as dietary supplements illegally contained active pharmaceutical compounds found in prescription drugs. The agency warned that these products likely represented only "a small fraction of the potentially hazardous products with hidden ingredients." Additionally, over the past several years, FDA has issued warnings to dozens of companies for illegally marketing supplement products, including CBD products, citing safety concerns.[4] This includes over a dozen companies marketing these products for COVID-19.

Mandatory product listing should be a key requirement for all dietary supplements

Mandatory product listing—or the requirement for dietary supplement manufacturers to file a comprehensive list of the ingredients their products contain and in what amount, warnings and precautions, and allergen statements, among other information—is a low-cost, low-burden regulatory tool that would enable FDA to obtain a complete picture of the marketplace and to provide more robust surveillance and consumer protections. A listing requirement strengthens FDA's ability to more efficiently respond to emerging safety concerns and to prioritize its limited resources and expertise across the thousands of supplement products being sold.

Additionally, it allows the agency to quickly identify and alert consumers about potentially unsafe products—a feature that is especially important as more novel ingredients, like CBD, are introduced and in cases where evidence of previously unknown consumer risks arise. For example, in 2019, FDA issued a warning about supplements containing the synthetic compound vinpocetine after a National Institutes of Health study revealed the significant risks it poses to pregnant women. If FDA had a comprehensive listing of all supplements on the market, it could have consulted the listing database for products that contained this ingredient and more quickly warned consumers or mandated a recall—rather than painstakingly tracking down each individual product. Moreover, if the information captured through a mandatory listing requirement was publicly available, it could also serve as an important transparency tool for retailers and consumers and allow them to make informed decisions about the supplement products they sell or purchase.

FDA's limited window into dietary supplements also makes it difficult to accurately assess the magnitude and quality of CBD supplement products being sold to American consumers. If the category of dietary supplements is to be expanded by Congress to include those with CBD, then it is vital to include important guardrails—such as mandatory product listing—so that FDA has more robust tools to regulate this newer industry and keep consumers safe. A listing requirement in CAOA would provide a safety net for consumers while empowering FDA to explore outstanding public health questions related to CBD products.

[4] https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products

FDA needs adequate resources to oversee this growing industry

Additionally, If Congress creates a legal path to market for CBD dietary supplements, it must appropriate adequate resources to ensure FDA's Office of Dietary Supplement Programs (ODSP) has the necessary capacity to undertake increased oversight duties. The $3 million currently allocated for dietary supplement programs within the FY22 Agriculture-FDA Appropriations bill is a great first step to shore-up resources; however, additional funding will be necessary to ensure that FDA resources match the needed demand for increased authorities and oversight.

As CAOA, or any subsequent CBD-related federal policy, advances to legalize CBD-containing dietary supplements, we urge you to protect consumers and make mandatory product listing a requirement for all supplements a part of the legislation. We thank you for your commitment to public health and to the important role that the FDA plays in regulating dietary supplements, and we look forward to working with you to ensure enactment and implementation of improvements to supplement oversight. Should you have any questions, or if we can provide any assistance, please do not hesitate to contact Elise Ackley at the Pew Charitable Trusts at eackley@pewtrusts.org or (202) 540-6464.

Sincerely,

Elizabeth Richardson
Project Director, Health Care Products
The Pew Charitable Trusts