Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM 2157 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6143

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April 14, 2022

The Honorable Carolyn B. Maloney Chairwoman Committee on Oversight and Reform U.S. House of Representatives Washington, D.C. 20515

Dear Chairwoman Maloney:

We write to request that the Committee on Oversight and Reform hold a hearing to examine the failure of the Food and Drug Administration (FDA) to develop a regulatory regime that effectively oversees the sale of hemp-derived extracts such as cannabidiol (CBD). Across the United States, inauthentic products are sold under the likeness of legal hemp but are improperly labeled, contaminated with harmful chemicals, and marketed to children. We must hear directly from the FDA to ensure the agency has a plan to institute a regulatory solution that can effectively monitor the sale of hemp products and protect the health of children.

The 2018 Farm Bill, which enjoyed bipartisan support, legalized hemp and cannabis derivatives with very low concentrations of delta-9-tetrahydrocannabinol (THC) and preserved the FDA's regulatory authority over legal hemp and CBD products. After passage of the bill, FDA commissioner Scott Gottlieb wrote that "Congress explicitly preserved the (FDA's) current authority to regulate products containing cannabis or cannabis-derived compounds" and that for the FDA "it is even more important with the passage of this bill to clarify its regulatory authority over these products." However, the FDA has failed to take steps to ensure the safety of these products, putting the health and safety of the American people at risk.

¹ Abernethy, Amy, *Hemp Production and the 2018 Farm Bill*, Congressional Testimony before the Senate Committee on Agriculture, Nutrition and Forestry, July 24, 2019.

² Gottlieb, Scott, Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds, Food & Drug Administration, Dec. 20, 2018.

The legal limit for THC, the chemical that creates an intoxicating effect, is 0.3 percent in hemp products.³ The FDA's failure to establish a regulatory regime for hemp is enabling mislabeled products that contain more THC than the legal limit to be sold. Unfortunately, mislabeled products have caused many adverse health events in children. In South Carolina, a 2 year-old child was transported to the hospital for consuming a mislabeled CBD gummy, a 14 year-old received medical treatment, and a 15 year-old had an adverse reaction after eating a THC-laced gummy.⁴ Following these events, local sheriff Mike Crenshaw said that "this is an unintended consequence of our state legalizing hemp" because "[t]here are no current regulations concerning these products."⁵ Beyond these events, the ingestion of THC can have serious long term effects on children, including altering important aspects of their brains, increased risk of fertility issues, and immune system problems.⁶

Another concerning development is the sale of Delta-8 Tetrahydrocannabinol (Delta-8 THC). Often sold for use in vape devices, Delta-8 THC is manufactured from CBD derived ingredients. It is troubling that the product contains intoxicating chemicals, giving users the "high" feeling of federally illegal marijuana. The production and sale of Delta-8 THC undermines the congressional intent of the 2018 Farm Bill. The bill was intended to legalize non-intoxicating hemp products, not a synthetic alternative to marijuana.

The newly confirmed FDA commissioner, Robert Califf, has not publicly expressed an official position on this critical issue. We respectively request that the Committee hold a hearing in order for the FDA to explain how it plans to resolve the serious issue of mislabeled CBD products. By doing so, we will empower good-faithed hemp farmers and protect American consumers—especially children—from intoxicating cannabis.

Thank you for your attention to this important request.

Sincerely,

James Comer Ranking Member

³ Abernethy, Amy, *Hemp Production and the 2018 Farm Bill*, Congressional Testimony before the Senate Committee on Agriculture, Nutrition and Forestry, July 24, 2019.

⁴ Shaw, Amanda, *Police issue warning after 2-year old ingests THC-laced gummies*, WYMT, Mar. 29, 2022. ⁵ *Id.*

⁶ Dowshen, Steven, Marijuana, NEMOURS CHILDREN'S HEALTH, May 2018,

⁷ 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC, Food & Drug Administration, Mar. 18, 2022.