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Council For Federal Cannabis Regulation

U.S. House Committee on Appropriations
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
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submitted by

The Council for Federal Cannabis Regulation

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Assuring Adequate Resources at the U.S. Food and Drug Administration for the Establishment of the Center for Cannabis Products

The Council for Federal Cannabis Regulation (CFCR) is a nonprofit organization working to educate federal policymakers and regulators about the unique issues and challenges related to cannabis that must be addressed to develop a sound, science-based regulatory framework for drugs, foods, dietary supplements, veterinary products, and cosmetic products. CFCR fully appreciates how truly unprecedented the transition from total prohibition and stigmatization to regulation has been and will continue to be for cannabis. For that reason, we seek to impress upon this Subcommittee how crucial it is that the U.S. Food and Drug Administration (FDA) have adequate resources for the establishment of the Center for Cannabis Products (CPC) that can be operational in FY 2023.

CFCR has assembled a team of leading scientists, entrepreneurs, regulatory lawyers and representatives of hemp, pharmaceutical, nutraceutical, consumer packaged goods, wellness, cannabis and other enterprises, and patient advocacy organizations, all of whom are all stakeholders in a safe and well-regulated cannabis market. CFCR's Science and Regulatory Affairs Committee ("SRAC") has guided the drafting of the appropriations request in this testimony. CFCR's SRAC is co-chaired by **Dr. Vicki Seyfert Margolis** and **Dr. Rhona Applebaum**. A recognized science policy leader, Dr. Seyfert-Margolis was the Senior Advisor for Science Innovation and Policy in the Office of the Commissioner of the FDA. While at the FDA, she oversaw the development and execution of an agency-wide strategic plan for regulatory

science. Dr. Applebaum is the former Chief Science and Regulatory Officer of The Coca Cola Company. She also served in senior leadership positions with several food and beverage trade associations. Dr. Applebaum has been a member of various government advisory boards, committees, and delegations for FDA (including the Science Board to the FDA), USDA, and the State Department on issues related to trade, food safety, nutrition, and biotechnology.

CFCR is working to support FDA's access to: a) desperately needed resources, b) independent scientific and regulatory science experts; and c) the most current data and research. In order for FDA to operate within and advance a 21st century approach to regulating the wide variety of beneficial products yielded by a plant that has been federally illegal for eight decades, the U.S. must have a regulatory framework with safety and sound science at its core[1] consistent with FDA's mission and mandate.[2]

We appreciate that, in prior years, this Subcommittee has endeavored to ensure FDA received resources for cannabis-related regulatory activities to begin building the requisite expertise and understanding required to regulate cannabis-derived consumer and animal products at the federal level and provide an overarching national regulatory framework and enforcement policies for this commercial sector. Nonetheless, it is clear that more resources are required.

While the FDA has allocated substantial professional staff time on cannabis issues, the scope of the task in front of the agency is demonstrably far greater than the currently available resources. Shortly after passage of the 2018 Farm Bill, the FDA held a public hearing to obtain information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. The agency heard testimony from 100 witnesses, had more than 600 attendees in person and over 2,300 joining remotely. FDA received nearly 4,500 written comments, many of which urged the FDA to establish a regulatory framework intervention to preserve public health and safety interests.[3] In March 2020, the FDA re-opened the comment period to provide researchers and other stakeholders a clear way to submit information to the agency as it becomes available.[4] That same year sales of cannabidiol (CBD) derived from hemp were estimated to have reached $4.6 billion in the U.S.[5] Although FDA submitted proposed guidance to the White House, it was never published, and

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[1] Details on CFCR's entire well credentialed leadership team, including CRCR's Board of Directors, committee chairs, advisory board members, and partner organizations, can be viewed at: **www.uscfcr.org**.

[2] "The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation." FDA Mission

[3] See FDA's March 2020 Report to House and Senate Committees on CBD in response to the Further Consolidated Appropriations Act of 2020, available here.

[4] FDA, Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing (May 21, 2019).

[5] Mike Sill, "The Future Of The CBD Industry In 2022 And Beyond," Forbes (Oct 21, 2021).

the industry continues to be mired in uncertainty, with some bad actors producing unsafe products unchecked.

Since passage of the 2018 Farm Bill, we have closely followed the FDA's efforts to balance its responsibility to protect public health and to develop policies and guidance for the industry. Among other things, the agency has issued warning letters involving misbranding violations and marketing of unapproved drugs, published objections to New Dietary Ingredient (NDI) notifications involving full-spectrum hemp extract products, published guidance to encourage clinical research using cannabis and cannabis-derived compounds, held a Scientific Conference on sex and gender differences in use and responses to CBD and other cannabinoids, published a warning against the use of CBD, THC, and marijuana in any form during pregnancy or while breastfeeding, and launched an agency Cannabis-Derived Products Data Acceleration Plan (DAP). Additionally, the FDA's National Center for Toxicological Research (NCTR) has been conducting important studies on CBD toxicities and pharmacokinetics. We are concerned, however, that the agency's Centers' cross-cutting work on cannabis product policy has no separate funding source, even though FDA continues to dedicate scarce resources to guidance and product review in this rapidly growing market.

The domestic CBD market is expected to continue to grow exponentially and to diversify as companies develop formulations based on less well-known compounds from cannabis plants, including but not limited to cannabinol (CBN) and cannabigerol (CBG).[6] Yet companies continue to operate in a regulatory gray area where issues of financial services and capital access remain constrained. A consumer product market of this size, growing at such an accelerated rate with such significant public health and safety implications, needs an adequately funded FDA to ensure public health and safety remains first and foremost, based upon effective guidance practices, rules, and regulations.

While CFCR is pleased that the FDA recently formed an intra-agency Cannabis Products Council (Council) to work on cannabis product policy, enforcement, outreach, and data collection, absent dedicated and sufficient appropriations for the Council's work, the group will continue to face significant challenges and progress will be delayed. As the Subcommittee is aware, the FDA's ability to provide regulatory clarity is essential to protecting public health and stabilizing the market with safety testing, good manufacturing practices, reliable measurements, labeling standards, directions for use, and ensuring any adverse events are captured within the FDA Adverse Event Reporting System (FAERS). A clear framework should be based on an understanding of dosage, drug interactions, toxicity profiles, therapeutic benefits, and the role

[6] Market research firms predict the growth of CBD infused products globally to exceed $150 billion by 2028. See Cision PR Newswire release (August 5, 2021) and Grand View Research market analysis report summary (May 2022).

of the endocannabinoid system and, most importantly, assuring consumer confidence and safety.

Significant public health equities are at stake as our nation transitions from federal cannabis prohibition to a new cannabis marketplace. The agency has an important role to play in balancing the goal of incentivizing innovation, research, and investment for drugs derived from cannabis, while ensuring we have a trusted, safe, and transparent marketplace for foods and dietary supplements. The agency cannot continue to move at a glacial pace when cannabis products already proliferate across the U.S. and are used by millions of Americans daily.

For these reasons, CFCR recommends that Congress provide sufficient appropriations to fully fund a new **FDA Center for Cannabis Products (CPC)** as envisioned by the draft Cannabis Administration and Opportunity Act, circulated for comments, currently expected to be introduced in the Senate by Senators Chuck Schumer (D-OR), Cory Booker (D-NJ), and Ron Wyden (D-OR) this summer.[7] With sufficient funding, the newly proposed CPC could absorb the work being done by the existing Cannabis Product Council at FDA, and integrate the Data Acceleration Plan (DAP), which has already been deployed by FDA, as well as other activities ongoing at the agency.

Specifically, we request the Subcommittee provide an initial $10,000,000 for FY 2023 to establish the CPC at FDA. This figure is based on previous funding requests for Centers of Excellence, and other similar offices at FDA whose remits span products across different Centers at FDA.

CFCR appreciates the opportunity to share our FY 2023 appropriations recommendations with the Subcommittee. CFCR is fully dedicated to the safety of the consumer, accessibility of cannabinoids, and working closely with this Subcommittee, FDA, HHS, Congress, consumers, the industry, and the appropriate legislative entities to provide adequate funding, through appropriations or other means, for the establishment of the FDA Center for Cannabis Products. We are available as a further advisory resource for the proposed FDA Center for Cannabis Products and this Subcommittee. CFCR recognizes that much is being asked of the federal agencies within the context of regulation and wishes to bring a uniform and informed approach to the understanding of this industry for the benefit of all.

For further information, please contact Sarah A. Chase, Executive Director of the Council for Federal Cannabis Regulation: sarah@uscfcr.org

[7] See July 14, 2021 Press Release, Majority Leader Schumer, Senate Finance Committee Chair Wyden And Senator Booker Release Discussion Draft Of Cannabis Administration And Opportunity Act, Legislation To End The Federal Cannabis Prohibition And Unfair Targeting Of Communities Of Color and accompanying discussion draft, one-pager, and summary available here.