August 17, 2023

Honorable Cathy McMorris Rodgers
Chairwoman
Committee on Energy and Commerce
United States House of Representatives

Honorable Bernard Sanders
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate

Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
United States House of Representatives

Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

RE: Response to July 27, 2023, Request for Information Concerning Cannabidiol

Dear Chairs Sanders and McMorris Rodgers and Ranking Members Cassidy and Pallone:

On behalf of COGR, an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes, we appreciate the opportunity to submit comments in response to the July 27, 2023, Request for Information Concerning Cannabidiol ("RFI"). COGR focuses on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions and advocates for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens.

COGR's member institutions are leaders in the conduct of biomedical research, including human and animal research using cannabidiol (CBD) and cannabis. We have a cannabis research working group consisting of experts from COGR member institutions across the U.S. that conduct cannabis-related research. Although much of the RFI focuses on CBD approval paths and marketing regulations, Section 12 of the RFI focuses on questions concerning the safety of CBD. Researchers at COGR member institutions have a substantial interest in conducting important research using cannabis and/or CBD to evaluate safety, effectiveness, and side effects in humans and animals. Accordingly, our comments below focus on item 12 of the RFI:

> ***What actions, if any, should the Federal government take to better understand the potential benefits or harms of CBD products and other cannabinoids?***

Comments: The public's increasing acceptance and use of products containing CBD and other cannabinoids creates an imperative for scientific research to better understand the potential benefits and harms of these substances. Depending on the source of the CBD being studied (e.g., type of plant, chemical synthesis) and its THC content, such research may fall under the

Agriculture Improvement Act of 2018's[1] ("Act") provisions for hemp or, alternatively, be regulated under the Drug Enforcement Administration's (DEA) stricter controls for the study of marijuana, a Schedule I Controlled Substance. Under these controls, it can take a year or more to obtain the necessary DEA and state registrations necessary to conduct a research protocol using cannabis or CBD, even though the same or similar products may be obtained by members of the public from many state-authorized dispensaries.

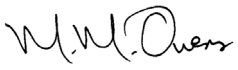
Ambiguities in the Act and the DEA Interim Final Rule (IFR) implementing the Act[2] make it difficult for researchers to determine which regulations apply. For example, under the DEA IFR it appears that researchers must not only determine that the product they wish to study contains no more than 0.3% THC to meet the Act's definition of hemp but must also consider if the CBD was derived from a plant or was chemically synthesized in a lab.[3] Further, there is some ambiguity in the IFR as to whether plant-derived CBD containing no more than 0.3% THC qualifies as hemp regardless of whether the specific cannabis plant from which it was derived or extracted was a hemp plant or a marijuana plant. Such uncertainty leads to confusion and resulting delays and burden that impedes research.

Additionally, when the CBD product being studied is considered a Schedule I Controlled Substance, DEA limits the source of products for testing to DEA-approved suppliers, as opposed to product types that may be widely available to the public via state-authorized dispensaries. Thus, the research that can be legally conducted often cannot evaluate the safety and effectiveness of those products most commonly used by consumers.

We urge the federal government to establish a process that permits researchers studying CBD to obtain, synthesize, and conduct research on CBD products without the need for a DEA Schedule I registration regardless of whether the CBD is derived from a hemp plant, a marijuana plant, or chemically synthesized. Such action would foster research that is vital to understanding both the potential benefits and harms of products that consumers are currently using and assist the government in developing appropriate approval paths, manufacturing controls, and labeling.

Thank you for the opportunity to offer these comments in response to the RFI. Should you have any questions regarding this response, please contact me or Kristin West, COGR's Director for Research Ethics and Compliance at kwest@cogr.edu.

Sincerely,



Matt Owens
President

[1] Pub. L. 115-334 (Dec. 20, 2018).
[2] 85 F.R. 51639 (Aug. 21, 2020).
[3] *See, e.g.*, U.S. Dept. of Justice, DEA, Response Letter to Rod Kight (Feb. 13, 2023)(classifying delta 9-THCO and delta-8-THCO as controlled substances as opposed to hemp because they can only be obtained synthetically).