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JOHNS HOPKINS
MEDICINE

DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

03/13/2026

Congressman Morgan Griffith
2110 Rayburn HOB
Washington, DC 20515

Dear Congressman Griffith,

I am a Professor in the Department of Psychiatry and Behavioral Sciences at Johns Hopkins University and am also a longstanding member of the College on Problems of Drug Dependence (CPDD), the oldest professional organization dedicated to understanding the intersection of drug use and behavior. For the past 26 years I have conducted a number of controlled research studies aimed at understanding the health effects of both acute and chronic cannabis use, with a particular focus on characterizing how differences in route of administration, chemical composition, formulation, and dose impact the absorption, metabolism, and effects of these drugs when consumed by humans.

I wholeheartedly support the language in the Fiscal 2026 Agriculture Appropriations Act passed by congress in November 2025 that explicitly places the unregulated retail market of intoxicating cannabinoid products purportedly derived from hemp into Schedule I of the CSA when it takes effect in November 2026. These products, often containing very high doses of delta-8-THC, delta-9-THC and other semi-synthetic cannabinoids, pose a very real danger to public health and should be controlled. However, as you are aware, the language in that bill also greatly restricted allowable amounts of delta-9-THC or related naturally occurring cannabinoids believed to be "intoxicating" to a threshold of 0.4 mg per container in total, which would result in making the majority of "full-spectrum" hemp products illegal later this year. One contributing factor in the federal legalization of hemp in the 2018 Farm Bill was that non-intoxicating hemp products can provide substantial health benefit to Americans with severely debilitating illness for which alternative treatments either do not exist or have failed a given patient due to poor efficacy or safety. These include children with rare forms of epilepsy, extreme cases of autism, cancer patients of all ages, those struggling with treatment-resistant anxiety or depression, and a host of other health concerning health problems. We applaud your initiative to establish a federal regulatory framework for hemp-derived CBD products intended for human use within the Food and Drug Administration (FDA) and believe we can assist with this effort to provide guidance that will maximize the public health benefit of a legal hemp market and concurrently limit the public health risk associated with unregulated sales of harmful hemp derivatives.

Recently one of your staffers contacted CPDD seeking expert guidance related to a recommendation of threshold doses of delta-9-THC that should be allowed in retail hemp products that is informed by the latest science. As a member of a CPDD workgroup that provides policy recommendations related to substance use, and cannabis in particular, below, I

provide you specific policy recommendations on behalf of the CPDD policy workgroup that we believe balances access to products desired by those using CBD products for health-related purposes while also protecting public health from products with high abuse liability. Along with each recommendation, a summary of the current scientific evidence base that supports the recommendation is provided. Accompanying this letter, you will also find a number of scientific publications referenced below.

Before getting into specific delta-9-THC dose recommendations, there are some universal recommendations we have that apply to the entire category.

1) **All retail hemp products should contain at least a 20:1 ratio of CBD:THC (or non-intoxicating:intoxicating cannabinoids more broadly once the FDA has published their list). Finished retail hemp/CBD products should have a relative chemical composition that reflects the federal definition of hemp and these should not be allowed to be manipulated to increase abuse liability or health risks.**

2) **The federal regulatory framework should include standards for hemp cultivation, processing, testing, and labeling that are evidence based.**

3) **Age restrictions for the purchase of any hemp/CBD product intended for human consumption should be implemented.**

With that said, we believe it is important to differentially regulate hemp product categories based on intended route of administration. Clinical research conducted by myself and others shows substantial differences in drug absorption and abuse liability between inhaled, oral, and topically applied cannabis products. Our recommendations (with subsequent justification) are that hemp product regulation includes the following dose limits:

1) **Hemp products intended to be orally ingested should be limited to no more than 2.5 mg Total THC (defined as the combination of delta-9-THC and any other naturally occurring isomers or analogues of delta-9-THC) per serving.**

An oral dose format is by far the most common for retail CBD products. I recently conducted a controlled laboratory experiment in which we evaluated the effects of twice daily exposure of an orally ingested "CBD oil" that contained 100mg CBD combined with one of 5 doses of delta-9-THC (0.5mg, 1mg, 2mg, 2.8mg, or 3.7mg) that approximates the range of delta-9-THC doses commonly found in retail full-spectrum CBD oil products. Study participants (60 healthy adults) were given their first dose under observation in my laboratory and then took additional doses, twice daily, for 14 days. We assessed them throughout the day after the first dose and again on Days 2, 7, and 14 of taking the study drug as well as 1 week after they stopped. Participants completed a test battery that evaluated subjective ratings of interoceptive drug effects, cognitive and psychomotor performance, cardiovascular function and drug testing outcomes. There were no differences in subjective drug effect ratings, cognitive or psychomotor ability, or cardiovascular effects between individuals taking drug products containing only CBD and those containing CBD plus doses of delta-9-THC up to 3.7mg per dose. These results were recently published in the peer-reviewed scientific journal *The Journal of Analytical Toxicology* (PDF attached).

In addition to this controlled laboratory study, there is substantial real-world data related to the public health risk and abuse liability of oral doses of delta-9-THC. Since 1986, dronabinol, an FDA approved formulation of encapsulated delta-9-THC has been available for prescription in 2.5 mg, 5 mg, and 10 mg doses. In 2016, the FDA approved an oral dronabinol solution containing 5 mg delta-9-THC/mL. The FDA-recommended starting doses for these products are

2.1 to 5 mg (depending on the health indication) and the risk of diversion or abuse has been negligible in the 40-year history these products have been on the market. In 1998, a detailed evaluation of dronabinol abuse liability by Calhoun and colleagues (PDF attached) concluded that there was no evidence of doctor shopping, illicit street sales, or problematic use behavior among patients who had received a prescription. Moreover, there has been no indication that oral hemp products that predominantly contain CBD as the primary chemical constituent have been misused or abused for intoxicating purposes since the federal legalization of hemp in 2018. Note that this explicitly excludes "hemp" products for which the primary chemical constituent is an isomer or analogue of delta-9-THC that was synthetically derived from hemp.

We recommend a maximum of 2.5 mg delta-9-THC per dose in oral hemp products (versus something higher) because that is the lowest and most common starting dose for prescription dronabinol, there was no evidence that doses near or below that threshold disrupted daily functioning in our laboratory study, most "full spectrum" CBD oils in the retail market fall below this threshold, and it is also compatible with average dose behavior we observed in patients using full spectrum CBD products to manage symptoms of anxiety or depression (PDF attached).

2) **Hemp products intended for topical administration should not have dose limits related to delta-9-THC content due to demonstrated poor transdermal permeability and no evidence of abuse liability.**

The second most common retail CBD product format is topicals (i.e., creams, lotions, salves, etc. that are intended to be applied directly to the skin). It may seem odd to recommend no dose restriction for any product category, but delta-9-THC has extremely poor transdermal bioavailability, even in products that contain permeation enhancers. My colleague, Dr. Tory Spindle, recently completed a laboratory study in which healthy adults were given topically applied retail CBD products twice daily for 10 days. Prior to the study, he purchased and analyzed 105 retail topical hemp products and selected the 5 products most likely to maximize exposure to delta-9-THC. This included the products with the highest delta-9-THC content (a cream that contained 100 mg delta-9-THC), different formulations (lotion, cream, patch), and ingredients known to facilitate transdermal absorption of drug substances (DMSO, ethanol). Data analysis showed that no study participant experienced a subjectively perceptive drug effect, there was no detection of delta-9-THC or any metabolites in the blood or urine of the study participants, and no side effects were experienced aside from occasional irritation of the skin at the site of administration. This study was recently published in the *Journal of Analytical Toxicology* (PDF attached).

Similar to the oral dose CBD product story, there is no evidence to indicate that topical CBD products are being misused by youth or have any abuse liability whatsoever, at any dose. Because delta-9-THC is not transdermally absorbed at concentrations or at a speed required to produce an intoxicating drug effect, control of the delta-9-THC content of these products is not necessary.

3) **Hemp products intended to be inhaled should only be allowed if the drug substance is packaged in a metered-dose device, contains no artificial flavors, and contains no more than 1 mg total THC per dose delivery (i.e., per "puff").**

CBD products intended for inhalation are relatively rare compared with oral and topical products, but a market does exist. In controlled laboratory studies, vaporization of delta-9-THC has been shown to be a faster and more efficient method of drug delivery compared with oral ingestion. In a prior laboratory study, we showed that vaporization of cannabis flower containing 100 mg CBD and 3.7 mg delta-9-THC produced moderate subjective drug effects,

including some measures that suggest abuse liability, in healthy adults, but no evidence of impaired functioning or acute side effects (PDF attached). Multiple published clinical trials from an Israeli pharmaceutical company shows that a metered dose inhaler that delivers 0.5 mg or 1 mg of delta-9-THC is effective at reducing pain in patients with chronic pain, does not produce drug effects different from placebo, and is safe for daily use among older adults in the absence of abuse liability (PDFs attached). Moreover, there is extensive research among nicotine and tobacco products that clearly shows both pulmonary health risk and increased abuse liability for e-cigarette products that contain palatable flavors. Because inhalation has a higher risk of health burden and abuse liability, we recommend only allowing inhalable hemp products that meet these stringent criteria and recommend against allowing the sale of raw hemp flowers outside of regulated state cannabis programs.

4) **Hemp suppositories should contain no more than 2.5 mg per dose.**

There is very little science that has been conducted with hemp/CBD products to inform this recommendation, but there is even less demand for these products. It is a very small market that appears to be exclusively focused on true therapeutic use, but is in need of quality control standards. The recommendation here for 2.5 mg per dose is to be in line with the oral dose recommendation, which is most similar, relative to other routes of administration, based on general knowledge of pharmacology and pharmacokinetics.

We have intentionally excluded recommendations related to total "package" dose limits for a few different reasons.

1) Businesses can easily circumvent that rule by individually wrapping doses, which is wasteful.
2) Individuals with a legitimate health need should not be restricted from buying up to a 1-month supply of a product required for them to maintain their health. This is common across health-product categories.
3) The economics of appropriately manufactured hemp/CBD products mitigates the likelihood that anyone develops a lasting pattern of abuse based on consumption of large containers of hemp/CBD products that meet the above dose restrictions (cheaper, higher potency cannabis products are readily available as alternatives from both licit and illicit markets).

If you would like to discuss concrete max dose recommendations per "package" or "container" please let me know and we will revisit this language.

In addition to the above, I would like to note the following points of information that relate to the importance of establishing evidence-based delta-9-THC dose limits in hemp/CBD products. If the language in the Fiscal 2026 Agriculture Appropriations Act that redefines hemp is retained as is, it will eliminate full spectrum CBD products from the market and only CBD isolate products will remain. While CBD isolate products can be effective, studies show that the CBD doses needed are substantially higher to achieve efficacy. For example, in one study on the use of artisanal CBD oils for treating epilepsy, my colleagues and I found that full spectrum CBD oil use was associated with significantly better health and fewer medication-related adverse events among users compared with those with epilepsy who did not use CBD oil. The median absolute CBD dose of those using full spectrum CBD oil was 50.0 mg CBD/day with a weight-adjusted dose of 1.4 mg/kg/day. In contrast, the FDA-approved formulation of CBD (Epidiolex) has a recommended starting dose of 5mg/kg/day with a planned titration up to 10mg/kg/day after 1 week followed by a further increase to 20mg/kg/day as needed. The problem with that is both the increased cost to the consumer and increased risk for CBD-drug interactions and potential for liver toxicity. In a recent FDA funded study, significant liver toxicity was observed in 6% of

healthy adults given CBD at 5mg/kg/day, and those participants were neither sick nor taking other medications. Liver toxicity was also observed in a subset of participants in the clinical trials of Epidiolex. Thus, the elimination of full spectrum CBD products that do not cause intoxication from the market may have the unintended consequence of increasing harm to those who use these products.

Another worry about the elimination of full spectrum CBD products from regulated retail markets is that this will likely result in these products moving into black markets where poor manufacturing and quality control will result in substantially more harm to consumers and overall public health than trace doses of THC. Pre-2018 Farm Bill behavior shows that consumers of full spectrum CBD oils are willing to relocate their families for access to these products given the health benefits they had realized. They will not simply stop seeking these products due to the change in law. Where demand like that exists, suppliers will emerge. In a black market, those suppliers are not likely to meet the standards expected in a regulated market. Those that use real hemp products (i.e., CBD-dominant products derived directly from the hemp plant without synthetic manipulation) are typically older adults, very sick children, or young adults dealing with debilitating health conditions. They are not getting high, nor are their products being diverted to youth who want to get high. The cost of these products is prohibitive for those seeking intoxicating effects given the low amounts of THC contained in them.

I am happy to provide more detail or discuss this further as needed. Thank you very much for your time and consideration of this letter.

Regards,

Ryan Vandrey, PhD