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Statement for the Record: FDA Inaction on Regulatory Pathway for Cannabinoids

Thank you, Chairperson Comer, for allowing me to present a statement on behalf of cbdMD. At cbdMD, we are keenly aware there are rules and guidelines for providing safe dietary supplement products to consumers under the Dietary Supplement Health and Education Act (DSHEA). We have adhered to the four corners of those guidelines through our commitment to third party cGMP certifications, proper labelling with adequate instructions for use, adverse event tracking and reporting, and independent safety testing of our hemp derived cannab inoid ingredient. We go the extra mile by publicly posting current Certificates of Analysis detailing the chemical analysis of every product we sell, which is something no other dietary supplement does. With regards to safety and efficacy, we have made significant investment in both safety and clinical studies for efficacy. We have successfully navigated the regulatory submission process in other countries (UK, EU, several Latin American countries). Despite our wealth of data proving the safety and efficacy of our products, we have attempted to work through this process with the US FDA to no avail.

The Agency has posted guidance documents, held scientific meetings, and opened a docket for the submission of cannabidiol safety data. Despite all of these efforts, they continue to ask for more data. The multi-system safety study we executed on our broad spectrum extract was more than sufficient for the rigorous review in the UK, and was done to the highest global standard known as OECD. Our trade association, the Natural Products Association, filed a Citezen's Petition on our behalf, which pointed out that extract of cannabis was sold in commerce in the United States and listed by the United Stated Pharmacopeia in the late 1800's, prior to the shift to prohibit cannabis in this country, and most importantly requesting the data compiled in our safety study be provided the same opportunity for review in the U.S. as any other botanically derived product intended for consumption as a dietary supplement. Our study explored many of the endpoints for which FDA has expressed concern, including reproductive toxicology and genetoxicology. We strongly argued that CBD is not drug precluded and is in fact, a new dietary ingredient that can be regulated under current authorities afforded under DSHEA. FDA issued a public statement in January whereby they summarily denied the three Citizen's Petitions filed to date on CBD, including ours. The statement included messaging around CBD and their concerns shifted from safety alone to include cannabinoid's potential activity in the body.

Cannabinoids are not the first constituent of a botanical dietary ingredient to exhibit pharmacological activity. Food is well-known for having biochemical and physiological effects on the cells, tissues, and organs, otherwise known as pharmacological effects. In fact, the sole purpose of a dietary supplement in the diet is to have pharmacological activity in the human body. Let's be very clear and honest here and state for the record that a consumer would have no reason to buy a dietary supplement unless it had pharmacological activity and the FDA clearly knows this. Otherwise, it would just be snake oil. Some of the well known ingredients which have a long history of use in dietary supplements while exhibiting pharmacological activity including: caffeine, EGCG, EPA/DHA, carnitine, N-acetyl cystine, and quercetin. Honey can exhibit anti-inflammatory effects through toll-like receptors. Paracelsus said it best,

"The dose makes the poison" and dietary supplements are not intended to be ingested in a dose that is pharmaceutical, but will absolutely exhibit pharmacological effects, according to this definition. The Structure-Function Claim Notification (SFCN) is a well-established, statutorily-mandated process by which dietary supplement manufacturers submit statements that they have used in marketing and the studies they have completed that support those statements. This has been the process for demonstrating the efficacy of botanically derived dietary supplements for over 30 years and is well within the current authorities of the FDA to require for hemp derived cannabinoids. Consumers purchase dietary supplements, rather than consume the food from which it was extracted, because the supplements exhibit activity in support of health and wellness greater than any benefit derived from food or in a form that is more convenient to obtain the pharmacological benefits. Hemp-derived cannabinoids are not special or different from any other botanical ingredient. They have a long history of use in food and traditional medicine. In the very low milligram levels commensurate with dietary supplements, they are safe and efficacious.

For FDA to flag CBD and cannabinoid products as potentially dangerous due to their pharmacological activity, and disseminate false and misleading statements, is disingenuous at best and borderline fraudulent at worst. There are hundreds of unique new dietary ingredient notifications for botanical ingredients that did not confuse FDA when they presented unique activity on the structure of function of the body. I know this for a fact as I worked in the Office of Dietary Supplement Programs for over 5 years, reporting directly to the Ofiice Director, and I worked on these issues. FDA has essentially presented the unsupportable position that cannabinoids are a new ingredient that does not fall into their defined regulatory categories. Cannabinoids did not come from an alien planet or get recently discovered in a cave. They are constituents of a plant that has been safely consumed for tens of thousands of years. There is a well-established process the FDA manages under current authorities for demonstrating the safety of botanically derived dietary supplements and submitting notifications to the Agency when a dietary supplement impacts the structure or function of the body. We consume dietary supplements because they have an effect on the body that we could not achieve with our diet alone.

As mentioned, we have a robust and adequate regulatory framework in place now under DSHEA to handle all hemp extracted cannabinoids, including CBD and THC, once the Agency properly recognizes them for what they are – well known and characterized constituents of an old dietary ingredient (extract of cannabis) that is exempted from drug exclusion and eligible for regulation under the current authorities in DSHEA . By taking a "drug" view of botanical extracts and applying an extremely overbroad interpretation of drug exclusion, the Agency is denying consumers access to safe, inexpensive, and effective alternatives to drug products. This same Agency that should be focused on protecting the public health is instead allowing bad actors to continue operating and proliferate the amount of dangerous products in commerce, when they have regulations in place now to effectively control this market.

The public comments from the FDA with regards to drug exclusion and the status of cannabidiol (CBD) as a dietary ingredient are merely statements of opinion and do not have the force of law until there is an enforcement action against the ingredient CBD by the Agency or a ruling by a court in an action to interpret the scope and application of drug exclusion. The opinion of the FDA is limited to their interpretation and unfounded broad application of the

drug exclusion criteria for dietary supplements containing CBD and that interpretation has never been adjudicated. FDA's position that "given what we know about the safety of CBD so far, it raises concerns for FDA about whether these existing regulatory pathways for food and dietary supplements are appropriate for this substance," is inappropriate by all standards. This is a systematic and intentional misdirection to support dereliction of duty at the highest level

Our initial response is that the FDA is lying and fearmongering to misdirect the public and our elected leaders from the truth. They have tools, and they have applied the tools before many, many times. They have tools under the labeling rules, they have tools under the rules for cGMP, and they have the most potent tools in their ability to review safety data in the new dietary ingredient notification (NDIN) process and inspect manufacturers for comliance. As stated above, I was at the FDA's Office of Dietary Supplement Programs for over 5 years and during my tenure at the Agency, I used those very same tools effectively on a number of scientific, compliance, and enforcement actions. The only real issue is the drug exclusion rule (i.e., race to market clause) and if drug exclusion were not being inappropriately applied the FDA could review safety data in an NDIN submission and make a determination of safety for the stated conditions of use and label on an ingredient by ingredient basis. Drug exclusion is the false flag being presented by the FDA to justify and support their inaction and claim they need additional authorities and millions of dollars to do their job. This is just not the case.

We spent in excess of $1MM on our safety dossier that included 5 OECD studies. Through those studies, which align with the regulatory process established for dietary supplements and are the highest standard of toxicology testing recognized globally,we identified levels that our ingredient may be safely consumed. Our level is significantly lower than the dose supported by studies for the CBD based drug Epidiolex. Milligrams per serving as opposed to several grams per serving. Further, our conditions of use are appropriate for dietary supplements and are not for the same conditions of use as a drug. For example, dietary supplement CBD products are intended to support relaxation, help reduce inflammation caused by daily activities, support health sleep patterns, and support a sense of well being. We do not, and would not ever, claim to treat seizures due to various forms of childhood epilepsy. We have successfully demonstrated the ingredient contained in our products is safe and our data was more than sufficient when reviewed by regulatory agencies in other countries. cbdMD submitted a novel food dossier to the EU and the UK. We are validated by both regulatory agencies as one of the first naturally derived cannabinoid dossiers and we are under active review of our toxicology data to support what is known as a Novel Food… similar to the New Dietary INgrediernt status in the United States. Furthermore, we anticipate approval in the UK in the very near future. We find it hard to believe that Europe has better science or unique tools to be able to analyze this data and recognize these products for what they are… food, and more specifically, dietary supplements. FDA should hold itself out as a leader in safety, but instead it is happy to bury its head in the sand and lag behind other countries.

FDA recently shifted its tactics around messaging on CBD to question rodent models for animal safety, despite the fact that they have served as appropriate preclinical safety models for every drug and dietary supplement approved to date. In point of fact, the animal toxicology studies underpinning the approval of Epidiolex were conducted on rodents, the same as cbdMD's OECD studies. They have also questioned their ability to regulate hemp products using the current framework and authorities, citing the multitude of product formats that

hemp products are found in as concerning. The FDA is the federally mandated Agency responsible for drugs, foods, and inhalable products, including several other areas. In direct contravention to the Agency's recent statements, cannabinoid products fit neatly into the categories regulated by the FDA. Products that are labeled for inhalation in a non-combustible manner are regulated by the Center for Drug Evaluation and Research (CDER). Products that are labeled for inhalation in a combustible dose form are (or can easily be) regulated by the Center for Tobacco Products (CTP). Products that are ophthalmic are regulated by CDER. Products labeled for topical use are either regulated by CDER or the Center for Food Safety and Applied Nutrition (CFSAN), where the Office of Colors and Cosmetics (OCAC) is located. Products that are labeled for ingestion are regulated in CFSAN by the Office of Dietary Supplement Programs (ODSP) or in the Office of Food Additive Safety (OFAS). Each of the Centers and Offices described above has ***existing*** regulations, guidance documents, and subject matter experts to review product submissions that contain novel botanical ingredients. Hemp is a botanical ingredient, like t he hundreds of other botanical ingredients whose components and constituents have been used in products labeled for inhalation, ingestion, topical use, or others.

The laws that govern dietary supplements address combinations of ingredients, another area FDA has included in the red herring statements about their concerns with hemp products. Under the current framework, the manufacturer is responsible for ensuring that an ingredient or combination of ingredients is safe for consumers before marketing a product. Unlike drugs, dietary supplements are not allowed to cause any harm, and therefore by extension are not permitted to contain combinations of ingredients that present harm to consumers. Responsible, regulatorily compliant dietary supplement companies, including companies that manufacture products containing hemp-derived cannabinoids, ensure and document for inspection that any ingredients they use in manufacturing are safe for consumers. No dietary supplement manufacturer should make a product that contains a combination of ingredients that is potentially harmful and the FDA currently has the authority to inspect and verify compliance. The laws pertaining to dietary supplements also address the other areas that FDA has highlighted as a concern, including labeling, cGMP compliance, and warnings on packaging. The onus is on the manufacturer to ensure that their product complies with all applicable regulations and the FDA's inspection and enforcement authorities under current law allow them to ensure such compliance or remove products from the market, if only they would do their job. The current framework has existed since 1994 and has successfully protected consumers while allowing them to have access to non-pharmaceutical options to maintain or improve their health. In fact, it was never the intent of the drafters of DSHEA and the drug exclusion clasuse to prohibit an article from being both a drug and dietary supplement at the same time. The drafters envisioned that the intended use and the labelling and marketing of the article would determine the classification and that only in cases where the intended use of the article was the same would drug exclusion be applied. That cannot be said about hemp derived CBD dietary supplements.

In the absence of a federal standard, states have been forced to do the job of the federal government and locally regulate hemp derived dietary supplements by passing legislation to provide consumer access to hemp-derived products while ensuring that consumers are protected from harm. In doing so, there is now a patchwork of state laws that were well-intentioned but cause more confusion and hinder responsible manufacturers from producing

products as they must comply with a 50-state standard rather than one federal standard. State officials and offices often do not have the requisite scientific expertise or resources to address dietary supplement or food labeling, testing, etc.

While FDA was busy issuing statements and warning letters pertaining to egregious claims instead of doing their job and actually regulating these products as dietary supplements, the market shifted to products that contained designer ingredients that do not qualify as dietary supplements and are not manufactured according to GMP standards, knowing FDA was not going to enforce. These substances are often controlled substances, are synthetically produced, or elicit effects that cause them to be deemed to be controlled substances. Any substance that is scheduled under the Controlled Substances Act (CSA) should not be sold to consumers through direct-to-consumer or retail channels. Semisynthetic derivatives or biosynthetic cannabinoids have no place in a regulatory submission either. Those substances would not be considered legal dietary ingredients by FDA for a regulatory submission as a food additive or a dietary supplement. Dietary supplements must contain ingredients that are extracted from a naturally derived, botanical source. Food additives are allowed to be semisynthetic or biosynthetic in origin, however, the designer cannabinoids that have emerged on the market do not meet the requirements for their intended use to be a food additive and therefore, have no place in the current regulatory framework. FDA issued warning letters about delta-8 tetrahydrocannabidiol-containing products but has not issued a warning letter that only addressed a product's legal status based upon the ingredient alone (CBD).

As we discussed, states have authorizing and implementing regulations allowing the manufacture and sale of hemp extracted orally ingestible CBD products, major retailers across the country openly and conspicuously sell hemp extracted orally ingestible CBD products, the Securities and Exchange commission allows the listing and trading of hemp extracted CBD company securities, major banks and insurance companies write accounts for hemp extracted orally ingestible products, and the courts in multiple jurisdictions have stayed or dismissed lawsuits challenging the legal status of CBD until such time as there is a final agency action on the ingredient or the status is adjudicated in court. All of which goes to show that the FDA is not being truthful, and the market is moving forward without their oversight. They have tools and they refuse to use them. We can speculate on the reasons behind their position, but it is clear they are simply abdicating their duties to protect the public health and instead choosing to deny consumers access to safe and efficacious products. We are deeply disappointed that FDA has chosen to make excuses for their dereliction, rather than use their tools and find a reasonable solution.

The FDA has spent more time plotting their public relations campaign to malign hemp extracted cannabinoid ingredients than they have spent addressing any public health matter and reasonably regulating these ingredients. The real issue is about the role of natural products and pharmaceutical IP in the marketplace and the FDAs historical refusal to properly recognize natural products in that ecosystem. This is most clearly manifested in the issue presented before you of the FDAs failures and inaction when it comes to properly regulating botanically derived, orally ingested, hemp extracted cannabinoids as dietary supplements. DSHEA was never intended to exclude these natural products, even when an approved drug exists, except in the rare cases where the drug and the dietary supplement are effectively the same thing, meaning the same dose marketed for the same purpose. Congresses intent from the start was

clear, that articles could exist at the same time as both a drug and dietary supplement, and that such article could continue to exist as a dietary supplement so long as it is properly labelled and marketed.

It is our position at cbdMD, based on a reasonable interpretation of applicable federal law, that our products are fully compliant and legal dietary supplements under the Food Drug and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act. We maintain compliance the same as all responsible dietary supplement brands by addressing the four corners of the Act: GMP, Labelling/Claims, Adverse Event Reporting, and Ingredient Safety. We would welcome an audit and inspection by the FDA, as any responsible dietary supplement manufacturer would. We have a fully documented safety dossier and have completed multiple double blind, placebo controlled clinical studies to demonstrate the efficacy of our products. We have sold millions of servings to hundreds of thousands of consumers without any adverse events. Our products have been consumed by Olympic athletes, UFC champions, top professional golfers, motorsports champions, and athletes in the NFL, NHL, NBA and MLS just to name a few. First responders rely on our products to help them with maintain health and wellness. cbdMD has earned customer trust and established ourselves as leaders in the industry. We will not stand idely by while the FDA uses fearmongering to smear our brand and industry and remove a consumer's choice to use our products to maintain and improve their health and wellness. We are considering all of our options to ensure that our customers are not denied access to safe, efficacious dietary supplements and we hope that this oversight hearing can shed light into why the FDA has failed in their statutory obligations and possibly bring a reasonable conclusion to this farce without the need to seek redress in the courts.

We have included questions below, which we believe FDA should respond to on the record:

1. The FDA has received an ongoing appropriation for research on CBD. What research have they done to date and when will those results be made public?
    a. Are the testing levels consistent with general use by the public in food, or are they only replicating the extremely high levels more appropriate for drug studies?
    b. Were they designed according to current toxicological principles?
    c. What were the dose ranges used?
    d. Were they designed to derive a "no observed adverse effect level" (NOAEL)?
    e. If the Agency has initiated and/or completed tests in which species, were they performed?
2. What is the biological and chemical basis for determining that hemp products are so drastically different from other botanical ingredients that they are not able to be regulated by the framework that has functioned appropriately for all other botanical ingredients?
3. Why has the FDA taken such a unique stand in CBD, when another cannabinoid CBN, with a similar safety profile, has been allowed to be sold as a dietary supplement?
    a. Are other cannabinoids viewed as being drug precluded or are they allowed to proceed through a food additive or NDIN path?

4. What adverse events have been reported to FDA that are associated with CBD dietary supplements and foods, excluding products labeled or marketed as delta-8 THC or related compounds including delta-10 THC, HHC, THC-O, and THC-P?
    a. Have adverse events been reported for products containing the designer compounds listed above?
    b. What is FDA's plan to enforce against products with designer compounds if they have adverse events attributed to those products?
5. If FDA has concerns with rodent models for hemp safety studies, has FDA considered this impact on preclinical pharmaceutical safety studies?
    a. Has FDA considered a framework supporting the submission of *in silico* or *in vitro* studies in lieu of animal safety studies?
6. Explain in detail the Agencies understanding and interpretation of the drug exclusion rule as applied to a botanically derived article intended to be sold as a dietary supplement which does not purport to serve the same function as an approved drug, which is presented in significantly smaller servings, and which is not marketed for the prevention, treatment, or cure of the same indication as the approved drug.

Thank you for this hearing and for the opportunity to submit this statement today.

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