NATURAL PRODUCTS ASSOCIATION

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Testimony of Kyle Turk

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The Natural Products Association (NPA) is the leading and largest trade association representing the entire natural products industry. We advocate for our members who supply, manufacture, and sell natural ingredients or finished products for consumers. NPA is the voice of responsible industry stakeholders before federal, state, and local governments. Founded in 1936, NPA represents approximately 650 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers, and distributors of natural products including foods, dietary supplements, and health/beauty aids. As the leading trade association for the natural products industry, we have spearheaded the charge to include cannabidiol (CBD) food pathway to market, however, there has not been any regulatory guidance from the United States Food and Drug Administration (FDA).

Background

On March 1, 2019, the FDA submitted a federal register notice involving cannabidiol for stakeholder notice and comment. The FDA provided interested persons with the opportunity to submit comments about the World Health Organization (WHO) recommendations to impose international manufacturing and distributing restrictions, under international treaties on certain substances. The comments received were considered in preparing the United States' position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria. As a party to the 1971 Convention on Psychotropic Substances, whenever the CND proposes to add, transfer, or remove a drug from one of the schedules, the Secretary of State must transmit a notification of this process to the Secretary of Health and Human Services (Secretary of HHS) and allow for public notice and comment. Regarding CBD preparations, WHO and its Expert Committee on Drug Dependence (ECDD) prepared a health hazard evaluation.[1] Cannabidiol while found in cannabis and cannabis resin, is not found to have the same psychoactive properties and results in no potential for abuse and potential to produce dependence.

[1] World Health Organization. (2017). Cannabidiol (CBD) Pre-Review Report Agenda Item 5.2. Expert Committee on Drug Dependence. Thirty-ninth Meeting. Geneva, 6-19 November 2017.

FDA contains a page on their website titled "FDA and Marijuana," where they clearly state that "FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201 (ff)(3)(B)(i) and (ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act. Moreover, the page goes on to add further clarity that "[t]here is an exception to section 201 ff)(3)(B)(i) and (ii) if the substance was 'marketed as' a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable." However, based upon available evidence, FDA has concluded that this is not the case for THC or CBD. NPA is also aware of the warning letters FDA has issued to companies marketing CBD as a dietary supplement.

Despite, the FA's actions and message, the market for CBD products in the United States is surging. According to a report issued by New Frontier Data, the United States CBD industry grew by nearly 40% in 2017, reaching $367 million in annual sales across hemp-derived and marijuana-derived markets. At present, the only federal approved CBD product is Epidolex, a pharmaceutical product manufactured by GW Pharma and approved by the FDA in 2018.

State of Regulatory Status

NPA applauds the efforts of the sponsors and the committee to address this issue. The time for enforcement of CBD is long overdue. Across the country, we are seeing state after state recognizes the gaps left by the FDA and begin to develop their regulatory standards. While it is of our opinion that the best approach is for one uniform national standard. We understand the FDA has yet to take responsibility for this public health issue and establish a regulatory framework for manufacturers that would include establishing a safe daily level of consumption, inspecting facilities for manufacturing practices, and testing products for impurities such as high dosages of tetrahydrocannabinol (THC), pesticides and heavy metals. Which is why we support the passage of House Bill 1581.

In the past three years, over 3,000 CBD products have come to market without a consistent approach to regulation or any plan on how consumer access will be balanced with consumer safety by our public health officials at the Food and Drug Administration. NPA commissioned a poll that found seven in ten Americans believe the FDA is overdue to establish safety standards for the CBD products in the marketplace. To make matters worse, 41% wrongly assumed the FDA had already developed these safety standards.

CBD was first marketed as an active pharmaceutical ingredient (API), which creates some legal hurdles in marketing it as a dietary supplement or conventional food. The industry needs to be

provided with guidelines they need and consumers the assurance that what they are consuming is safe and is manufactured to quality standards. FDA has previously provided a path to market as dietary supplements/foods for natural products that contain an API by establishing a daily exposure level similar to what they did with monacolin K, the same ingredient that is in the prescription cholesterol-lowering drug lovastatin[2], which is found in Red Yeast Rice.

While CBD was technically a federally "scheduled" substance before the passage of the 2018 Farm Bill in December, sales of CBD products continued to rise. At the present moment, there are well over 3,000 CBD products on the market. Since the passage of the 2018 Farm Act, which eliminated hemp from the definition of marijuana under the Controlled Substances Act- we've seen a significant increase in the production and sales of CBD products. FDA clearly states that "FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the Federal Food, Drug, and Cosmetic Act."[3]

Despite this, the warning letters FDA has issued to companies marketing CBD as a dietary supplement, largely focus on claims. The Food and Drug Administration has enforcement authority over labeling requirements. Two well-recognized types of claims are health claims and structure-function claims. Health claims describe the relationship between foods and dietary supplements and reduced risk of a disease or health-related condition. These claims are subject to premarket review and authorization by the FDA. Structure-Function claims describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body for example, "calcium builds strong bones." Also, they may characterize how a nutrient or dietary ingredient acts to maintain the structure or function. The FDA requires manufacturers must have substantiations that such claims are truthful and not misleading. Following the most recent string of warning letters, the FDA released a statement. FDA not only sited how recipients of warning letters have violated the Federal Food, Drug, and Cosmetic Act, but they also cite the lack of scientific information supporting the safety of CBD in food and indicated that they cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in humans or animal food. As outlined in some of the warning letters issued by the FDA, violations included marketing CBD products as a dietary supplement since these products do not meet the definition of a dietary supplement. FDA Principle Deputy Commissioner Amy Abernethy, M.D., Ph.D. even went as far as to say "We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe."

Because the FDA has not determined that CBD is generally recognized as safe, we at NPA have long advocated for FDA to test CBD products for heavy metals, pesticides, and THC all of which are proposed in this bill. Currently, through the United States Department of Agriculture, there are 37 hemp analytical testing laboratories. Through these testing facilities, any laboratory testing hemp for THC must be registered with the Drug Enforcement Agency. Unfortunately, the combined volume of hemp produced, and the lack of facilities has led to industry-wide concerns.

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[2] Red Yeast Rice, National Center for Complementary and Integrative Health
https://www.nccih.nih.gov/health/red-yeast-rice

[3] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)
https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd

This is why we have proposed to establish a national testing center and corporate stewardship program for manufacturers of CBD products at the National Center for Natural Products Research at the University of Mississippi. This program would provide an independent verification program for product analysis. The program would randomly select 1,000 products per year that would purport to contain hemp/CBD. These products would be tested using known standards for their content of impurities, THC, CBD, and other cannabinoids. The data generated from this program would be provided to the FDA and published in a public-facing database for anyone to access.

With over 3,000 products on the market, we believe that not testing products for impurities, such as lead, or other heavy metals is unacceptable for a federal agency whose mission is to protect public health. Product testing like what is proposed in House Bill 1581 should be conducted by federal authorities. However, the current situation in New Hampshire and states all across the country leave legislatures like yours no choice but to protect the public from potentially contaminated and harmful products. Though the overall market situation for CBD-containing products is fraught with problems in terms of quality and consistency, responsible companies would welcome an avenue to be recognized for compliance. Some of these companies even expressed a strong desire for clear guidance during the FDA's May 31, 2019 hearing on CBD.

NPA and our member companies are concerned that without a clear regulatory pathway in place, tainted products will continue to enter the marketplace, leaving consumers susceptible to harm and discouraging legitimate companies from engaging in interstate commerce. Clear federal guidelines from the nation's public health agency awards compliant companies with the regulatory clarity they deserve when operating in interstate commerce. While we believe regulatory standards from the FDA are the best way to move forward with this promising new product while protecting consumers we are supportive of the standards outlined in this legislation. Thank you again for allowing me the opportunity to talk about the risks involved with not regulating CBD.