Congress Introduces Bill to Legalize Ingestible CBD

HR 841 Has Bipartisan Support, Ensuring the FDA Recognizes the Products as Dietary Supplements

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THE US FOOD AND DRUG Administration (FDA) maintains the position that it is illegal to "introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 USC § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."[1]

This prohibition is relevant to cannabidiol (CBD) companies because CBD is an active ingredient in at least 1 known "drug product that has been approved under section 505 of the FD&C Act," but CBD does not fall into the recognized exceptions to that rule.[2]

Regardless, this prohibition has not stopped the proliferation of CBD products across the marketplace and continues to be a challenge for those who are mindful of the FDA's position.

Congress finally introduced legislation on February 4, 2021, that compels the FDA to approve CBD for use in dietary supplements.[3]

House Resolution 841 (HR 841), also called the "Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2021," was introduced by Virginia Rep. Morgan Griffith (R) and Oregon Rep. Kurt Schrader (D), with 12 Democratic and 5 Republican co-sponsors. This bipartisan measure helps ensure that the FDA recognizes CBD products as dietary supplements.[3] The FDA is holding these products in legal limbo, leaving them unregulated on the shelves of various retailers.

The congressional bill makes hemp subject to all the same regulations as any other dietary supplements, subject to new dietary ingredient filings, good manufacturing practices (GMP), and labeling and marketing provisions. Under the proposed bill, hemp's definition as a cannabis plant with less than 0.3 percent tetrahydrocannabinol (THC) (the psychoactive constituent of cannabis) remains the same. The focus on THC also means that other cannabinoids and terpenes within hemp can be approved for use in dietary supplements.

Under HR 841, hemp-derived CBD and other non-THC hemp extract manufacturers would be required to comply with the existing comprehensive regulatory framework for dietary supplements. This would help ensure that hemp products are deemed safe, prepared using GMP, and properly labeled. Insisting that CBD be manufactured by GMP guidelines would protect consumers and should address the FDA's concerns for the development and distribution of safe products. The bill's passage would also help stabilize the hemp market and possi-

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bly open a promising economic opportunity for hemp growers.

For many years, CBD consumers, hemp farmers, and small businesses, have struggled because of the FDA's failure to legally recognize and regulate the sale of CBD and other hemp-derived products. The FDA's decision concerning hemp extract and how it can be marketed, along with its decision to classify hemp extract as CBD, has created a massive and unnecessary cloud of uncertainty. The price of hemp crude extract dropped significantly because of an increase in growers and processors (the supply side) in 2019.[4] However, with major retailers and wholesalers on the sidelines (the demand side) because of the FDA's position that CBD ingestibles (for example, gel capsules and tinctures) cannot be marketed as dietary supplements, the lack of stocking from major retailers and wholesalers has undermined the retail potential of CBD significantly.

In short, when ingestibles cannot be stocked in the pharmacy setting, the marketplace is negatively affected. As a result, nonpharmacy retailers and online shopping have become the main channels where growth is occurring. However, consumers are not well served when it comes to understanding dosing, formulations, and potential drug interactions, and when shopping through these platforms. On the other hand, consumers trust pharmacies and pharmacists to provide the information they need about CBD.

For example, more places sold hemp-derived CBD products in 2020 than in 2019, with the number of retailers that sold at least 1 item for this category increasing by 37%. Although growth slowed toward the end of 2020, sales increased 12% for the 4-week period ended in November 2020 from a year earlier. Online retailers thrived in 2020 compared with brick-and-mortar stores that had their operations hampered by the COVID-19 pandemic in 2020. Health product and vaping stores were the next leading retail centers, making up 29% to 31% of all sales. Left behind were major packaged-goods retailers, such as pharmacies, that are still awaiting a clear path from the FDA about how CBD products can be marketed and used.

HR 841 is a strong bipartisan bill in which Congress is taking the lead, frustrated by the FDA's foot-dragging. Bill sponsor Schrader is from a major hemp-producing state, as are the 32 Kentucky representatives who co-sponsored this bill. Although it is unknown whether the bill will ultimately become law, federal legislators are taking a position that may finally resolve the uncertainty that the FDA created.

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