The Regulatory Framework of Hemp-Derived CBD in the United States

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Hemp-derived cannabidiol (CBD) products have been on the rise in the United States for a number of years. However, CBD exploded in popularity after the United States passed the Agricultural Improvement Act of 2018 (2018 Farm Bill), which among other things removed hemp and its derivatives, extracts, and cannabi-noids, including CBD, from the U.S. Controlled Substances Act. Consequently, hemp is no longer treated as a federally illegal substance, yet, this does not mean that all CBD products are lawful.

Only hours following the passage of the 2018 Farm Bill, the U.S. Food and Drug Administration (FDA) announced that it was unlawful to add CBD to a host of consumer products, such as foods and beverages, and that CBD by definition could not be considered a "dietary supplement." The FDA, which retains jurisdic-tion over such products under the 2018 Farm Bill, argued that its prior approval of a drug containing CBD prevents companies from adding CBD to foods and dietary supplements, absent formal FDA approval. Despite its position on the sale and marketing of CBD foods and dietary supplements, the FDA does not seem to take issue with other categories of products, including CBD cosmetics, provided these products are safe, properly labeled, and do not contain medical claims.

Notwithstanding the FDA's initial announcement (and many similar subsequent announcements), the CBD industry has taken off in the United States. This can be attributed to at least two factors.

First, many states have adopted laws that authorize the manufacture and sale of CBD products, including those expressly unauthorized by the FDA. State-level regulation of CBD varies greatly. Some states, such as Colorado and Oregon, allow the manufacture and sale of various categories of CBD products. Other states, such as Idaho and Mississippi, strictly prohibit the production and/or sale of any such products unless CBD is used for "medical treatment." A number of states, including California, Michigan, and Nevada, ban CBD foods and dietary supplements but seem to take no issue, at least expressly, with the sale of other products, such as CBD cosmetics. To top it all off, some of the states that legalized the sale of CBD products have their own set of regulations, including but not limited to registration and/or permitting, labeling, and testing requirements.

This patchwork of state-by-state regulations forces CBD manufacturers and distributors to follow a variety of regulations in each state where these products are sold and forces them to limit sales to jurisdictions in which CBD products are deemed lawful—all in the face of the FDA's current enforcement position.

This brings us to the second reason: enforcement (or lack thereof). Up until early 2020, the FDA sent out only about twenty public warning letters and took no public enforcement action. Its position changed slight-ly in the wake of COVID-19 at which point the Federal Trade Commission (FTC), which works closely with the FDA on marketing enforcement actions, filed at least one formal administrative complaint against a CBD company. Nevertheless, federal enforcement has been low and generally focused on companies making allegedly unsubstantiated medical claims. Likewise, state enforcement efforts have been limited. Even in states that aggressively bar CBD products, such products are notoriously easy to find. Yet, despite low enforcement actions, CBD companies should understand that other claims may result from an FDA and/or FTC warning letter, including state law consumer protection claims based on prohibiting unfair and deceptive trade practices, claims under the Lanham Act for false and misleading advertising, consumer and shareholder actions relating to CBD and even product liability claims.

In sum, CBD companies should not let the national proliferation of CBD blindside them. Instead, CBD stake-holders must navigate through this space wisely and carefully and should obtain sound legal advice to understand all applicable federal and states laws to mitigate the risk of violations, and thus, reduce the danger of enforcement actions.

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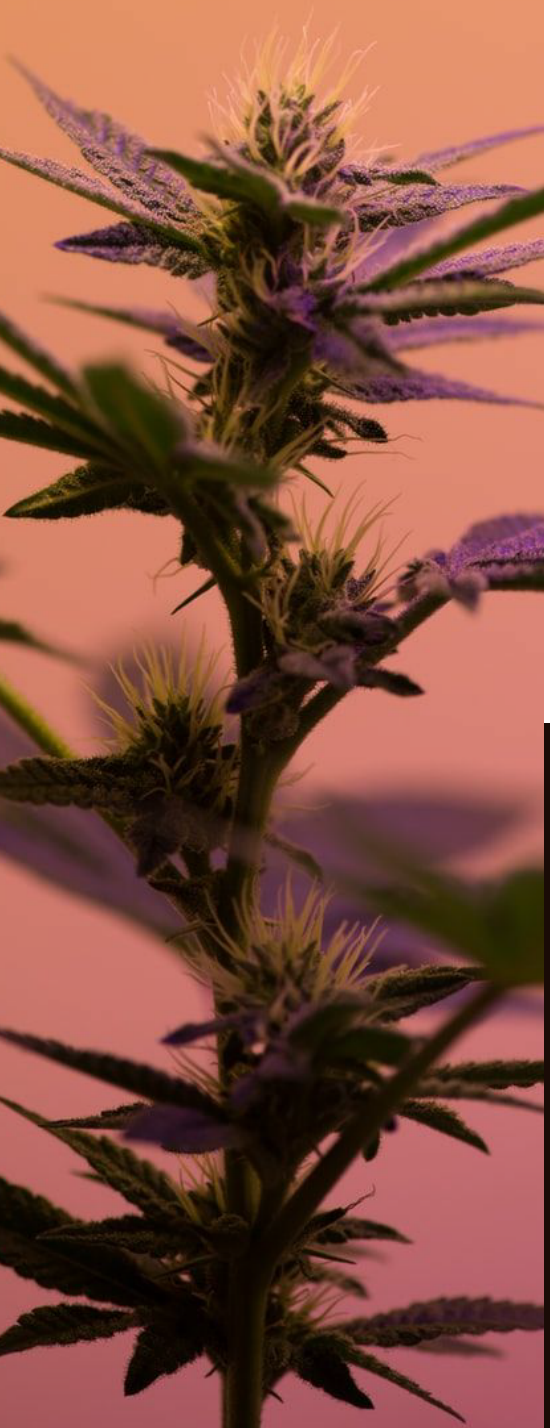

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