FDA Inaction Threatens Future of Hemp/CBD Industry

Introduction

A recent Politico headline announced "Hemp was supposed to boost farmers. It's turned out to be a flop." Indeed both industry insiders and outside observers seem to have soured on the hemp boom that wasn't.[1] The operative question then, is why?

As with any market, especially a new market, the factors that lead to success or failure are near endless, and individual decisions play a large roll. For the emerging hemp industry, one factor looms particularly large: regulatory uncertainty.

Key Points

- FDA regulatory uncertainty has derailed the American hemp industry
- This uncertainty hurts both the industry and consumers
- The FDA has repeatedly shown a lack of urgency in protecting consumers
- Congress must act to force the FDA to promulgate non-drug regulations that are fair to consumers and the industry

The United States & CBD

Following the legalization of hemp and its derivatives in the 2018 Farm Bill, hemp-derived cannabidiol, also known as CBD, was widely introduced into cosmetics, foods and beverages, and pharmaceuticals throughout the U.S. CBD is a non-psychoactive extract from the hemp and cannabis plants that is widely used by consumers for its calming properties and increasingly prescribed by medical professionals for its help in managing conditions ranging from cancer to epilepsy to mental health disorders. Although CBD can be – and often is – made into ingestible products, CBD is most widely available around the country in topical forms as it is "currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement" on the federal level.[2]

Industry analysts have repeatedly revised their projections of the industry's growth. Following the passage of the 2018 Farm Bill, analysts and Kentucky farmers alike were optimistic about the industry, but these projections have since been tempered as a lack of follow-up from the FDA has created significant roadblocks to growth. A 2019 forecast from Cowen & Co. estimated $15 billion in CBD sales in the United States by 2025,[3] but a 2020 analysis from the same group lowered their estimate to $10 billion in sales by 2025 because of the lack of guidance from the Food and Drug Administration.[4]

In short, while the production of CBD is legal, its consumption is not, and that discrepancy has already wiped $5 billion in potential sales off the board, with the promise of more losses to come in an already struggling economy.

CBD & Hemp in Kentucky

Kentucky is in a prime position to capitalize on growth in the CBD industry as many believe hemp, and specifically hemp grown for its CBD content, could become the next cash crop. In 2019, 92% of the 24,900 acres of hemp harvested in Kentucky went to CBD production,[5] while nationally, hemp-derived CBD sales account for only a quarter of all annual hemp market sales.[6] More than any other state, Kentucky's budding hemp industry has felt the pain of continued price crashes and bankruptcies attributable to the FDA's continued refusal to regulate hemp-derived CBD as a food or supplement, as Congress intended.

CBD & Hemp in Kentucky cont.

Following the passage of the 2018 Farm Bill, hemp growers, who were eager to capitalize on the renewed interest in hemp following the 2014 Farm Bill, began producing hemp in anticipation of CBD food and supplement products reaching mass market retail shelves in short order. Thanks to the FDA inaction, that was not possible. The result has been a massive surplus in hemp biomass supply coupled with plummeting prices. In Kentucky between 2018 and 2019, the number of approved hemp growers jumped from 210 to 978.[7] At the beginning of 2019, CBD-rich hemp was sold at about $5 per percent CBD, but by the beginning of 2020, that price had dropped to less than $1 per percent CBD.[8] At these new prices, profit margins have disappeared and caused some Kentucky companies to file for bankruptcy and some farmers to lose hundreds of thousands of dollars when companies refused to buy their hemp.[9]

The overproduction was driven in part by the projections of exorbitant growth in the CBD industry, which itself was in part based on a belief that the FDA would follow Congressional intent and expeditiously create a pathway for the introduction of hemp-derived CBD into the food and supplement channels. This growth unexpectedly stalled as the FDA continued to put off issuing guidelines for CBD products and manufacturing practices. Kentucky Agriculture Commissioner Ryan Quarles argues that "[i]f the FDA would simply act, it would be encouraging for Kentucky's hemp processors and producers." The FDA issuing regulations for CBD – as a nutritional supplement or as a food – would boost demand for Kentucky's hemp, but without any guidance whatsoever on CBD, the hemp industry will likely stay in its holding pattern following the price crashes and bankruptcies. Still, there is hope. The 2021 growing season for hemp can be still be saved if Congress acts this fall and directs FDA action.

Regulatory Uncertainty and the role of the FDA

The FDA maintains discretion to issue guidelines for CBD product manufacturers and approve CBD products as well as to enforce action against companies selling CBD products regardless of the lack of regulations. Although the FDA has been slow to introduce guidelines for the industry, the FDA and the Federal Trade Commission have eagerly issued warnings to manufacturers making unsubstantiated health claims.[10]

Currently only one CBD product has been approved by the FDA – Epidiolex – a prescription drug used to treat two severe forms of epilepsy.[11] It is the FDA's position that, because the FDA approved Epidiolex as a prescription drug before it was legally marketed to consumers as a food or supplement, CBD is illegal to introduce into foods or supplements.[12] Thus, according to FDA, CBD does not meet the definition of a dietary supplement under §§ 201(ff)(3)(B)(i) and 201(ff)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 321(ff)(3)(B).[13] Regarding non-ingestible forms of CBD, the FDA has issued a blanket warning for nearly all other topical products containing CBD stating that these products are often marketed with unproven claims and are of unknown quality – two problems that could be addressed through FDA regulation. These topical products exist in a gray area, as the FDA has not concluded their production is illegal but has also not issued any guidance for their production.

The FDA has yet to issue draft or final rules for the manufacture or production of CBD products, citing many unknowns regarding "the science, safety, effectiveness and quality of products containing CBD."[14] The FDA has taken few steps toward developing these broader regulations. In June, the FDA submitted draft guidance to the White House Office of Management and Budget for clinical CBD research that could potentially pave the way for CBD regulations, but here again the FDA seemed to focus on prescription applications to the exclusion of foods and supplements. While some interpreted this as a positive development toward more substantial CBD guidelines, it more likely represents yet another delay.

The FDA's halting approach to CBD regulation has left the entire industry – from farmers to manufacturers to retailers – in limbo. As it stands, large retailers are unwilling to commit to an unregulated industry and low-quality products are saturating the market through unregulated natural product channels.[15] The economic reality is that the FDA has taken enough oversight interest in CBD to keep good manufacturers from entering the market but not enough interest to drive bad manufacturers out of the market.

A Bright Spot in the United Kingdom

In the United Kingdom (UK), several forms of CBD pharmaceuticals are approved for medical use, and CBD oils are available legally as food supplements from health stores.[16] Before recent reforms, non-medical ingestible CBD products occupied a legal gray area marked by inconsistent enforcement, ambiguous laws, and unchecked marketing claims – like most CBD products in the U.S. today. Earlier this year, the Food Standards Agency (FSA) released a new plan to regulate the CBD industry and provide more information to consumers.

The FSA set a March 2021 deadline for CBD companies in the U.K. to submit valid novel food authorization applications for each product containing CBD.[17] After March 31, 2021, only those products with valid applications will be allowed to remain on the market. With these applications, the FSA will be able to ensure that food products containing CBD meet legal standards for safety and content.

For consumers, the FSA has released several advisories related to CBD.[18] The agency has urged those who are pregnant, breastfeeding, or prescribed any medication not to consume CBD product; the agency has encouraged others to keep daily consumption of CBD below 70 mg, a figure they arrived at using, ironically, FDA's own data.

These regulations give manufacturers in the UK the certainty and clarity they need to invest in the production and distribution of CBD products, while allowing CBD consumers in the U.K. to make informed decisions about their use and protecting them from products that fail to meet safety standards.

Recommendations for Reform in the US

The CBD industry is in need of clear regulation now to ensure that CBD products are safe for consumption, consumers are protected from fraudulent claims and concoctions, and to allow the industry to fully emerge from its current state of uncertainty. The FDA has recognized that CBD products may potentially cause harm to those who use them because of "unknown quality" and "unsafe manufacturing practices"[19] but has neglected to use its authority to issue regulations to require CBD producers to raise their quality and production standards. Clearly, the agency feels no urgency on this issue, despite the financial toll on farmers and businesses and the dangers pushed off onto consumers. When a federal agency fails to heed Congressional intent, Congress has a duty to act.

The lack of clear guidelines from the FDA has impeded the growth of the CBD industry in several ways.[20] The FDA has not issued guidance on the permissibility of ingestible forms of CBD, so only a few large retailers, like CVS, Walgreens, and Rite-Aid, have ventured into the market. While this is an encouraging step, these rollouts are limited and do not include ingestible products, which represent the greatest potential revenue stream for Kentucky farmers. Further, the FDA has failed to introduce guidelines for the manufacturing and quality assurance and quality control of CBD products, so many smaller companies that make a variety of CBD products are producing low-quality, mislabeled products that expose consumers to undue harm while tarnishing the reputation of the industry as a whole.

Two-level Regulatory Structure

Congress must direct the FDA to issue CBD regulation – as the Food Standards Agency (FSA) in the U.K. has. A two-level structure, where pharmaceutical-grade (i.e., recommended doses of 750mg or greater) CBD products are more strictly regulated than nutritional supplements containing CBD, is the most appropriate structure for CBD regulation in the U.S. Because CBD can be used in such a wide array of products, a regulation structure that treats pharmaceutical and non-pharmaceutical products containing cannabidiol equally would be both cumbersome to the industry and inefficient for the FDA. Instead, CBD products used for medical purposes, like the treatment of epilepsy,[21] should be treated as pharmaceuticals, but CBD products used for non-medical purposes, like relaxation or beauty, should be regulated as nutritional supplements or food additives – like caffeine[22] and melatonin.[23]

Pharmaceuticals

- The FDA has already approved one CBD product for pharmaceutical purposes and should be encouraged to consider more pharmaceutical applications for CBD.

Dietary Supplements

- In July 2019, during a hearing before the Senate Agriculture Committee, the FDA stated it was still anywhere between three to five years away from even an expedited establishment of a legal regulatory pathway for the use of CBD in dietary supplements and conventional foods.

- Congress must issue a limited waiver of § 201(ff)(3)(B) of the FDCA to clarify that hemp-derived CBD is a legal dietary supplement so long as the dietary supplement containing CBD complies with the applicable requirements under the FDCA and all other FDA regulations that apply to dietary supplements.

- As with compounds like caffeine, the FDA should set recommended limits for daily CBD consumption.

Even with these new reforms geared toward encouraging growth in the hemp and CBD industries, it is crucial that the FDA continues enforcement action against unscrupulous manufacturers that fail to comply with FDA and FDCA regulations.

Congressional Action

To date, the FDA has shown an unwillingness to act in a timely and appropriate manner to protect the 14% of American adults who currently consume CBD,[24] leaving the aforementioned uncertainty and opportunities for fraud and abuse. It is urgent that Congress acts this year to direct the FDA to promulgate appropriate regulatory guidance for food and/or supplement products containing hemp-derived cannabinoids, including cannabidiol (CBD). Previous attempts to nudge the FDA have proven inadequate, and it is now clear that the only way to prevent further harm to consumers and the US hemp industry alike is for Congress to direct FDA action with specific timelines. The FDA's failure to regulate these products in accordance with clear Congressional intent has created a consumer market rife with fraud[25] and without oversight for food safety, labeling accuracy, or traceability. Action is needed now to eliminate the health and safety risks faced by consumers from products containing less than what is promised (e.g., no CBD),[26] or promoting more than is possible (e.g., unsubstantiated and misleading claims to the treatment of life-threatening diseases and conditions). There is still time to save the 2021 growing season for Kentucky farmers—but only if Congress acts immediately.

There is broad bipartisan support for CBD in Congress, and now is the time to ensure government does not derail an American industry still in its infancy.

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