Is the Farm Bill Forcing the FDA to Regulate CBD Products Sold by State-Licensed Marijuana Businesses?

How can the FDA justify regulating hemp-derived CBD products while ignoring similar products produced and sold through state-licensed marijuana businesses?

DENVER, COLORADO, USA, January 3, 2019 /EINPresswire.com/ -- Hemp farmers, formulators of CBD products and entrepreneurs entering the hemp and CBD industries were delighted when the Agricultural Improvement Act (the "Farm Bill") was signed into law by President Trump. Those same entrepreneurs and farmers enthusiastic responses will likely be tempered when they understand that Congress has now enacted legislation creating more problems than existed prior to the passage of the Farm Bill.

The Farm Bill provides a role for the Food and Drug Administration (FDA) to regulate products containing cannabis or cannabis-derived products. This includes both the non-psychoactive cannabinoid, CBD, as well as cannabis or cannabis-derived products that include the psychoactive cannabinoid THC.

In the past, the FDA has refrained from regulating cannabis products produced under state-legal marijuana programs and avoided, for the most part, regulating CBD-derived products produced from hemp. The unintended consequence of the passage of the Farm Bill now means that the FDA is required to get involved in something it has sought for many years to avoid.

It would seem to be arbitrary for the FDA to regulate hemp-derived CBD products as food additives or as health, wellness or nutritional products without the agency regulating the same products containing CBD sold through state-licensed marijuana businesses. To do so would essentially destroy the federally-legal hemp industry while leaving the federally-illegal state marijuana industry untouched.

Commissioner Scott Gottlieb, interviewed by CNBC anchor Joe Kernan on November 20, 2018, suggested that federal action on cannabis policy is inevitable and would occur shortly. Gottlieb said that recreational cannabis doesn't "fall within our purview right now." He also stated "But look, we do regulate compounds that are making drug claims and we regulate botanical use of marijuana. We have approved compounds derived from marijuana, but there is no demonstrated medical use of botanical marijuana. That's the bottom line."

Immediately after the Farm Bill was signed into law, Gottlieb issued a statement clarifying the

FDA's policy regarding cannabis-derived products. "In short, we (FDA) treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products-meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance." Gottlieb ended by saying, "...the FDA will advance new steps to better define our public health obligations in this area We'll also continue to closely scrutinize products that could pose risks to consumers"

Complicating the FDA's policy regarding CBD was the approval in June 2018 of G.W. Pharmaceutical's Epidiolex. It is a pure form of plant-derived CBD and is specifically recommended for the treatment of seizures associated with two types of epilepsy. This FDA action resulted in CBD being classified as a drug. Because CBD is now an FDA-approved drug, it should not be able to be sold as a food additive or for health, wellness or nutritional purposes.

There is an option that could exist for the hemp-derived CBD industry. It is feasible that the same CBD products could be sold, without purporting therapeutic claims, as hemp-flower oil or phytocannabinoid-rich hemp oil.

How the passage of the Farm Bill impacts the use of CBD as a food additive is also an unknown. The FDA could take the position that food, including drinks with CBD, cannot be marketed within the state borders where they were produced or interstate until the safety of CBD as a food additive is demonstrated.

Congress, probably unwittingly, has forced the FDA's hand to regulate cannabinoid-derived products produced and sold through state-licensed marijuana businesses. It is hardly a job the FDA relishes doing and probably an issue it wished to never address. If and when the FDA begins this task the public outcry from consumers, patients and state-licensed marijuana businesses will be loud and long.

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