The Farm Bill's Delegation of the Regulation of CBD to the FDA: The Impact on a New Legal Industry

The FDA will slow what could have been America's fastest-growing new industry

DENVER, COLORADO, USA, December 22, 2018 /EINPresswire.com/ -- U.S. growers of hemp and producers of hemp-derived products, including CBD, were ecstatic when President Trump signed the "Agricultural Improvement Act" (the "Farm Bill") into law. My conclusion is that it's premature to "crack open the champagne."

The Farm Bill retained a role for the Food and Drug Administration (FDA) in regulating products containing cannabis or cannabis-derived products. These include both the non-psychoactive cannabinoid CBD as well as marijuana and marijuana-derived products that include the psychoactive cannabinoid THC.

In the past, the FDA has refrained from regulating marijuana products produced under state-legal regulatory regimes and avoided regulating CBD-derived products produced from hemp. Because of the media attention regarding the benefits of CBD and now the passage of the Farm Bill, the FDA is now forced to get involved.

Immediately after the Farm Bill was signed into law, FDA Commissioner Scott Gottlieb issued a statement clarifying the agency's policy regarding cannabis-derived products, including hemp-derived products that contain CBD.

The FDA statement included, "In short, we 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."

While the FDA indicated that they intended to hold public forums regarding hemp and CBD policies, the agency also stated, "...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."

A complication is the FDA's approval in June of G.W. Pharmaceutical's Epidiolex as a drug for the treatment of epilepsy. Epidolex is a pure form of CBD and is specifically recommended for the treatment of seizures associated with two types of epilepsy. Since it is now classified as a drug, FDA policies state that CBD can not be sold as a food additive nor for health, wellness or therapeutic purposes.

Despite the media attention regarding CBD and its health and medical benefits, it's unlikely that the FDA will allow CBD products other than those have been approved by the agency as drugs to be sold. This would likely apply to both those sold in the state where they are produced,as well as those sold interstate. However, the possibility exists that the same CBD-derived products will be able to be sold, without therapeutic claims, not as CBD, but as hemp oil, phytocannabinoid-based hemp oil or something similar. This assumes that the FDA determines that these products are safe.

Regarding food products, including drinks that include CBD, it's likely that the FDA will take the position that they can not be marketed either within the state borders where they are produced or interstate until their safety as food additives are demonstrated based on FDA regulations.

Based on current FDA regulations, it's likely that the most efficacious pathway for allowing CBD-derived products to be sold will be as food supplements and not as health, wellness or nutritional supplements. But, it is unlikely that these products will be able to state that they contain CBD, but more than likely could be marketed as hemp-derived oil, phytocannabinoid-rich oil or something similar.

Since the FDA Statement was issued immediately upon the signing of the Farm Bill, it's likely that the agency will relatively quickly clarify its policies on CBD-derived products.

Congress intended to fully legalize hemp as a new agricultural crop. Unfortunately, because of the wording of the Farm Bill, hemp, which had the potential to be the fastest and most lucrative new American crop will not provide the financial profit farmers nor CBD producers anticipated.

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