January 10, 2019

Changes in Federal Regulation of CBD and Other Hemp Products Will Create New Opportunities for Investment, but Regulatory Challenges Remain

On December 20, 2018, President Trump signed the Agriculture Improvement Act of 2018 (P.L. 115-332), commonly referred to as the "2018 Farm Bill," into law. One of the most notable changes to current law in the $867 billion bill is the creation of a regulatory framework for the federal legalization of the production of cannabis sativa (hemp), including the "de-scheduling" of certain hemp derivatives under the federal Controlled Substances Act ("CSA").

Hemp legalization enjoyed bipartisan support and has been touted by many as having the potential for creating new opportunities for investment—not only in hemp cultivation, but also in the manufacturing and distributing of hemp-derived products, including cannabidiol ("CBD"). CBD, in particular, has received press attention for its potential health benefits, and it is beginning to be offered in consumer products ranging from food products to cosmetics. CBD is also the active ingredient in Epidolex, which was recently approved by the Food & Drug Administration ("FDA") for the treatment of severe forms of epilepsy.

Despite these headlines, legalization of hemp cultivation and the production of products from hemp derivatives, including CBD, will be far from immediate. Notably, many federal, state and local regulatory barriers remain and require careful navigation by investors and stakeholders looking to enter, or expand their current activities in, this growing space. This Alert describes the relevant provisions of the 2018 Farm Bill and then highlights some of these legal and regulatory areas that stakeholders will need to consider.

History of Hemp Regulation and Context for the 2018 Farm Bill

Prior to enactment of the 2018 Farm Bill, all cannabis sativa plants and cannabis products, including products containing CBD, were regulated by the federal Drug Enforcement Agency ("DEA"). The basis for this historical jurisdiction is that hemp plants and cannabis extracts, including CBD, were expressly included in the definition of "marihuana" under the CSA as a "Schedule I" Controlled Substance (i.e., no currently accepted medical use and a high potential for abuse). However, there has been movement toward legalization of hemp and hemp derivative products over the past five years.

Impact of the 2018 Farm Bill

The 2018 Farm Bill carves out hemp and hemp derivatives (including CBD) that have a delta-9 tetrahydrocannabinol ("THC") concentration of 0.3% or less from the definition of marijuana under the CSA, shifting primary regulation of CBD and other qualifying hemp derivatives from the DEA to the Secretary of the U.S. Department of Agriculture ("USDA"). THC is the psychotropic component of these plants, whereas CBD has no reported psychotropic impact. However, any cannabis plant or product with a THC content of higher than 0.3% would remain under the definition of marijuana in the CSA, making its manufacture, possession or distribution illegal and subject to potential enforcement by the DEA and the U.S. Department of Justice at the federal level.

Under the 2018 Farm Bill, states that desire to be primarily responsible for the regulation of industrial hemp production must submit a plan to the USDA that lays out the procedures for oversight of such production within the state or territory for approval. Hemp producers in states that do not have an approved plan must satisfy requirements under a federal plan set forth by the USDA. Both state and federal plans must, among other requirements, set forth a procedure for licensure of hemp producers and a procedure for testing THC concentration levels of the hemp produced. As such, the industrial production of hemp will still be subject to federal regulation, but its elimination from coverage under the CSA addresses barriers that prevented interstate commerce, including distribution across state lines and banking activities associated with controlled substances.

The 2018 Farm Bill does not specify a time frame for the state and federal licensure programs to be established; and it could take some time before there are licensed producers from which the hemp products necessary to manufacture CBD may be obtained. Significantly, anyone who engages in the industrial production of hemp—including both companies that grow and companies that distribute hemp or hemp-derived products—without a proper state or federal license will be subject to penalties, and multiple violations will constitute a felony. Additionally, the 2018 Farm Bill does not preempt state and local laws and regulations—including the need to obtain state licenses—that govern the distribution, packaging and sale of hemp and hemp derivatives, such as CBD, nor does it preempt federal laws that govern importing CBD from foreign jurisdictions.

Continued FDA Regulation of Hemp and CBD

The 2018 Farm Bill expressly does ***not*** affect FDA's jurisdiction and authority over products that contain CBD or hemp as an ingredient in other products. The regulatory issues for CBD and hemp products from an FDA perspective turn on how the products are classified by FDA based on the intended uses of the products and their ingredients. In an announcement after enactment of the 2018 Farm Bill, FDA Commissioner Gottlieb reiterated that FDA treats products containing cannabis or cannabis-derived compounds the same as it does any other FDA-regulated products, and indicated that FDA will continue to take enforcement action against companies illegally selling cannabis and cannabis derived products. FDA has in the past sent warning letters to firms marketing products containing CBD. For example, a Colorado company was warned for marketing "CBD All-Natural Hemp Oil" as effective in treating everything from cancer and diabetes to high blood pressure and Alzheimer's disease. In its warning letter, FDA stated that the company was improperly marketing its CBD products as a dietary supplement, and was making claims that its products could be used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

In his recent announcement, Commissioner Gottlieb expressed continued concern over the number of drug claims being made for unapproved products containing CBD or other cannabis-derived compounds. He emphasized that selling unapproved products with unsubstantiated therapeutic claims both violates the law and potentially puts patients at risk. Commissioner Gottlieb also asserted that it continues to be unlawful to market foods containing added CBD or THC or dietary supplements containing CBD or THC, regardless of whether the substances are hemp-derived and regardless of the claims being made. FDA takes this position based on the operation of statutory "exclusionary clauses" in the Food, Drug and Cosmetic Act related to food additives and dietary supplements. Specifically, FDA has determined that both CBD and THC, which are now active ingredients in FDA-approved drugs, were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements, and due to the operation of the exclusionary clauses, FDA concludes that it is currently illegal to introduce CBD or THC into the food supply or to market these ingredients as dietary supplements.

Commissioner Gottlieb acknowledged that FDA is considering whether to use its authority to issue regulations that would permit the marketing of CBD in foods or as dietary supplements. FDA plans to hold a public meeting in the near future to solicit feedback regarding pathways for marketing products containing cannabis or cannabis-derived compounds. Not all products derived from hemp plants may raise the same regulatory issues as CBD or THC. In conjunction with Commissioner Gottlieb's announcement, FDA announced the completion of its evaluation of three "Generally Recognized as Safe" notices for certain hemp seed-derived products that are distinct from CBD and THC—hulled hemp seeds, hemp seed protein, and hemp seed oil—which means that these three ingredients may now be legally marketed as food additives.

Other Regulatory Considerations

When considering investment in CBD or hemp businesses, additional regulatory considerations that should be taken into account include the Federal Trade Commission's regulation of unfair and deceptive product labeling and marketing, as well as state law regulation of food safety. Additionally, as noted above, the manufacturing, distribution and sale of hemp and CBD products will be subject to state licensure and the associated requirements on the distribution and/or retail sale of cannabis-related products. States have the authority to regulate matters related to the health and safety of its own

citizens, such that the 2018 Farm Bill and regulation by the USDA will not necessarily preempt state or local laws regulating the manufacture and distribution of cannabis-related products that are not directly in conflict with federal law.

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While legalization of hemp and hemp derivatives under the 2018 Farm Bill is a significant step in expanding CBD business opportunities, significant federal, state and local regulatory risks and uncertainties remain, both in terms of how these products are being regulated and in terms of how these products (in their various forms) can be marketed. Accordingly, investors and companies considering venturing into the hemp or CBD space should not treat the 2018 Farm Bill as blanket authorization to proceed. Rather, these investors and companies should understand and address other regulatory barriers that have not been impacted by passage of the 2018 Farm Bill. Should you have any questions regarding this Alert or matters involving the 2018 Farm Bill or hemp- or CBD-related regulation generally, please contact your usual Ropes & Gray advisor.