

## Things to Consider If You Decide to Invest in the Hemp and CBD Industries

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### Client Advisory

April 18, 2019 by Alexander G. Malyshev

In a previous article, I provided an overview of various pitfalls a potential investor should watch out for when deciding to invest in state-legal cannabis enterprises. As noted in that piece, the number one issue facing any potential investor is the fact that marijuana remains a Schedule I drug under U.S. law, and therefore participating in the industry remains illegal under federal law despite state by state legalization.[1]

As of December 20, 2018, that is not the case for “Hemp” and its derivatives. This is big news, and you need to look no further than a local Walgreens, Rite Aid, or CVS to understand why: Hemp products are everywhere. That is especially the case for products containing Cannabidiol or “CBD,” the non-intoxicating active ingredient derived from Hemp, which is considered to be a panacea by some.[2] Industry observers know that the range of products containing or “infused” with CBD is only limited by the imagination. However, this has gotten the attention of the U.S. Food and Drug Administration (“FDA”), which has warned that the sale of consumables and dietary supplements containing CBD across state lines may be violating the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) and section 351 of the Public Health Service Act (“PHSA”) because, among other things, as discussed below, CBD is an active ingredient in an FDA approved drug.

As a result, it makes sense to review some of the issues relevant to this newly legal, and still evolving, industry.

### I. Investing In The Hemp Cultivation Industry

Hemp is a strain of Cannabis, specifically Cannabis sativa L., which contains only trace amounts (less than 0.3% on a dry weight basis) of delta-9 tetrahydrocannabinol (“THC”), the intoxicating ingredient found in Cannabis.[3] In short, it is Cannabis that won’t get you high.

But, until December 20, 2018, Hemp – like all Cannabis – was considered to be a Schedule I drug and, as a result, it was generally illegal to farm, transport, or sell Hemp in the United States. This changed with the passage of the 2018 Farm Bill, which contains several sections dealing with the cultivation and sale of Hemp. Of specific note are sections that:

- Provide a definition for what constitutes Hemp, and remove Hemp from the definition of “marihuana” under the Controlled Substances Act (“CSA”);[4]
- Create a framework for States or Indian Tribes who wish to allow the cultivation of Hemp within their borders to apply for approval through submission of a plan to the Secretary of Agriculture (which would cover, among other things, their procedures for verifying that the plant being grown actually qualifies as Hemp);[5]
- Outline the consequences for Hemp producers who violate those plans, ranging from no criminal liability for an isolated negligent violation, to suspension from any program for five years once a producer has racked up three negligent violations in a five year period, and finally referral to the U.S. Department of Justice for “culpable” violations;[6]

- Provide a framework for cultivation in locales where a plan was not approved in accordance with a plan formulated by the Secretary of Agriculture;<sup>[7]</sup> and
- Allow the transportation of Hemp and Hemp products across state lines, and precludes States or Indian Tribes from prohibiting such transportation.<sup>[8]</sup>

Because Hemp is no longer a controlled substance, and because it is explicitly legal to transport it across state lines, there should be new opportunities to invest in cultivation related businesses once States and Indian Tribes formulate their plans and the Secretary of Agriculture (hopefully) approves them. In considering such an investment, a potential investor should conduct a diligent investigation into whether the business is in compliance with a plan promulgated in accordance with the Farm Bill. Investors should also inquire about any prior violations, and what safeguards are in place to prevent plan violations (by, for instance, having controls in place to prevent cross pollination of Hemp plants with other strains of Cannabis that may be grown nearby for state legal medical or recreational marijuana programs).

## II. FDA Compliance For CBD-Focused Businesses

Once cultivated, Hemp has many uses. Hemp seeds can be ingested both in the raw and as hemp seed oil (which is sometimes used in products such as granola), while Hemp fiber is used to make apparel and accessories in the same way cotton is. Many of these products have been on the shelves for quite a while. However, it is CBD that is grabbing the spotlight at the moment, and which brings with it additional issues to watch out for.

CBD, together with THC, are the two main active ingredients in Cannabis. As noted above, THC is reduced to a trace amount in industrial Hemp, but CBD (which is non-intoxicating) remains untouched. This allows the manufacture of CBD oils, which industry advocates believe have a wide range of beneficial qualities. A non-exhaustive list of CBD products available on the market (not all in the U.S.) includes:

- CBD infused beverages and foods;
- CBD chewables;
- CBD tinctures;
- CBD moisturizers and creams;
- CBD shampoos;
- Supplements and protein powders containing CBD; and
- Ointments containing CBD

Strictly speaking, it is perfectly legal to extract CBD and to sell products containing CBD. But there is a very large caveat to this statement.

The FDA asserted jurisdiction over certain Hemp derived products (namely medicines, foods, and dietary supplements containing CBD) under the FD&C Act and section 351 of the PHSA. This is in part because the FDA has previously approved Epidolex, an epilepsy drug which contains CBD as its main active ingredient. Because the FDA now considers CBD an active drug ingredient, it generally prohibits the marketing or sale of (among other things) any human drugs, human foods and dietary supplements, or animal food and drugs, that contain an active drug ingredient without prior approval. The FDA has taken the same position with respect to products that contain CBD,<sup>[9]</sup> and FDA Commissioner Scott Gottlieb issued several public statements regarding CBD in the wake of the passage of the 2018 Farm Bill. In his most recent statement on

April 2, Commissioner Gottlieb outlined the steps the FDA has taken (and intends to take) with respect to regulation of the industry.[10] These include:

- Setting a public hearing for May 31, 2019, and providing an opportunity for written public comment, for stakeholders to share their views regarding product safety;
- Forming a high-level internal agency working group to explore potential pathways for dietary supplements and food “infused” with CBD to be lawfully marketed (the working group will consider, among other things, the impact of such marketing on public health);
- Updating the agency “frequently asked questions” page with respect to the requirements such products carry;[11] and
- Issuing multiple warning letters to companies marketing CBD products with unfounded claims.

While the FDA is just in the beginning stages of setting the ground rules for the marketing and sale of various products containing CBD derived from Hemp, its cannabis FAQ page states, unequivocally, that in the FDA’s view neither THC nor CBD products may be sold as dietary supplements and, where interstate commerce is involved, neither THC or CBD may be added to human or animal food.[12] Thus, companies that market and sell CBD infused consumables (whether marketed as food or as dietary supplements) do so at their own peril.[13]

These considerations may not apply to products derived from other parts of the plant, for which the FDA has already conducted an evaluation.[14] The FDA set May 31, 2019 as the date for a public hearing to obtain information about the “safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds.”[15] To say that the regulatory framework is in flux is an understatement, and an investor looking to invest in the industry should question a potential investment target about their compliance with (and general awareness of) the regulatory framework.

### III. Banking Remains A Challenge

Another thing that the Farm Bill did not address is the business of banking for the now legal Hemp industry. While, in theory, de-scheduling should allow Hemp cultivators, and CBD producers, to access the banking system more freely, industry reports indicate that this has not been the case.[16] Indeed, some industry payment processors (like U.S. Bancorp. subsidiary Elavon) have decided to exit the Hemp and CBD industry altogether, apparently citing the uncertain regulatory framework in which it was operating.[17] While the current version of the proposed Secure And Fair Enforcement (SAFE) Banking Act introduced in Congress aims to provide protections to institutions that provide services to state-legal cannabis businesses (and by extension to the Hemp industry) by granting them certain safe harbors, and the American Bankers Association has thrown its support behind the Act, passage remains uncertain.[18] Thus, a potential investor should question the target company about its banking and payment processing arrangements, as well as any viable alternatives should its arrangements be terminated.

### IV. Conclusion

The Hemp industry (and specifically the segment of the market dedicated to CBD) appears to be poised for growth. Knowing the right questions to ask will provide valuable insight both into the potential business opportunity and the management team, who should be aware of and be able to intelligently speak to some of the challenges that still remain. The areas outlined above are a good place to start.

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[1] See “Despite The Trend Towards Legalization, Challenges Remain For Investors Considering Investment In State-Legal Cannabis Industries,” *Client Advisory* (March 26, 2019) available at <https://www.clm.com/publication.cfm?ID=5647&Att=172>.

[2] See “Walgreens to sell CBD products in 1,500 stores,” CNBC (March 28, 2019) available at <https://www.cnbc.com/2019/03/27/walgreens-to-sell-cbd-products-in-some-stores.html>; “CVS to sell CBD products in 800 stores in 8 states,” NBC News (March 21, 2019) available at <https://www.nbcnews.com/health/health-news/cvs-sell-cbd-products-800-stores-8-states-n986016>; “Rite Aid will start selling CBD products in 2 states, stop selling e-cigarettes in all stores,” CNBC (April 11, 2019) available at <https://www.cnbc.com/2019/04/11/rite-aid-will-start-selling-cbd-products-in-2-states.html>.

[3] See Agriculture Improvement Act of 2018 (the “Farm Bill”), Pub. L. 115-334, § 10113 (SEC. 297A. Definitions). Available at <https://www.congress.gov/bill/115th-congress/house-bill/2/text>.

[4] See Farm Bill § 10113, Sec. 297A (Definitions); 12619 (Conforming Changes to the Controlled Substances Act).

[5] See Farm Bill § 10113, Sec. 297B.

[6] See Farm Bill § 10113, Sec. 297B, at (e) (Violations). Violations include (i) failing to provide a legal description of the land on which the producer produces Hemp, (ii) failing to obtain a required license from the State or Tribal government, or (iii) growing something other than Hemp (as defined by the statute). *Id.*

[7] See Farm Bill § 10113, Sec. 297C.

[8] See Farm Bill § 10114.

[9] See April 3, 2019, Notice of Public Hearing and Request for Comment on “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments” available at <https://www.govinfo.gov/content/pkg/FR-2019-04-03/pdf/2019-06436.pdf>.

[10] See April 2, 2019, Statement from FDA Commissioner Scott Gottlieb, M.D. on “new steps to advance agency’s continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products,” available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635048.htm>.

[11] See “FDA Regulation of Cannabis and Cannabis Derived Products: Questions and Answers,” available at <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm> (last visited April 18, 2019).

[12] See *id.* Questions 9 (explaining that the “FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]”), Question 10 (explaining that “under section 301(l) of the FD&C Act [21 U.S.C. § 331(l)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public[.]”).

[13] It remains to be seen how aggressive of a position the FDA takes with respect to its interpretation of what constitutes interstate commerce where CBD infused consumables are involved.

[14] For instance, the FDA takes the position that hulled hemp seed, hemp seed protein powder, and hemp seed oil, are generally safe for human consumption. See FAQ Question 12 (“In December 2018, FDA completed its evaluation of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company’s conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. These GRAS notices related only to the use of these ingredients in human food.”).

[15] See <https://www.federalregister.gov/documents/2019/04/03/2019-06436/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds>.

[16] See “Hemp Companies Left Looking for Banking Alternatives,” *Hemp Industry Daily* (April 15, 2019) available at <https://hempindustrydaily.com/hemp-companies-left-looking-for-banking-alternatives/>.

[17] See “U.S. Bank Subsidiary Backs Out of Banking CBD Industry,” *Green Market Report* (April 5, 2019) available at <https://www.greenmarketreport.com/u-s-bank-subsidiary-backs-out-of-banking-cbd-industry/> (citing an e-mail from Elavon stating that “After several months supporting this merchant segment, it has become clear that the pace of an evolving Federal and State regulatory framework makes it extremely difficult to validate the qualifications required to operate within this industry[.]”).

[18] See H.R. 1595 available at <https://www.congress.gov/bill/116th-congress/house-bill/1595/text?q=%7B%22search%22%3A%5B%22SAFE+Banking+Act%22%5D%7D>; American Bankers Association March 25, 2019, Memorandum to the House Financial Services Committee, available at <https://www.aba.com/Advocacy/LetterstoCongress/Documents/ABA-Memo-on-HR-1595-SAFE-Banking-Act.pdf>.

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