kightlaw

January 22, 2019

Dr. Shawn E. Seitz
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Attn. Dr. Seitz,

Re: Minnesota Board of Pharmacy Position on CBD, and Implications.

I. INTRODUCTION

This letter addresses the Minnesota Board of Pharmacy (MBP) position on CBD in products intended for human consumption. It also necessarily includes a discussion of federal law pertaining to CBD from hemp, and the interaction between state and federal law, to the extent that they disagree. The specific legal question addressed in this letter is: "Does state law in Minnesota prohibit the sale of hemp derived CBD, and more generally, to what extent do individual states have authority to criminalize hemp as that term is defined in the Agricultural Improvement Act of 2018[1] (2018 Farm Bill)?"

Subject to the qualfications indicated in this letter, the answer to this question is that while the Minnesota Board of Pharmacy urges consumer caution when purchasing CBD products, neither it nor any other regulatory agency in Minnesota prohibits or makes it a criminal act to purchase CBD products in Minnesota. Furthermore, the 2018 Farm Bill prohibits states from interfering with interstate commerce in hemp.

II. THE 2018 FARM BILL

The 2018 Farm Bill gave hemp[2] exempt status from the Controlled Substance Act (CSA) definition of marijuana. Under federal law, neither hemp, nor derivitaves from it are controlled substances. The 2018 Farm Bill expanded the definition of hemp to include derivatives and extracts (including CBD), and dropped the term "industrial hemp", which was a remnant of the 2014 Farm Act.[3] Certain portions of the 2014 Farm Act remain intact until sunset provisions are triggered, and the pilot program structure is phased out.

[1] https://docs.house.gov/billsthisweek/20181210/CRPT-115hrpt1072.pdf
[2] "*the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.*"
[3] 7 U.S. Code § 5940 - Legitimacy of industrial hemp research, sometimes referred to as "Section 7606" after the section authorizing it in the bill that became the Act.

While cultivation of hemp must still take place under a state pilot program as imagined by the 2014 Farm Act, interstate commerce in hemp is now legal in all 50 states. The 2018 Farm Bill contains explicit provisions that limit the capacity of individual states to interfere with interstate commerce in hemp.

(SEC. 10114. Interstate Commerce).

> *(a) RULE OF CONSTRUCTION.—Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp (as defined in section 297A of the Agricultural Marketing Act of 1946 (as added by section 10113)) or hemp products.*
>
> *(b) TRANSPORTATION OF HEMP AND HEMP PRODUCTS.—No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.*

Many of the important hemp provisions in the 2018 Farm Bill are implemented through amendments to the Agricultural and Marketing Act of 1946. These key hemp amendments classify hemp as an agricultural commodity, make hemp eligible for federal crop insurance, and provide further defense against state interference with interstate commerce in hemp. The final paragraph of the Agriculture and Marketing Act reads:

> "*Nothing in this Act authorizes interference with the interstate commerce of hemp (as defined in section 297A of the Agricultural Marketing Act of 1946, as added by section 2).*"

The 2018 Farm Bill was a pivotal piece of legislation that completely reimagines the federal position on hemp, and creates a legal market for hemp in all 50 states. The 2018 Farm Bill also explicitly prohibits individual states from interfering with interstate commerce in hemp.

III. MINNESOTA POLICY ON CBD

There are typically several state regulatory agencies involved in regulating hemp in any given state. The state department of agriculture typically issues and manages cultivation registrations. The state board of health often has certain regulatory requirements, and issues policy position papers. The state board of pharmacy can also issue guidelines for CBD products. The Minnesota Board of Pharmacy (MBP) issued one such public advisory toward the end of 2018[4] that cautioned consumers who buy products in this new and largely unregulated market. Similar to the FDA stance[5], the MBP differentiates between drugs and dietary supplements, based on the types of health claims made. It also acknowledges that food products are not under its purview.

[4] https://mn.gov/boards/assets/2018_12_04_CBD_Advisory_Pharmacy_Board_tcm21-361597.pdf

[5] FDA differentiates between drugs and dietary supplements based on the type of health claims made, and also regulates food differently than either. Hemp is NOT a dietary supplement, according to the FDA.

As is all too common with many of these state agency policy statements, The MBP misstates the federal legal stance on CBD, stating:

> *"Neither federal nor state law allows cannabinoids such as CBD to be extracted from hemp and then sold in products for human or animal consumption."*

This is not an accurate characterization of federal law. The 2018 Farm Bill made hemp and hemp extracts, including CBD exempt from CSA control. The recent DEA rescheduling of Epidiolex[6] from Schedule I to Schedule V following FDA approval to treat certain rare forms of epilepsy had no impact on the status of CBD from hemp. Again, the MBP characterization of the impact of the FDA approval and subsequent DEA response is incorrect:

> *"The FDA has clearly stated that CBD cannot be sold as either a drug or a dietary supplement, with the exception of Epidiolex, a CBD-containing product that was recently approved by the FDA for treating certain childhood seizure disorders"*

While it is true that the FDA prohibits CBD from being marketed as a dietary supplement, and the addition of CBD to food products, it has not taken any actions to enforce these positions. Regardless of the accuracy of these statements, the MBP policy position paper does not have the force of law, nor does it prohibit commerce in hemp. Instead, the position paper invents federal prohibitions that don't exist, and does not impose any state restrictions on hemp. It simply cautions consumers to have a "buyer beware" mentality when consuming such products. In an interview with CBS New Minnesota[7], Executive Director of MBP, Cody Wiberg corroborated this interpretation. The piece alludes to instances where testing reveals that no CBD exists in products that are advertised to contain CBD, or that other harmful substances are contained in them. The policy paper does indicate that it does not apply to medical cannabis manufacturers, which are regulated by the Minnesota Department of Health.

IV. FOOD, DRUG AND COSMETIC ACT

FDA Commissioner Scott Gottlieb recently released a statement addressing the 2018 Farm Bill, and the future of FDA regulation of hemp, and hemp derived products.[8] The statement did not represent a significant shift away from current FDA policy on hemp and CBD, which remain subject to The Food Drug and Cosmetic Act (FDA Act).[9] FDA enforcement actions to this point have been limited to warning letters for improper health and labeling claims. CBD products are legal under the FDA Act so long as they are not marketed as dietary supplements[10] and no claims are made about the ability of products to *diagnose, cure, mitigate, treat or prevent disease* (emphasis added). *[21 U.S.C. § 321(g)(1)(B)]*

[6] A medicinal CBD extract from marijuana made by GW Pharmaceuticals.
[7] https://minnesota.cbslocal.com/2018/10/08/hemp-derived-cbd-products-minnesota-legality/
[8] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm
[9] 21 USC § 301 *et seq*.
[10] FDA Act [21 U.S.C. § 321(ff)(3)(B)(ii)]

The FDA has held that an article cannot be marketed as a dietary supplement when an Investigative New Drug Applications (INDA) has been initiated and made public. Epidiolex contains CBD isolate derived from marijuana and was recently approved by the FDA. This position does not apply to "full-spectrum" hemp extracts containing the full array of naturally occurring phytonutrients in hemp. Unlike CBD isolate, full-spectrum extracts of hemp have been present in the food supply as part of a coterie of naturally occurring compounds for centuries. The INDA issued for Epidiolex does not count as an INDA for full-spectrum extracts for hemp. Commissioner Gottlieb indicated in his statement that FDA policy regarding CBD and dietary supplement labeling could be subject to review in the future.

The source of CBD (hemp vs. marijuana) is still the key to determining the legal status of CBD under the CSA, despite a portion of Commissioner Gottlieb's statement appearing to impact the "Source Rule"[11].

> *"…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. This is true regardless of the source of the substance, including whether the substance is derived from a plant that is classified as hemp under the Agriculture Improvement Act."*

Full-spectrum hemp extracts are not FDA-regulated products. CBD from marijuana in Epidiolex is subject to CSA control, whereas CBD from hemp is exempt by definition from the CSA. The source of CBD, whether in a full-spectrum extract or an isolate can mean the difference between a legal and a non-legal product. CBD isolate is of greater concern to the FDA partly because it is harder to determine the source of CBD isolate, as compared to full-spectrum extracts. The FDA position that adding CBD isolate to ingestible products violates the FDA Act[12] has never been enforced. The source of CBD isolate should still be the determining factor of legality.

The Commissioner's statement also indicated an intention to create more legal avenues to get CBD products to market, stating:

> *"While products containing cannabis and cannabis-derived compounds remain subject to the FDA's authorities and requirements, there are pathways available for those who seek to lawfully introduce these products into interstate commerce. The FDA will continue to take steps to make the pathways for the lawful marketing of these products more efficient."*

This statement appears to acknowledge that the 2018 Farm Bill did create a legal market for hemp, and that FDA policy must evolve accordingly. Commissioner Gottlieb makes many indications in his statement that FDA policy is subject to change. It will be important to track FDA action carefully for changes to supplement and ingestible product policies.

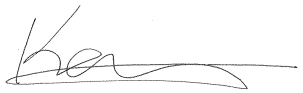
[11] The "Source Rule" refers to our legal theory that the legal status of CBD depends on its source; CBD from hemp is legal, whereas CBD from marijuana is a controlled substance.

[12] http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietsuppsexclude

IV. CONCLUSION.

Hemp, and full-spectrum hemp derivatives are legal at the federal level, and for interstate commerce in all 50 US states. It is advised that no explicit or implied health claims be made in advertising materials about hemp and CBD products. It is further advised that an extensive ingredient list accompany each ingestible product containing CBD. As the provisions of the 2018 Farm Bill continue to be implemented, and federal regulatory schemes for hemp are issued, we will see clarification of individual state attitudes toward such products. The MBP consumer warnings do not appear to be backed up by any enforcement action, or expose purveyors of extracts containing CBD from hemp to criminal liability. Full-spectrum hemp extracts are distinguishable from, and not contemplated by the MBP, or FDA statements concerning Epidiolex. CBD products are legal under federal law, and no law in Minnesota can interfere with state commerce in hemp and hemp by-products.

Sincerely,



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