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Executive Summary

The Unregulated Distribution And Sale Of Consumer Products Marketed As Delta-8 THC

Executive Summary

There is a rapidly expanding crisis in the United States involving a psychoactive form of THC which is derived from unregulated industrial hemp, referred to as Delta-8 tetrahydrocannabinol or Delta-8 THC. Delta-8 THC is an “isomer” (chemical analog) of Delta-9 THC, the molecule better known as the source of marijuana’s high, which reportedly has 75% of potency of Delta-9 THC. Over the past year or so, sales of this drug have spread across the country through such outlets as tobacco stores, newsstands, and local pharmacies, as well as internet sales. While efforts to legalize and to regulate the sale of cannabis and cannabinoids derived from cannabis should encompass Delta-8 THC, the fact that it is being sold outside of the regulated marketplace with no oversight or testing and is readily available to children is alarming, and it presents a public health risk of potentially wider impact than the vape crisis.

This Delta-8 THC crisis has been spawned by a supposed loophole in the federal 2018 Farm Act, which legalized the cultivation and sale of “industrial hemp,” a form of cannabis that contains negligible quantities of psychoactive chemicals, as well as products naturally derived from industrial hemp. Despite such arguments by supporters of unregulated Delta-8 THC distribution, there is no such “loophole:” the 2018 Farm Act does not legalize the production of psychoactive drugs simply because the base material has been extracted from industrial hemp, and the DEA’s current rulemaking clearly confirms this position. Moreover, Delta-8 THC is being marketed and sold in violation of consumer protections provided by the Food and Drug Act and FDA rules, as well as in violation of state laws—and a growing list of states have acted to specifically address the Delta-8 THC issue.

To highlight the dangers of the unregulated sale of Delta-8 THC and similar products, the USCC has commissioned testing of Delta-8 THC products procured from various states and as well as examination of the labelling and marketing of these products. These tests reveal that not only do Delta-8 THC products commonly have vastly varying amounts of Delta-8 THC, they but they also can contain amounts of Delta-9 THC in clearly illegal quantities, as well as pesticides and heavy metals. The packaging of such products is often misleading or outright false as to the ingredients of the product and its legal status, and often includes unsubstantiated claims about medical or other benefits. The results of this survey are summarized in this paper.

The members of the US Cannabis Council support the safe and regulated sale of cannabis products. The unregulated sale of untested cannabis products hurts, can cause catastrophic public harm to, and will hinder further reform toward a safe, well-regulated, federally legal cannabis industry. While further action should be taken by federal authorities and states to confirm that the unregulated sale of Delta-8 THC has not been sanctioned, state and federal authorities have several paths currently available to enforce the law and to address this crisis.

The USCC supports prompt action from regulators, law enforcement, and the cannabis community to stem the Delta-8 THC crisis including the following:

1. Action by state Attorneys General to apply Consumer Protection Act and/or the States' Unfair and Deceptive Act and Practices law to stop the sale and distribution of Delta-8 products, as was done to clamp down on the unregulated sale of "alcopops"
2. The issue of cease-and-desist letters from state law enforcement to all unregulated producers of Delta-8
3. Rulemaking under state regulation to ensure that Delta-8 THC is produced and marketed only through state-licensed cannabis programs
4. Further action by the Federal Drug Enforcement Agency to clarify that the Farm Act 2018 does not legalize the sale of unregulated Delta-8 THC

1. Introduction

In December 2018, the United States Congress passed the Agriculture Improvement Act, more commonly known as the 2018 Farm Bill. This law removed hemp -- defined as cannabis with concentrations of Delta-9 tetrahydrocannabinol (Delta-9 THC) below .3% -- from the definition of marijuana in the Controlled Substances Act (CSA). Inasmuch as the Farm Bill exempted only Delta-9 THC, some have taken this to mean that other extracts from industrial hemp were effectively legalized, including delta-8 tetrahydrocannabinol (Delta-8 THC), a lesser-known psychoactive cannabinoid. This novel legal interpretation has driven an explosion of Delta-8 THC production and intra- and inter-state commerce across the country over the past two years.

In August 2020, the DEA promulgated an Interim Final Rule (2020 IFR) which confirmed that hemp-derived THC products were not legalized by the 2018 Farm Bill. Some industry players are claiming that the final rule does not confirm the illegal status of Delta-8 THC because it fails to mention this substance by name and are challenging the rule. Some players have even stated support for the production and marketing of Delta-8 THC products. More established industry groups including the US Hemp Roundtable, however, have rejected the argument that unregulated Delta-8 THC has been legalized and believe that the availability of Delta-8 THC products could undermine efforts to bring other hemp products to market. The crisis has been furthered by the reluctance of some state regulators to weigh in on the interpretation of the federal Farm Act 2018 or, absent further federal guidance or specific state regulation, to act against the unregulated Delta-8 THC market.

At present, products purporting to contain Delta-8 THC are being marketed across the country through unregulated retail outlets and the internet. These products are not subject to ingredient testing to detect

and prevent dangerous contaminants such as lead, heavy metals, certain pesticides, etc. Moreover, notwithstanding the claims from these manufacturers and distributors that these hemp-derived products do not contain more than the federal limit of .3% Delta-9 THC, independent testing (described below) has found the opposite. Indeed, recent independent testing of these Delta-8 products sold in Florida has found substantial amounts of Delta-9 THC as well as heavy metals. Moreover, these products are being sold to children.

As a general matter, there is no evidence that Delta-8 THC is inherently dangerous or problematic, but like any medication or intoxicant, particularly one with psychoactive properties, it should be carefully regulated to ensure that it is (a) sold to adults or those authorized by law to purchase, and (b) safe for consumers and patients to use through testing, labeling, and the other regulatory requirements that are part of effective state cannabis programs.

What is Delta-8 THC?

When people refer to THC, they are typically talking about Delta-9 THC, the primary form of THC found in cannabis. Delta-9 THC is possibly the most potent psychotropic cannabinoid and produces its intoxicating effects by interacting with the CB1 receptor in the human body. However, other isomers of THC do exist. Isomers are variations of molecules with identical chemical formulas but a distinct arrangement of atoms. Delta-8 THC is one such isomer of Delta-9 THC.

A commonly accepted scientific definition of Delta-8 THC comes from the National Cancer Institute:

An analogue of tetrahydrocannabinol (THC) with antiemetic, anxiolytic, appetite-stimulating, analgesic, and neuroprotective properties. Delta-8-tetrahydrocannabinol (delta-8-THC) binds to the cannabinoid G-protein coupled receptor CB1, located in the central nervous system; CB1 receptor activation inhibits adenylyl cyclase, increases mitogen-activated protein kinase activities, modulates several potassium channel conductances and inhibits N- and P/Q-type Ca²⁺ channels. This agent exhibits a lower psychotropic potency than delta-9-tetrahydrocannabinol (delta-9-THC), the primary form of THC found in cannabis.

Delta-8 differs in structure from Delta-9 THC in the placement of a double bond between carbon atoms 8 and 9 rather than carbon atoms 9 and 10. Due to its altered structure, Delta-8 THC has a lower affinity for the CB1 receptor, and therefore has a lower psychotropic potency than Delta-9 THC. Relative to the psychotropic potency of Delta-9 THC, Delta-8 THC has been estimated to be about 75% or perhaps two-thirds as potent. Delta-8 THC has been described as “marijuana light” or “pain relief with less psychoactivity.” Although Delta-8 THC does exist naturally in the cannabis plant, it is only present at very low levels. The cost-effective manufacturing process of Delta-8 THC involves the isomerization of CBD via exposure to an acidic environment. Delta-8 THC can also be manufactured from Delta-9 THC.

2. Current Commercialization of Delta-8 Products: Product Safety and Legality Issues

Delta-8 THC products have become widely available across the U.S. since businesses began selling Delta-8 THC products in 2019. Consumer sales expanded rapidly in 2020 and continue to grow in 2021, leading

one industry expert to state that it is the “fastest growing segment” of products derived from hemp. One prominent Delta-8 THC retailer saw sales increase exponentially every month over the past year. Delta-8 THC is now available for purchase at gas stations, drug paraphernalia shops, and convenience stores. Anecdotally, Delta-8 THC product sales have been especially strong in states without medical or adult-use cannabis laws.

Recent media stories now include reports of Delta-8 products falling into the hands of minors with dangerous results. For example, in April, authorities raided a southeastern Wisconsin (Waukesha County) CBD store after two children overdosed from a product their parent said was from the store. Investigators reportedly stated that they tested some products at the store that were found to contain 20 percent THC.¹ Other states have similarly raised concerns about the accessibility of Delta-8 THC products to minors through unregulated distribution points and consequently have issued warnings through poison control centers. See, e.g., West Virginia.²

3. Delta-8 THC Product Testing

In connection with preparing this paper on Delta-8 THC products, 16 samples of non-cannabis based, over-the-counter products featuring Delta-8 THC were procured in April 2021 for chemical testing. All samples were legally obtained from various non-regulated retail stores or online retail vendors from across the U.S. including from California, Florida, Nevada, Texas, Michigan, Massachusetts, North Carolina, and Indiana. The samples were analyzed for a suite of chemicals including cannabinoid profiles, heavy metals, residual solvents, and exploratory analysis for unknown compounds. The purpose of the analyses was to determine whether the samples, which were advertised as containing no more than the federal legal limit of Delta-9 THC (.3%), actually complied with that limit and, in addition, whether the samples were generally safe from a consumer safety perspective.

Methods

All samples were processed by ProVerde Laboratories, an independent testing facility in Milford, MA, for cannabinoid profiles by solvent dilution and UPLC-UV analysis, residual solvents by full evaporative technique (FET) GC/MS headspace analysis, and elemental analysis by microwave digestion and ICP-MS analysis. In addition, a portion of each sample was subjected to analysis by solvent dilution and GC/MS liquid injection analysis for exploratory analysis and unknown identification.

Results

All investigated samples contained a mixture of THC isomers with Delta-8 THC featured as the primary cannabinoid per the product’s label claim. Notably, however, all samples also contained illicit Delta-9 THC at levels substantially higher than the USDA 0.3% upper limit, with the exception of a single sample of a tincture where the total cannabinoid concentration was substantially diluted to 10 mg/mL. The mean Delta-9 THC value was about 3.4%, with a range of about 1.3% - 5.3%. None of the tested samples were 2018 Farm Bill compliant. **The mean Delta-9 THC concentration of the sample set was more than 10 times greater than the USDA limit of 0.3%. Accordingly, all samples are non-compliant (illegal) products.**

All investigated samples contained a mixture of various other elements including:

- Heavy Metals: Lead was detected in four of the 16 samples investigated, though the detected levels in the four samples was below the USP limit for inhalation.
- Other Metals: Seven of 16 samples failed USP limits for inhalation on copper (Cu), chromium (Cr) or nickel (Ni).
- 7-10 compounds in each of the samples analyzed were of unknown identification and thus unknown toxicological significance.

Residual Solvents Analysis

Dichloromethane and methanol were found once in different samples of the set of 16. Hexane was found in three of the 16 samples. All detected levels were below US limits for inhalation. Acetone was detected in every sample. Ethanol was detected in 13, ethyl acetate in seven, Heptane once, isopropanol in nine of the 16 samples; all detected levels were below US limits for inhalation.

Unknown Ingredients

The testing also identified ingredients in most of the samples that have some similarities to known cannabinoids but are not found in the current NIST mass spectral library. These compounds appear to be either isomers of known cannabinoids or new, unknown compounds with no toxicological characterization available, which is concerning.

4. The Federal Legal Status of Delta-8 THC

Attached is a memorandum of law prepared by the law firm of Cadwalader, Wickersham & Taft (the “Cadwalader Memo”). The Cadwalader memo analyzes the state of federal law as it applies to Delta-8 THC. As summarized below, the Cadwalader memo concludes that there are several reasons why claims that Delta-8 THC is federally legal as a result of the 2018 Farm Bill or otherwise are incorrect.

i) The 2018 Farm Bill: Implications for the Legal Status of Delta-8 THC

Many commentators and marketers suggest that Delta-8 THC is legal on the federal level under the 2018 Farm Bill, which defined “hemp” as “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.” 7 U.S.C. § 1639o. The 2018 Farm Bill also revised the CSA definitions of “marihuana” to exclude the new definition of hemp and the definition of “tetrahydrocannabinols” to exclude “tetrahydrocannabinols in hemp.” Because Delta-8 naturally occurs in small quantities in cannabis,³ advocates of Delta-8 THC argue that these changes could be interpreted as exempting Delta-8 from control under the CSA.

However, the Drug Enforcement Administration (“DEA”), in August 2020, issued an “interim final rule” (IFR) to codify in the DEA regulations the CSA amendments made by the 2018 Farm Bill (Aug. 21, 2020). The DEA recognized the revised definition of “marihuana” and clarified that to qualify for the “hemp” exception

to the definition of marihuana, “a cannabis-derived product must itself contain 0.3% or less Δ9-THC on a dry weight basis.” But the DEA also clarified that the “definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the Δ9-THC content of the derivative” and that “a cannabis derivative, extract, or product that exceeds the 0.3% Δ9-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ9-THC on a dry weight basis.”

ii) Synthetically Derived THC

The DEA also noted in the IFR that the 2018 Farm Bill “does not impact the legal status of synthetically derived tetrahydrocannabinols because the statutory definition of ‘hemp’ is limited to materials that are derived from the plant *Cannabis sativa* L. For synthetically derived tetrahydrocannabinols, the concentration of Δ9-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.” Neither DEA regulations nor the CSA define “synthetically derived.” However, the level of naturally occurring Delta-8 THC found in hemp is negligible and Delta-8 THC products are all produced from hemp extracts by conversion through chemical reaction of naturally occurring cannabinoids into Delta-8 THC. As of April 2021, the DEA published Controlled Substance by DEA Drug Code Number 7370 lists “Delta-8 THC” among “other names” for tetrahydrocannabinols.⁴

iii) The Federal Analog Act

Even if CBD-derived Delta-8 is not viewed as “synthetically derived,” Delta-8 would likely still be at high risk of being treated as a “controlled substance analogue” by the DEA. The Federal Analogue Act, 21 U.S.C. § 813, treats a controlled substance analogue, if intended for human consumption, to be treated for the purposes of federal law as a controlled substance in Schedule I of the Controlled Substances Act. A “controlled substance analogue” is any substance that has: (1) a substantially similar chemical structure to a schedule I or II controlled substance; and (2) a substantially similar stimulant, depressant, or hallucinogenic effect on the central nervous system. As to the first prong, the chemical structure of Delta-8 and Delta-9 are virtually identical.

With regard to the second prong, experts estimate the effect of Delta-8 to be approximately 75% of the potency of Delta-9, which may easily meet the second requirement that the analogue have a “substantially similar” effect on the central nervous system. Given the near-universal agreement that the 2018 Farm Bill was not meant to legalize intoxicants, it would be consistent with the law for the DEA to view enforcement under the Federal Analogue Statute as consistent with the Farm Bill’s intent.

iv. Delta-8 and the FDCA

The 2018 Farm Bill also made clear that nothing in it would affect or modify the FDA’s authority under the Federal Food Drug and Cosmetic Act (“FDCA”). After the 2018 Farm Bill’s passage, the FDA Commissioner publicly stated that “it’s unlawful under the FDCA to introduce food containing added CBD or [Delta-9] THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.” It is the FDA’s position that it is “illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements.” The FDA has also

stated that Delta-9 THC and CBD products cannot be sold as dietary supplements or food additives under the FDCA.

While the FDA has not issued a statement specific to Delta-8, there is no basis to believe the FDA will treat it differently from CBD and THC. Any substance intentionally added to food is a food additive, and therefore subject to pre-market review and approval by the FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use. Other than certain hemp seed products, no cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Therefore, sales of Delta-8 remain prohibited by the FDA as a food additive or dietary supplement. As for Delta-8 vaping products, there is no reason to believe the FDA will treat them differently from CBD vaping products—if sold as a tobacco product then they may not be sold without FDA pre-market authorization. If sold as a drug, then vaping products cannot be marketed without an FDA-approved drug application. As a result, Delta-8 products in their present market form as vaping products and consumables are illegal under the FD&C Act. Notably, to date the FDA has not aggressively pursued state licensed marijuana sellers under the FDCA, but whether the FDA would take that same approach to unlicensed sellers of Delta-8 is unclear.

5. Approaches to Delta-8 THC at the State Level

In many states, a plain reading of the hemp program laws indicate that the sale of Delta-8 THC would not be permitted because in defining hemp, the states have not distinguished between THC Delta-9 and its derivatives and isomer. Beyond that, broadly speaking, states fall into three categories: states that prohibit Delta-8 THC by rule or guidance (as described above, or in regulatory guidance), states (two) that permit regulated Delta-8 THC by rule or guidance, and states that have not specifically addressed the issue. Notably, many states that explicitly ban Delta-8 THC products (as opposed to relying on the apparent exclusion in the definition of hemp) rely upon a state agency's determination that Delta-8 THC is a synthetic form of THC and thus prohibited under the CSA and related DEA guidance, including the IFR.

A good example of this is North Carolina where the Department of Agriculture website states “Currently, DEA takes the position that synthetically derived THC is illegal as a controlled substance. Since Delta-8 THC appears at negligible and non detectable concentrations in hemp, Delta-8 THC is normally derived from chemical conversion from CBD into Delta-8 THC. Therefore, it appears from DEA's August 21, 2020 Interim Final Rule, titled “Implementation of the Agriculture Improvement Act of 2018,” that it will treat Delta-8 THC derived from chemical conversion or other synthetic methods as illegal.”

The attached chart highlights a sampling of 13 states' positions on Delta-8 THC and includes an analysis of applicable state laws as well as related guidance provided in connection with our review of this issue. The state categorizations are representative of the results of a 50-state regulatory agency survey conducted by an independent law firm for this report.

Turning to a state that permits Delta-8 THC, the Florida Department of Agriculture and Consumer Service (FDCAS) issued a statement on the topic of Delta-8 THC, which suggests that Delta-9 THC content remains the standard for determining whether a product qualifies as a hemp product. The statement reads: “Any

hemp or hemp extract products offered for sale or sold in Florida must comply with all labeling rules and have a certificate of analysis that shows a total THC ($\text{THCA} \times .8777 + \text{THC Delta 9} = \text{total THC}$) content of 0.3% or less. Any hemp or hemp extract product that does not comply with all statutes and rules is subject to enforcement and possible destruction by the Florida Department of Agriculture and Consumer Services.” According to FDCAS, this guidance means as long as the total THC as defined above is below 0.3%, the product sold may contain and be marketed as Delta-8 THC. Notably, manufacturers in Florida represent one of the principal sources of Delta-8 THC products sold in other states and via the internet.

Nevada is an example of a state that has adopted an approach to treat Delta-8 THC like Delta-9 THC so that these products may only be sold through the state’s regulated cannabis framework. The Nevada Revised Statutes, in a section updated on July 1, 2020, provide that the definition of “THC” specifically includes Delta-8 THC. Referencing this definition in the law, the Nevada Cannabis Compliance Board (CCB), which oversees the state’s regulated cannabis market, recently offered the following in a newsletter: “Products exceeding 0.3% THC, including Delta-8 and Delta-9 THC, would be considered cannabis. As such, a license from the CCB would be required to make it or sell it.”

As this topic gains more national attention, it is possible that more states will begin to take a reasonable and responsible approach of regulating Delta-8 THC similarly to Nevada by permitting the manufacturing and sale of Delta-8 THC products only through state-licensed cannabis businesses. States without state-licensed cannabis businesses may choose to specifically ban Delta-8 THC products at the state level, which is within their authority. Until a state takes a position publicly, consumers and businesses are left guessing as to the legal status of these products.

In addition to agency guidance, several states have pending bills or newly enacted laws addressing Delta-8 THC. Other recent state legislative and regulatory activities concerning Delta-8 THC as of this writing include:

- **Hawaii HB 422** was introduced into the Hawaii House on January 25, 2021. The bill adds Delta-8 THC to the list of controlled substances.
- **Illinois HB 0147** has passed the Illinois House and is currently in the Senate. The bill directs the Illinois Department of Agriculture to establish testing, packaging, and labeling requirements for all non-marijuana cannabinoid products. This would extend to Delta-8 products.
- **Louisiana HB 640** was introduced in the Louisiana House on April 2, 2021 and is scheduled for a floor debate on May 10, 2021. The bill makes several minor changes to the state’s hemp production program and defines “Total THC Concentration” to include Delta-8, Delta-10, Delta-6a(10a), Delta-6a(7), Delta-7, and Delta-9 THC.
- **Michigan HB 4517** was introduced to the house on March 16, 2021 and includes language that amends the definition of THC to include “a tetrahydrocannabinol, regardless of whether it is artificially or naturally derived” and “a tetrahydrocannabinol that is a structural, optical, or geometric isomer of a tetrahydrocannabinol . . .” The bill also gives the marijuana regulatory agency the power to exclude specific tetrahydrocannabinols from the definition of THC if it determines that the tetrahydrocannabinol does not have the potential for abuse based on several specific factors.
- **North Dakota HB 1213** is awaiting the Governor’s signature. The bill amends the definition of THC to include Delta-9 and Delta-8 THC. The bill also amends the THC possession laws so that possession of an amount less than 2 grams is an infraction and possession of more than 2 grams is a misdemeanor.

- **North Dakota HB 1045** was signed by the Governor on April 26, 2021. The law allows the Commissioner of Agriculture to set the allowable THC concentration in hemp and defines THC to include Delta-9, Delta-8, Delta-10, and Delta-7 THC. The bill also prohibits North Dakota hemp licensees from selling hemp or hemp products that were “created using the isomerization of cannabinoids to create isomers of tetrahydrocannabinol, including Delta - 8, Delta - 9, and Delta – 10 tetrahydrocannabinol.”
- **Oklahoma HB 1961** was introduced in the Oklahoma House on February 1, 2021. The bill would bring delta-8 under the purview of the state’s regulated marijuana program by defining marijuana to include Delta-8 and Delta-10 tetrahydrocannabinol with a concentration in excess of .3% on a dry weight basis.
- **Oregon HB 3000** was introduced in the Oregon House on January 21, 2021 and a public hearing was held on April 20, 2021. The bill gives regulatory authority over “artificially derived cannabinoids” to the Oregon Liquor Control Commission. The bill also defined THC to include “all tetrahydrocannabinols that are artificially or naturally derived, including but not limited to Delta-8 tetrahydrocannabinol and Delta-9 tetrahydrocannabinol.”
- **Texas HB 2593** was amended in the Senate to add the following language to the definition of a controlled substance: “Controlled substance” means a substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Group 1, 1-A, 2, 2-A, 2-B, 3, or 4. The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance. The term does not include hemp, as defined by Section 121.001, Agriculture Code, or the tetrahydrocannabinols in hemp, except that the term includes a consumable hemp product, as defined by Section 443.001, if the sum of all tetrahydrocannabinol concentrations in the product is more than 0.3 percent on a dry weight basis. The addition of this language would make any product that contains > 0.3% of any form or combination of forms of THC (including Delta-8) a controlled substance. The bill was amended in the senate and now must go back to the House for concurrence.
- On May 14, 2021 the **Colorado Marijuana Enforcement Division** notified marijuana business owners that modified or synthetic versions of THC derived from industrial hemp could not be sold in Colorado stores.

Regardless of what individual state legislatures have determined in terms of the legality of Delta-8 THC, each state Attorney General has the power to ban Delta-8 THC from the shelves of stores in each of the 50 states, plus the District of Columbia. Indeed, state Attorneys General have utilized their powers in the past to prohibit products such as “alcopops,” “Four Loko,” and other inappropriate products marketed toward young people.⁵ Specifically, state Attorneys General have two extremely powerful tools in their arsenal — the individual state Consumer Protection Act and the Unfair and Deceptive Acts and Practices (UDAP) law. Taken together, these two laws provide the wide-ranging power for a state Attorney General to remove Delta-8 because it is potentially harmful to users, including underaged people, as well as the lack of transparency and disclosure of the packaging concerning the contents of Delta-8 and the potential consequences of its use. Thus, while some may argue about the legality of Delta-8, the state Attorneys General may exert their inherent powers authorized by the Consumer Protection Acts and UDAP to unilaterally eliminate Delta-8 from the marketplace.

6. Statements Made by Relevant Organizations

For the most part, hemp and marijuana industry trade organizations have expressed concern with the current situation in which a substantial unregulated and uncontrolled Delta-8 THC market has been allowed

to proliferate. Indeed, at least one hemp industry group, the US Hemp Roundtable (USHR), has issued a statement opposing the marketing and selling of intoxicating products as hemp, fearing that it jeopardizes the future of non-intoxicating hemp products such as CBD. The USHR press release states, “The U.S. Hemp Roundtable, the hemp industry’s national business advocacy organization, is opposed to marketing products, under the guise of the hemp name, for any intoxicating value or euphoric effect -- an irresponsible practice highlighted in recent news reports.” While the group’s press release does not directly reference Delta-8 THC, it does point to articles from Rolling Stone and The New York Times on the topic of Delta-8 THC.

Other actors in the space are skeptical about whether the Delta-8 THC is pragmatic for the cannabis industry. Morgan Phaxia, a co-founder of the cannabis investment fund Poseidon Asset Management, offered a statement that typifies this mindset, saying that the sale of Delta-8 THC is “playing a game around uncertainty, which we don’t need to do anymore.”⁶

Conclusion

As discussed above, there is no evidence that Delta-8 THC is an inherently dangerous or problematic substance; rather, it is an analog of Delta-9 THC which is increasingly accepted by a number of states for use by individuals suffering from a range of state identified medical conditions and as a recreational intoxicant for use by adults. That said, like any substance falling into these categories, distribution and sales of **Delta-8 THC should be carefully regulated and controlled so that consumers can be confident the products’ contents are known and safe as well as predictable in their effects.** The unregulated distribution of Delta-8 THC products is inconsistent with these principles and poses significant risks to adults and minors. Moreover, the continued proliferation of unregulated and unsafe Delta-8 THC products has the potential for confusing patients and consumers leading to a loss of confidence in the nascent cannabis industry. Only by including Delta-8 THC products in the existing Delta-9 THC regulatory scheme can we ensure that THC products continue to be distributed and used in a safe and appropriate manner.

A CALL TO ACTION

The Health Risks of Delta-8 THC and What's Needed Now

The sale of Delta-8 THC, the psychoactive cannabinoid synthesized from hemp, is making news across the United States, particularly in states where cannabis remains illegal. Sales of Delta-8 products have exploded at gas stations and convenience stores across the country, creating easy access for underage consumers as the market is flooded with information claiming that the compound offers a “legal” high.

This represents a major consumer safety issue, posing dangers greater than the “vape crisis” of 2019.

We as a regulated, tested, verified, and taxed industry are voicing our concern.

Indeed, most of the regulated cannabis industry agree that any product containing any psychoactive cannabinoids, such as Delta-8 THC, must be regulated, tested and controlled in the same manner as inhalable or consumed cannabis products in the regulated cannabis market. Unregulated, untested products should not be offered by unlicensed producers to consumers in stores, online, or anywhere.

The spread of Delta-8 THC is being driven by spurious legal arguments that the Farm Act 2018 legalized the sale of psychoactive cannabinoids merely because they are derived from chemicals extracted from hemp. The Drug Enforcement Agency’s August 2020 Interim Final Rule has clarified that the Farm Bill 2018 did not legalize “synthetic” compounds merely because the raw materials are extracted from hemp. Nevertheless, proponents of an unregulated Delta-8 THC market point to lack of specific references to Delta-8 THC in guidance from federal and many state regulators to insist that despite the law and existing guidance, a “loophole” or “grey areas” still exist. As a result, Delta-8 THC is currently being sold across the country with no safeguards in place. The product is easily purchased by minors. There are no requirements for testing of potency, pesticides, or adulterants. Childproof packaging is not required, and neither are warning or informational labels of any type.

Regulating Delta-8 THC is critical to avoid similar issues the industry saw with the vape crisis in 2019—when products from the unregulated market caused major health issues for consumers and damaged public trust for the entire industry. We are at risk for a similar crisis if regulators and state lawmakers - and concerned consumers - do not act:

- The process to convert CBD to Delta-8 THC may require the use of chemicals not safe for consumption.
- Many of the processors converting the compound in the unregulated market are not qualified chemists working with the appropriate lab equipment, and the potential for residual chemicals or contamination is real.
- Where Delta-8 THC producers make testing claims, there are no standards for such testing, leading to misleading claims. Furthermore, the labs claiming to verify product safety are not accredited and may not produce accurate results.

To date, over 12 states have adopted specific measures to ban Delta-8 sales, while other states such as New York, Illinois, Oregon, and California are adopting regulatory frameworks that allow for Delta-8 THC or any THC only if it is tested, verified, and sold through the regulated marketplace. Just this week, it was announced that hemp-derived Delta-8 and Delta-10 THC are now banned in Colorado dispensaries, a significant development given the state's leading position in cannabis legislative issues.

Most recently, The Michigan [Poison Center at Wayne University](#) issued a warning notice about Delta-8 after “two cases of severe adverse reactions were reported in children who {...} developed sedation, slowed breathing, low blood pressure and slowed heart rate, requiring admission to the intensive care unit.” According to the [University of Virginia Health](#) Poison Center, “Delta-8-THC ingestions reported to poison control centers have been associated with a variety of clinical symptoms, including drowsiness, bradycardia, and hypotension sometimes requiring vasopressors. Other patients report feeling confused and anxious, with tachycardia and generalized numbness.”

Leading cannabis industry organizations (the [USCC](#) and [US Hemp Roundtable](#)) have made their position clear:

Delta-8 is federally illegal (FDA and DEA) and is a safety risk due to it being a psychoactive product that is not being regulated and tested. We are extremely concerned that another vape crisis is coming if the agencies and state lawmakers do nothing. Any psychoactive product from hemp or cannabis should be tested, verified safe and only sold through the regulated marketplace.

If you are interested, we can share independently verified test results recently conducted on Delta-8 samples. Also, please note that representatives from the [USCC](#) and [US Hemp Roundtable](#) are available to discuss the dangers of having unregulated, untested, unverified Delta-8 THC in the public marketplace.

We look forward to connecting on this important issue soon.

Delta-8 THC Independent Test Results

Background

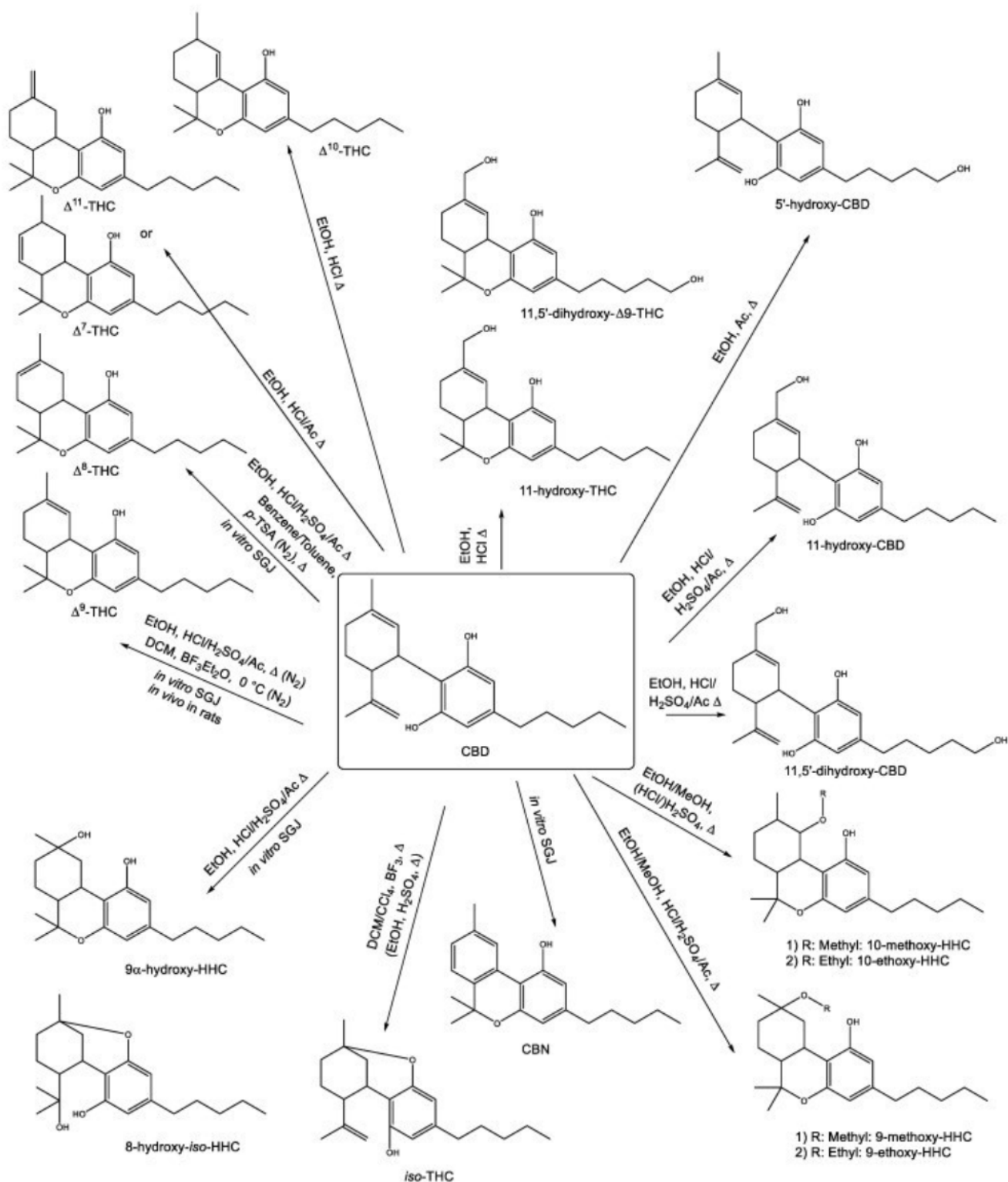
The legal hemp industry has been coexisting with the regulated cannabis industry for a number of years on a state-by-state basis. However, the passing of the 2018 Farm Bill by the USDA accelerated the entry of new hemp cultivators, processors, manufacturers, and retailers eager to profit off the newly deregulated cannabidiol (CBD) market. CBD based materials began appearing everywhere from grocers to pharmacies such as CVS, to gas stations, typically with substantial price tags for the CBD based materials. Unfortunately, the 2018 Farm Bill did not require or specify a safety testing protocol. The only requirement was that all materials must be regulated delta-9-tetrahydrocannabinol (D9-THC) compliant. The D9-THC compliance level was set at less than 0.3% by weight, which was already in use by many states' agricultural bureaus.

While no safety testing was required by the 2018 Farm Bill, many responsible CBD based businesses would electively perform safety testing consistent with the regulated cannabis industry, often utilizing the same laboratories and testing suites. Unfortunately, many businesses could either not afford the cost of testing, or simply did not care about the perceived safety of their products and there was (and still is) no mechanism to control the bad players in the legal hemp market.

To compound the problem, the surplus of available hemp and CBD rapidly rose due to the large influx of new contributors post the 2018 Farm Bill. The glut of available raw materials compounded by limited demand for CBD based products began to erode the market price of hemp biomass and associated CBD oils and isolate to the point where many CBD businesses could not continue. The solution to these business problems was to convert their devalued CBD into a higher value product by isomerization chemistry processes.

Research papers discussing the conversion of CBD into THC molecules were published many decades ago^(1,2) and these processes were revived by modern CBD manufacturers. Isomerization reactions typically involve organic solvents, acids, catalyst elements or salts, heat, and time. The THC molecule has 30 structural isomers, one of them is predominantly produced natively by the cannabis plant, the (6aR,10aR)-delta-9-THC isomer. The isomerization reaction is non-specific and results in the creation of mixtures of synthetic THC isomers with D8-THC often the dominant product. Other cannabinoid isomers, and many other unintended reaction byproducts (Figure 1) that are typically cannabinoid-like molecules, but with various functional group substitutions that render them unknown are also present. Without additional purification or cleanup, these reaction products almost always contain D9-THC at levels greater than the 0.3% limit in addition to the newly formed unknown compounds which have an uncharacterized safety profile and may be of high risk for consumer use.

Figure 1 – Overview of various chemical conversions of cannabidiol (CBD) to different conversion products and the respective conditions, which are reported in the literature.⁽³⁾



Scope

Sixteen samples of non-cannabis based, over-the-counter products featuring D8-THC were sourced in April of 2021. The samples originated in many different states within the U.S. including California, Florida, Nevada, Texas, Michigan, Massachusetts, North Carolina, and Indiana. The samples were analyzed for a suite of chemicals including cannabinoid profiles, elemental analysis including heavy metals, residual solvents, and exploratory analysis for unknown compounds. The purpose of the analyses was to evaluate the legality of the samples from a D9-THC perspective, and well as to evaluate general consumer safety of the products.

Methods

All samples were processed by ProVerde Laboratories in Milford, MA for cannabinoid profiles by solvent dilution and UPLC-UV analysis, residual solvents by full evaporative technique (FET) GC/MS headspace analysis, and elemental analysis by microwave digestion and ICP-MS analysis.

All samples were legally obtained from various non-regulated retail stores or online retail vendors.

This narrative describes the results and compares the samples.

Results

Cannabinoid Content

All investigated samples contained a mixture of THC isomers with D8-THC featured as the primary cannabinoid per the product's label claim. All investigated samples also contained regulated D9-THC at levels substantially higher than the USDA 0.3% upper limit with the exception of a single sample of tincture where the total cannabinoid concentration was substantially diluted to 10 mg/mL. The mean D9-THC value was about 3.4%, with a range of about 1.3% - 5.3%. None of the tested samples were 2018 Farm Bill compliant. The mean D9 concentration of the sample set was more than 10 times greater than the USDA limit of 0.3% and all samples are non-compliant (illegal) products.

Elemental Analysis

All investigated samples contained a mixture of various elements as trace composition.

Heavy Metals: No mercury (Hg), arsenic (As), or cadmium (Cd) were detected in any sample. Lead (Pb) was detected in four of the 16 samples investigated, but the detected levels in the four samples was below the USP limit for inhalation.

Other Metals: Of the remaining elemental panel, seven of 16 samples failed USP limits for inhalation on copper (Cu), chromium (Cr) or nickel (Ni).

The presence of elevated levels of copper, chromium and nickel are likely due to reaction catalysts and poor cleanup or purification and creates substantial additional risk to consumers.

Residual Solvents Analysis

All investigated samples also contained a mixture of chemical solvents. USP classifies chemical solvents into three categories; 1. Solvents to be avoided, 2. Solvents to be limited, and 3. Solvents with low toxic potential.

Class 1: No benzene was found in any samples.

Class 2: No acetonitrile or cyclohexane was detected in any samples. Dichloromethane, and methanol were found once in different samples of the set of 16. Hexane was found in three of the 16 samples. All detected levels were below US limits for inhalation.

Class 3: Dimethyl sulfoxide and pentane were not detected in any samples. Acetone was detected in every sample. Ethanol was detected in 13, ethyl acetate in 7, Heptane once, isopropanol in 9 of the 16 samples. All detected levels were below US limits for inhalation.

Butane, isobutane, and propane were also measured, but were not detected in any samples.

Vitamin E Acetate Analysis

VCE acetate (VEA) was a constituent of concern in 2019 due to a series of VEA laden vape carts that induced respiratory problems. VEA was not detected in any of the samples and does not appear to be a diluent or additive of concern.

Exploratory Analysis

Exploratory analysis showed a commonality of about 10 or 11 analytical peaks that appear to be forming as secondary reaction products. Cannabicitran (CBT), exo-THC, and CBN appear as small peaks in nearly every D8 cart sample investigated. Further, there are about seven peaks that reoccur in most of the samples that have mass spectra similar to known cannabinoids but can not be definitively identified with a current NIST mass spectral library. These compounds appear to be isomers of known cannabinoids or may have minor functional group or double bond positional adjustments rendering them as new, unknown compounds with no toxicological characterization available.

One sample in particular, the High Life - Gorilla Glue cart showed a substantially different unknown profile than most of the other samples. Several unknown cannabinoid-like compounds were present; however, the mass spectral fragmentation showed that the compound mass was not 314 atomic mass units (AMU) like all other standard cannabinoids but had been increased to 360 AMU. The difference of 46 AMU and considering the fragmentation rule of N+1 (47) suggests that these peaks may be CH₂SH substituted cannabinoids. The mass spectral comparison is presented in Figure 3.

If the reaction were performed using a sulfur catalyst and a particular acid selection, these types of molecules could be formed. Interestingly, this sample had one of the highest sulfur values of the group with over 4,000 ppm of sulfur detected.

The unknown compounds create substantial risk for consumer safety.

Authors

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P. Golombek, M. Muller, I. Barthlott, C. Sproll, and D. Lachenmeier: Conversion of Cannabidiol (CBD) into Psychotropic Cannabinoids Including Tetrahydrocannabinol (THC): A Controversy in the Scientific Literature, Toxics, June 3rd, 2020.

Table 1. Cannabinoid Concentration Results

Lab Sample #	TestDate	Brand	Product	State	Matrix	D9-THC	CBD	CBDV	CBG	CBC	CBN	D8-THC	EXO-THC
94183	5/6/2021	High Life	Gorilla Glue	MA	Vape Oil	4.4341	0	0	0	0	0.1355	76.1838	1.6967
94184	5/6/2021	3CHI	Caribbean Dream	IN	Vape Oil	3.7638	0	0	0	0	0	93.6328	2.7088
94185	5/6/2021	Organic CBD Nugs	Grape Ape	TX	Vape Oil	5.0307	0	0	0	0	0.1482	84.9216	1.4947
94186	5/6/2021	EightySix	Blue Dream	CA	Vape Oil	3.93	0	0	0	0	0.4571	66.3305	3.8952
94187	5/6/2021	ChillPlus	Pineapple Express	FL	Vape Oil	1.2958	0.7709	0	0	0	0	92.6559	1.216
94188	5/6/2021	The Hemp Doctor	Sour Diesel	NC	Vape Oil	4.8749	0	0	0	0	0.1148	92.1463	1.8425
94189	5/6/2021	Treetop Hemp Co	Skywalker OG	CA	Vape Oil	2.8742	0	0	0	0	0	80.0427	1.337
94190	5/6/2021	MoonWkr	Strawberry Gelato	NV	Vape Oil	2.4569	0	0	0	0	0.0682	92.2344	1.3653
94191	5/11/2021	VIIA	Lemon Diesel	CA	Vape Oil	1.4188	4.3451	0.16	0.1916	1.0283	0.7054	86.2685	1.312
94192	5/11/2021	Delta Effex	Grand Daddy Purp	CA	Vape Oil	1.8864	0.0317	0	0	0	0	91.1463	1.1818
94300	5/9/2021	Miracle Leaf Delta8	THC	FL	Tincture	0.13	0	0	0	0	0.1336	6.5171	0.2592
94301	5/11/2021	Urb Delta8	DAB5 Banana Runtz	FL	Vape Oil	4.8209	0	0	0	0	0.342	89.7287	3.141
94302	5/11/2021	Moon Men	Delta8 Shatter	FL	Vape Oil	3.3589	0	0	0	0	0	95.9689	1.7562
94303	5/11/2021	Privada RUNTZ	RUNTZ Delta8 DAB DART	??	Vape Oil	2.1138	0	0	0	0	0	92.7028	1.4847
94304	5/11/2021	MED Roots	DELTA EIGHT Strawberry Cough	MI	Vape Oil	3.3307	0	0	0	0	0.1541	83.7729	1.4845
94305	5/11/2021	Palm Treez	Delta8 Disidos	FL	Vape Oil	5.2925	0	0	0	0	0	90.6909	2.81

Red - Exceeds USDA Limit of 0.3% by wt. for D9-THC

Results reported in Wt. %

Cannabinoids with no detections in any samples were not presented

Table 2. Elemental Concentration Results

Lab Sample #	Test Date	Brand	Product	State	Matrix	Al	As	Ca	Cl	Co	Cu	Fe	Hg	K	Mg	Mn	Mo	Ni	P	Pb	S	Se	Zn	Zr
94183	4/10/2021	High Life	Gorilla Glue	MA	Vape Oil	0.182	0	0.011	0	0.004	0.055	4.085	0	3.479	0	0	0.593	8.201	0	4.384	0	0.063	0.007	
94184	4/10/2021	3CHI	Caribbean Dream	IN	Vape Oil	0.226	0	7.849	0	0	0.054	0.883	0	2.896	0	0	0.14	8.966	0	2.884	0	0.141	0.017	
94185	4/10/2021	Organic CBD Nugs	Grape Ape	TX	Vape Oil	0.226	0	5.819	0	0	0.073	1.725	0	3.092	0	0	1.409	5.042	0	3.263	0	5.334	0.006	
94186	4/10/2021	EightySix	Blue Dream	CA	Vape Oil	153.77	0	6.011	0	0.099	0.158	5.704	0	2.292	0	0	0.465	3.331	0	7.067	0	0	0	0.434
94187	4/10/2021	Chill Plus	Pineapple Express	FL	Vape Oil	2.018	0	6.74	0	0	2.221	2.841	0	2.488	0	2.618	0	1.153	4.095	0.933	3.373	0	2.145	0.036
94188	4/10/2021	The Hemp Doctor	Sour Diesel	NC	Vape Oil	0.216	0	7.052	0	0.118	45.911	3.717	0	2.426	0	0.072	0	8.411	1.84	0.324	3.84	0.01	51.578	0.006
94189	4/10/2021	Treetop Hemp Co	Skywalker OG	CA	Vape Oil	0	0	6.139	0	0.072	3.187	2.18	0	2.574	0	0	0	0.695	2.946	0.076	4.126	0	3.196	0.03
94190	5/6/2021	MoonWkr	Strawberry Gelato	NV	Vape Oil	0.438	0	1.019	0	1.419	0	5.044	0	0	0.677	0.124	210.729	0.884	0	1.345	0	0.29	0.022	
94191	5/6/2021	VIIA	Lemon Diesel	CA	Vape Oil	0.17	0	0	0	0	0	0.0575	0	0.805	0.103	0	157.248	0	3.25	0	1.802	0	0	0.007
94192	5/7/2021	Delta Effex	Grand Daddy Purp	CA	Vape Oil	0.359	0	2.511	0	1.055	0.331	10.079	0	17.362	2.753	0.244	803.803	0.366	0	0	0	0.717	0.345	0.02
94300	5/7/2021	Miracle Leaf Delta8	THC	FL	Tincture	0.279	0	3.956	0	0	0.319	0.316	0	7.021	1.98	0	27.075	0	1.623	0	0	0.002	0.15	0.007
94301	5/7/2021	Urb Delta8	DAB5 Banana Runtz	FL	Vape Oil	0.34	0	3.191	0	0.207	0.549	0.957	0	8.745	2.313	0	15.262	0	2.178	0	0	0.838	0.134	0.007
94302	5/7/2021	Moon Men	Delta8 Shatter	FL	Vape Oil	0.547	0	9.663	0	0	0.971	6.418	0	6.488	1.26	0	10.662	0	3.472	0	0	0	0.345	0.096
94303	5/7/2021	Privada RUNTZ	RUNTZ Delta8 DAB DART	??	Vape Oil	0.735	0	9.457	0	0	0.086	0.629	0	6.502	1.581	0	12.517	0	4.547	0	0	0	0.085	0.007
94304	5/7/2021	MED Roots	DELTA EIGHT Strawberry Cough	MI	Vape Oil	0.661	0	3.467	0	0	0.455	0.486	0	3.481	1.127	0	21.936	0	5.366	0	0	0.510	0.143	0.021
94305	5/7/2021	Palm Treez	Delta8 Disidos	FL	Vape Oil	0.447	0	3.2	0	0	0.768	1.435	0	10.034	2.383	0	5.873	0.363	1.991	0	0	0	0.359	0.039

Red - Exceeds USP Limit

Results reported in ppm

Table 3. Chemical Solvent Results

Lab Sample #	TestDate	Brand	Product	State	Matrix	Acetone	Acetonitrile	Benzene	Butane	Cyclohexane	Dichloro-methane	Dimethyl Sulfoxide	Ethanol	Ethyl Acetate	Heptane	Hexane	Isobutane	Isopropanol	Methanol	Pentane	Propane
94183	5/10/2021	High Life	Gorilla Glue	MA	Vape Oil	10.89	0	0	0	0	0	0	4.65	0	0	0	0	0	0	0	0
94184	5/10/2021	3CHI	Caribbean Dream	IN	Vape Oil	24.12	0	0	0	0	0	0	64.56	162.23	0	0	0	0	0	0	0
94185	5/10/2021	Organic CBD Nugs	Grape Ape	TX	Vape Oil	13.58	0	0	0	0	0	0	60.09	1511.76	0	0	0	50.42	0	0	0
94186	5/10/2021	EightySix	Blue Dream	CA	Vape Oil	13.92	0	0	0	0	0	0	111.83	250.64	0	0	0	3.03	0	0	0
94187	5/10/2021	ChillPlus	Pineapple Express	FL	Vape Oil	1.64	0	0	0	0	0	0	1.3	108.45	0	0	0	1.84	0	0	0
94188	5/10/2021	The Hemp Doctor	Sour Diesel	NC	Vape Oil	8.05	0	0	0	0	0	0	0	0	0	0	0	3.85	0	0	0
94189	5/10/2021	Treetop Hemp Co	Skywalker OG	CA	Vape Oil	3.62	0	0	0	0	0	0	6.85	0	0	0	0	27.53	0	0	0
94190	5/10/2021	MoonWkr	Strawberry Gelato	NV	Vape Oil	31.4	0	0	0	0	0	0	5.55	259.45	0	0.97	0	261.52	0	0	0
94191	5/10/2021	VIIA	Lemon Diesel	CA	Vape Oil	22.84	0	0	0	0	2.22	0	9.56	0	0	1.35	0	1.83	0	0	0
94192	5/10/2021	Delta Effex	Grand Daddy Purp	CA	Vape Oil	2.57	0	0	0	0	0	0	59.22	0	0	0	0	0	16.02	0	0
94300	5/10/2021	Miracle Leaf Delta8	THC	FL	Vape Oil	1.37	0	0	0	0	0	0	1.13	0	0	0	0	0	0	0	0
94301	5/10/2021	Urb Delta8	DAB5 Banana Runtz	FL	Vape Oil	3.12	0	0	0	0	0	0	1.62	0	11.02	0	0	0	0	0	0
94302	5/10/2021	Moon Men	Delta8 Shatter	FL	Vape Oil	2.48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
94303	5/10/2021	Privada RUNTZ	RUNTZ Delta8 DAB DART	??	Vape Oil	3.65	0	0	0	0	0	0	53.04	0	0	1.64	0	0	0	0	0
94304	5/10/2021	MED Roots	DELTA EIGHT Strawberry Cough	MI	Vape Oil	40.26	0	0	0	0	0	0	326.32	128.33	0	0	0	123.84	0	0	0
94305	5/10/2021	Palm Treez	Delta8 Disidos	FL	Vape Oil	10.91	0	0	0	0	0	0	1.76	8.18	0	0	0	0.38	0	0	0
					USP Limit	5000	410	2	-	3880	600	5000	5000	5000	5000	290	-	5000	3000	5000	-

Results reported in ppm

All Results were under USP limits (USP 467 - Residual Solvents)

Figure 2. Exploratory Analysis and Detail of Unknowns

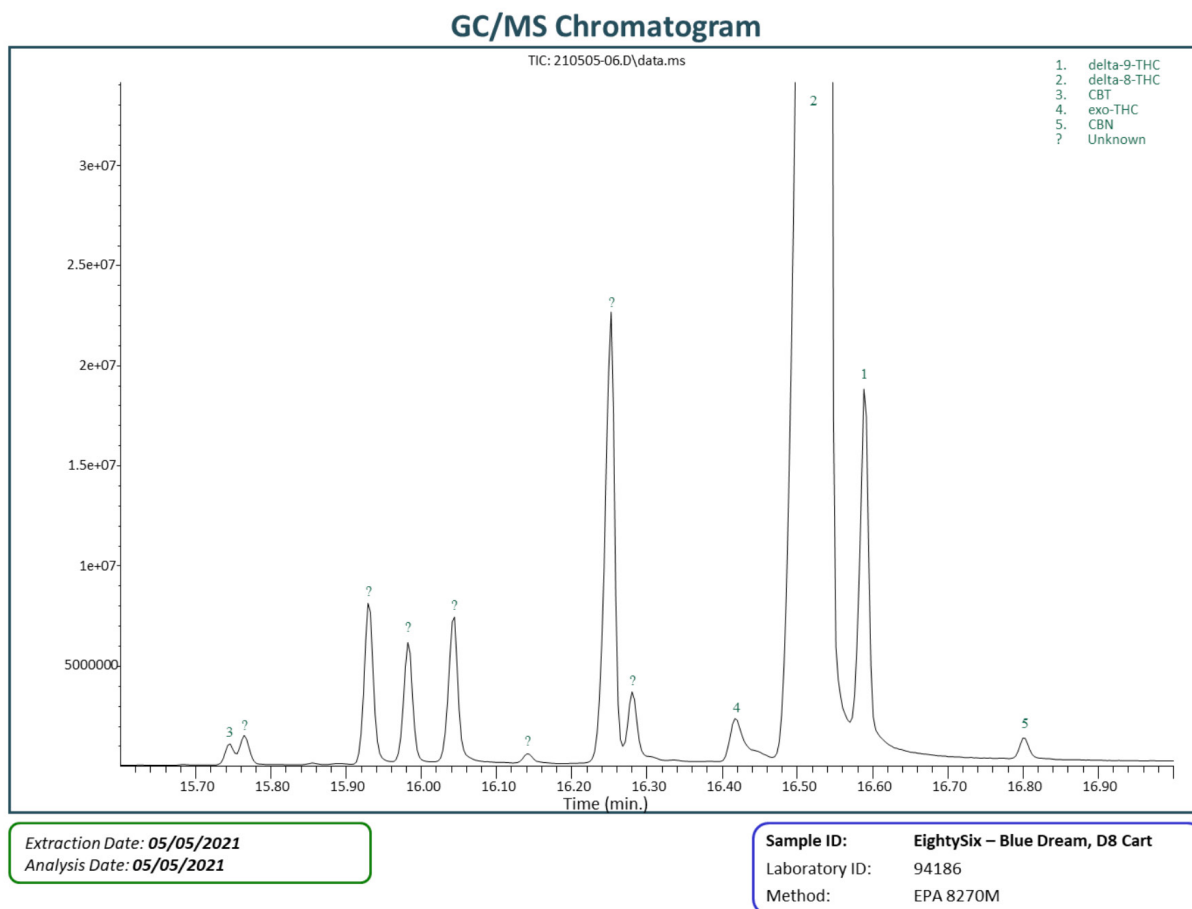
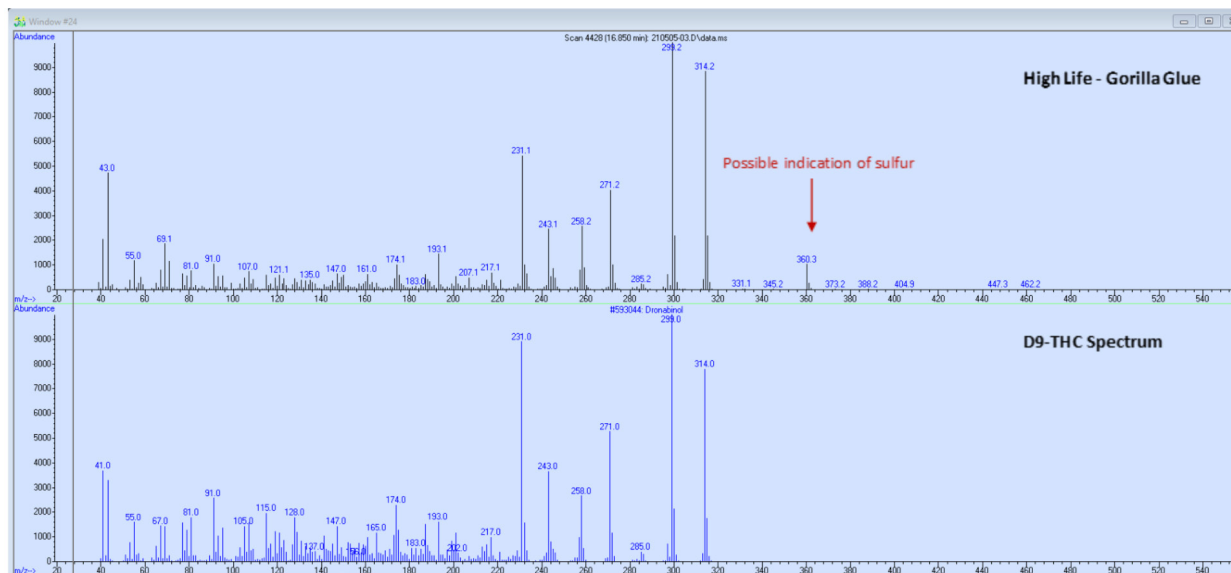


Figure 3. High Life - Gorilla Glue – Mass Spectral Comparison to D9-THC (as Dronabinol)



Federal Memorandum

C A D W A L A D E R

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Memorandum

To: US Cannabis Council
From: Cadwalader, Wickersham & Taft LLP
Date: May 13, 2021
Re: Federal Risks of Delta-8

Delta-8-Tetrahydrocannabinol (“Delta-8”) is the newest cannabinoid to hit the United States market after Congress legalized the production of hemp in 2018. Unlike CBD, which is non-psychoactive, Delta-8 is being marketed as a “legal” high with less potent, but similar effects to Delta-9-Tetrahydrocannabinol, the primary psychoactive in marijuana. Because Delta-8 is so new, much confusion exists around its legal status at the federal level, though most informed commentators believe that it will ultimately fall under the regulatory framework of the Controlled Substances Act (“CSA”).

Many commentators and marketers suggest that Delta-8 is legal on the federal level under the 2018 Farm Bill,¹ which defined “hemp” as “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.” 7 U.S.C. § 1639o. The 2018 Farm Bill also revised the CSA definitions of “marihuana” to exclude the new definition of hemp and the definition of “tetrahydrocannabinols” to exclude “tetrahydrocannabinols in hemp.” H.R.2 § 12619. Because Delta-8 naturally occurs in small quantities in cannabis,² they argue that these changes could be interpreted as exempting Delta-8 from control under the CSA.

However, the Drug Enforcement Administration (“DEA”), in August 2020, issued an “interim final rule” to codify, in the DEA regulations, the CSA amendments made by the 2018

¹ The “2018 Farm Bill” refers to the Agricultural Improvements Act of 2018.

² See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3736954/>

Farm Bill.³ 85 Fed. Reg. 51639 (Aug. 21, 2020). The DEA recognized the revised definition of “marihuana” and clarified that to qualify for the “hemp” exception to the definition of marihuana, “a cannabis-derived product must itself contain 0.3% or less Δ^9 -THC on a dry weight basis.” *Id.* at 51641. But the DEA also clarified that “definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the Δ^9 -THC content of the derivative” and that “a cannabis derivative, extract, or product that exceeds the 0.3% Δ^9 -THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ^9 -THC on a dry weight basis.” *Id.* The DEA further recognized that the effect of the 2018 Farm Bill was to “limit[] the control of tetrahydrocannabinols.” *Id.* Accordingly, tetrahydrocannabinols are deemed not controlled if they are “naturally occurring constituents of the plant material,” and “contain 0.3% or less of Δ^9 -THC by dry weight” “unless specifically controlled elsewhere under the CSA.” *Id.* The DEA also noted that the 2018 Farm Bill “does not impact the status of synthetically derived tetrahydrocannabinols (for Controlled Substance Code Number 7370) because the statutory definition of ‘hemp’ is limited to materials that are derived from the plant *Cannabis sativa* L. For synthetically derived tetrahydrocannabinols, the concentration of Δ^9 -THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.” Neither DEA regulations nor the CSA define “synthetically derived.” As of April 2021, the DEA-published Controlled Substance by DEA Drug Code Number 7370 lists “Delta-8 THC” among “other names” for tetrahydrocannabinols.⁴

Therefore, Delta-8 is at high risk of being treated as a Schedule I controlled substance by the DEA under the 2020 Interim Final Rule. Delta-8 is not commercially produced by direct extraction from hemp because the quantities of naturally occurring Delta-8 are so small. Instead, it is lab-made by converting hemp-extracted CBD to Delta-8 through a chemical process.⁵ The conversion from CBD to Delta-8 also often creates Delta-9 at a concentration about the 0.3% threshold, although apparently some producers are working to minimize Delta-9 conversion.⁶ Delta-8 can also be chemically converted from Delta-9 by an even simpler process than CBD-conversion.⁷ While none of these methods of conversion necessarily meet a strict scientific

³ https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0821.htm

⁴ https://www.deadiversion.usdoj.gov/schedules/orangebook/d_cs_drugcode.pdf. Some commentators have stated that the DEA uses the same code number for Delta-8 and “marihuana,” (see, e.g., <https://www.hklaw.com/en/insights/publications/2020/10/hemp-industry-brings-case-against-dea-to-clarify-deas-hemp-rule>), but the most recent update to the drug codes assigns “marihuana” drug code number 7360 and “tetrahydrocannabinols” like Delta-8 drug code number 7370.

⁵ <https://www.cannabistech.com/articles/how-delta-8-is-made-in-the-lab/>

⁶ See, e.g., <https://acslabcannabis.com/blog/extraction/the-ultimate-guide-to-delta-8-thc-synthesis-methods-safety-and-purity/>

⁷ <https://extractionmagazine.com/2021/02/19/converting-cbd-to-delta-8-thc/>

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definition of “synthesis,” they do involve chemical manipulation of CBD (and Delta-9) to produce Delta-8 (and Delta-9). Moreover, it will likely be difficult for authorities to determine whether Delta-8 was derived from CBD or converted from Delta-9. For those reasons, it remains very likely that the DEA will view CBD-derived Delta-8 as a “synthetically derived” tetrahydrocannabinol under Schedule I.

Even if CBD-derived Delta-8 is not viewed as “synthetically derived,” Delta-8 would likely still be at high risk of being treated as a “controlled substance analogue” by the DEA. The Federal Analogue Act, 21 U.S.C. § 813, treats a controlled substance analogue, if intended for human consumption, to be treated for the purposes of federal law as a controlled substance in Schedule I of the Controlled Substances Act. A “controlled substance analogue” is any substance that has: (1) a substantially similar chemical structure to a schedule I or II controlled substance; and, (2) a substantially similar stimulant, depressant, or hallucinogenic effect on the central nervous system. 21 U.S.C. § 802(32). As to the first prong, the chemical structure of Delta-8 and Delta-9 are virtually identical—the only structural difference between them is the location of a carbon double-bond in the molecule. In Delta-9, the double-bond exists between the 9th and 10th carbon atom, whereas in Delta-8 the double-bond exists between the 8th and 9th carbon atom. This minor structural difference gives Delta-8 increased chemical stability, and thus shelf life, and reduces the efficiency at which Delta-8 binds to the CB1 receptor in the brain—which is why the “high” created by Delta-8 is thought to be less potent than the effect created by Delta-9. Nevertheless, experts estimate the effect of Delta-8 to be approximately 75% of the potency of Delta-9, which may easily meet the second requirement that the analogue have a “substantially similar” effect on the central nervous system. Given the near-universal agreement that the 2018 Farm Bill was not meant to legalize intoxicants, the DEA may very well view enforcement under the Federal Analogue Statute as consistent with the Farm Bill’s intent.

Ultimately, the ambiguity around the DEA’s interpretation of the 2018 Farm Bill Amendments and the language in the Farm Bill defining “hemp” as both the plant and its “derivatives” may arguably provide defenses were the DEA to seek an enforcement action against a Delta-8 producer or retailer. Nevertheless, the risk that Delta-8 will be treated as a Schedule I drug remains high until tested in the courts or clarified by the DEA or Congress.

Delta-8 also remains subject to FDA oversight. The 2018 Farm Bill also made clear that nothing in it would affect or modify the FDA’s authority under the Federal Food Drug and Cosmetic Act (“FD&C Act”). 7 U.S.C. § 1639r(c). After the 2018 Farm Bill’s passage, the FDA Commissioner publicly stated that “it’s unlawful under the FD&C Act to introduce food containing added CBD or [Delta-9] THC into interstate commerce, or to market CBD or THC

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products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.”⁸ It is the FDA’s position that it is “illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements.” The FDA has also stated that Delta-9 THC and CBD products cannot be sold as dietary supplements or food additives under the FD&C Act.⁹

While the FDA has not issued a statement specific to Delta-8, it is likely that it will be treated similarly to CBD and THC. Any substance intentionally added to food is a food additive, and therefore subject to pre-market review and approval by the FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use. 21 U.S.C. §§ 321(s) and 348. Other than certain hemp seed products, no cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA.¹⁰ Therefore, sales of Delta-8 remain prohibited by the FDA as a food additive or dietary supplement. As for Delta-8 vaping products, the FDA will likely treat them similarly to CBD vaping products—if sold as a tobacco product then they may not be sold without FDA pre-market authorization. If sold as a drug, then vaping products cannot be marketed without an FDA-approved drug application.¹¹ As a result, Delta-8 products in their present market form as vaping products and consumables are illegal under the FD&C Act. To date, the FDA has not aggressively pursued state-licensed marijuana sellers under the FD&C Act, but whether the FDA would take that same approach to unlicensed sellers of Delta-8 is unclear.

In conclusion, retailers and producers of Delta-8 are at serious risk of federal enforcement for selling illegal products. A high risk exists that Delta-8 will ultimately be deemed as a Schedule I controlled substance by the DEA due to ambiguities in the DEA’s interpretation of amendments to the CSA by the 2018 Farm Bill. In addition, the FDA has not approved the use of Delta-8 as a drug, dietary supplement, or food additive, so the current Delta-8 products on the market—edibles and vaping products—are being sold illegally under the FD&C Act.

⁸ <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys#:~:text=Press%20Announcements-.Statement%20from%20FDA%20Commissioner%20Scott%20Gottlieb%2C%20M.D.%2C%20on%20signing%20of,cannabis%20and%20cannabis%2Dderived%20compounds&text=Scott%20Gottlieb%20M.D.,2018%20was%20signed%20into%20law>

⁹ <https://www.fda.gov/media/131878/download>

¹⁰ FAQ No. 10 <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>

¹¹ See, e.g., Report to the U.S. House Subcommittee on Appropriations and the U.S. Senate Committee on Appropriations Cannabidiol (CDB) at 12 (March 2020) <https://nysba.org/app/uploads/2020/03/FDA-CBD-Report-to-Congress-March-2020.pdf>

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