OMCIA
OHIO MEDICAL CANNABIS INDUSTRY ASSOC.

MEMORANDUM

TO: Senator Michael Rulli, Chairman, Senate General Government Committee
Senator Kirk Schuring, Vice Chairman, Sen. General Government Committee (SB 9 joint sponsor)
Senator Bill DeMora, Ranking Minority Member, Senate General Government Committee
Members of the Senate General Government Committee
Senator Steve Huffman, Senate Bill 9 joint sponsor
FR: Matt Close, Executive Director, Ohio Medical Cannabis Industry Association (OMCIA)
DT: March 7, 2023

RE: Senate Bill 9 – Ohio Medical Marijuana Control Program

On behalf of the Ohio Medical Cannabis Industry Association (OMCIA) and its members we would like to thank you for the opportunity to provide comments on Senate Bill 9. The OMCIA represents more than seventy medical marijuana licenses operating in Ohio's Medical Marijuana Control Program (MMCP) and the thousands of workers employed by our members.

The OMCIA appreciates Senator Huffman's and Senator Schuring's remarks during the January 17th Sponsor Testimony before the General Government Committee, and we echo their desire to keep the best interests of Ohio's patients in mind when considering a bill that makes substantial changes to the medical marijuana program. Unfortunately, the bill as introduced misses the mark to make the program more accessible and effective for patients and instead focuses its efforts on massive expansion measures to which the OMCIA remains completely opposed.

In early 2021 the OMCIA approached Senator Huffman asking him to sponsor a bill to fix the medical marijuana program by shifting complete regulatory authority to the Department of Commerce, along with other minor adjustments to the benefit of all licensees. All we wanted was a simple corrective bill that benefitted the whole program. Unfortunately, SB 261 was changed to add expansion and new licenses without consideration of the impact such expansion would have on a stagnant program. By the time SB 261 was introduced, the "corrections bill" more than doubled the cultivation area of Level 2 cultivators (from 9,000 square feet to 20,000 square feet), gave future preference for Level 2 cultivators to convert to Level 1 licenses and awarded cultivation licenses to a select handful of stand-alone processors.

As introduced, SB 9 appears to go further in the wrong direction for three primary reasons: 1) it includes a massive expansion well beyond SB 261, 2) it puts the program under the authority of an independent commission comprised of political appointees with lifetime appointments, and 3) it incorporates laboratory standards that will increase the cost of testing 2 – 5 times for operators, which only increases the cost of medical marijuana.

1) **Massive Program Expansion:** SB 9 increases the cultivation expansion proposed in SB 261 by immediately moving Level 2 cultivators to 15,000 square feet (SB 261 started at 6,000 sf and moved to 20,000 sf), awards free Level 2 cultivation licenses to a group of stand-alone processors, awards free processing licenses to any Level 2 without a processing license, and awards more than 60 new dispensary licenses to all cultivators. SB9 applies an "if we build it they will come" theory

to a limited, fledgling medical marijuana program. The market for medical marijuana in Ohio is not a free market. Patient access to the program is limited by the requirement of regular and expensive doctors' visits and state fees that are not covered by insurance. Product demand is further limited by restrictions on purchase amounts, potency caps, and limitations on allowable forms and methods of administration. Finally, limitations on advertising have contributed to a general lack of awareness and knowledge about the program itself. Consequently, Ohio's patient count has flatlined, averaging around 163,000 active patients since August 2022 despite an already ongoing Program expansion that has resulted in an oversupply of marijuana.

The bill also awards every Level 1 cultivator 2 new dispensary licenses and increasing their cultivation cap to 100,000 square feet (currently 75,000 sf). Regardless of these handouts to Level 1 cultivators, the OMCIA's position has not changed – **we do not support any new expansion of the MMCP outside of the expansion originally authorized in rule.**

2) **Regulation by a Commission of Lifetime Political Appointees:** Second, SB 9 eliminates the basic foundation of SB 261 – moving the entire program under the regulatory authority of the Department of Commerce. Instead, SB 9 takes the worst feature of the Board of Pharmacy – an autonomous Board that meets once a month to make decisions about a program it has very little involvement in running – and transplants this regulatory model to the Department of Commerce by creating a new independent Commission charged with regulating the program (Lines 1140 – 1196). This move takes all the authority away from the Director of the Department of Commerce and the experienced staff that has overseen the program for 5 years and gives it to a politically appointed Commission comprised of members who, for the most part, know nothing about Ohio's medical marijuana program.

3) **Expensive Testing Standards:** Finally, SB 9 (Lines 2169 – 2176) keeps a poorly conceived testing amendment that was added swiftly, without any discussion or industry input, to SB 261. Six of Ohio's licensed testing laboratories developed an extensive paper evaluating the impact of the amendment on the program when similar language was added to SB 261. The labs project these standards will increase the cost of testing by 2 – 5 times for licensed cultivators and processors. The inapplicability, redundancy, high cost and outdated nature of these standards only highlights the need for this topic to be handled by experienced regulators with actual knowledge about the program. *A complete copy of the paper is attached for your consideration (Attachment 1).* After the language was added into SB 9 all eight testing labs have worked together to identify changes that could be made to achieve the co-sponsors' goal of ensuring Ohio's patients are provided with accurate test results and safe medical marijuana products.

Our member companies stand to receive a 33% increase in growing capacity and half of the new dispensary licenses awarded under SB 9 – and we still adamantly oppose all expansion provisions in the bill because of the devastating impact they will have on the entire industry. **Why would our members oppose being awarded more grow space and new dispensary licenses valued at over a hundred million dollars unless we truly believed the expansion would destroy the industry we have worked tirelessly to build?**

Ohio's program is not affected with a lack of supply. A quick review of dispensary menus shows thousands of different products available to patients while cultivator, processor and dispensary vaults sit full. The price of medical marijuana products is competitive – neighboring Pennsylvania's price for a gram of plant material is $3.46 more than Ohio's (or 46% higher), yet they have 423,443 active patients and $6.3 billion

in sales. Additionally, the price of biomass available for use by standalone processors has decreased by 92.5%. **The problem is not a lack of supply. It is a lack of patients to consume what is already being produced.** Ohio's program is overregulated, overcomplicated and it is stagnating. Ohio operators are now experiencing the first true round of layoffs and production stoppages in the program, and SB 9 introduces more supply and additional dispensaries that will further dilute the patient base and drive many operators out of business.

Without resolution of the Top 3 issues outlined above we have no choice but to oppose this bill. However, these are not our only concerns with the bill. Adjustments also need to made to the following sections:

- The 1:1000 dispensary ratio for registered patients is too low, it should be 1:2,500 (Lines 1225 – 1237)
- The bill should use the term "active patients" not "registered patients" (Lines 1225 – 1237)
- One mile buffer around an existing dispensary could negatively affect dispensaries already under construction and may be impossible to achieve in smaller communities with restrictive dispensary zoning (Lines 1238 – 1240)
- Seeds & clones language negatively impacts Ohio-only cultivators (Lines 1949 – 1961)
- All medical marijuana licenses should be allowed to display images of products in advertising (Lines 1358 – 1359)
- Remove the fines or violation for advertising penalties (Lines 1365 – 1368)
- Restrict involvement of the Sheriff to criminal violations (Lines 1859 – 1868)
- Add to the curbside and drive through language "and any other method of dispensing approved by the division" (Lines 1369 – 1371 and 2107 – 2111)
- Revise testing language to say labs must test marijuana for potency, homogeneity and contamination "at least once prior to sale" (Lines 2158 – 2159)
- Add language that allows a cultivator's aggregate square footage to be situated on multiple properties

Respectfully, we submit to the Ohio Senate that there is a pathway forward that addresses the concerns raised by the sponsors, fosters positive program growth, removes opposition to the bill and can be supported by the professionals operating in this industry In the pages to follow, the OMCIA provides a list of measures (starting on page 7) the committee can consider that reflect the medical marijuana industry's best practices executed in other states and markets to truly increase the patient count and the program's success.

ITEMS FOR CONSIDERATION

IS PRICE REALLY THE ISSUE FOR PATIENTS AND STAND-ALONE PROCESSORS?

The price of medical marijuana has repeatedly been cited as a justification for a massive program expansion. Yet, Ohio's price for medical marijuana is currently $7.49[1] per gram (or $219 per ounce), significantly lower than the $17.00 per gram when the program started in 2019. This is also significantly less than current pricing of $11.53/gram[2] in Illinois' medical program and $10.95/gram[3] in Pennsylvania's.

[1] MMCP Program Update 1-16, 2022
[2] Illinois Medical Update 12-31-2022 ($14,255,331 in dry flower sales/1,235,762 grams of dry cannabis = $11.53)
[3] Pennsylvania Medical Marijuana Advisory Board Presentation November 2022, Slide 16

Even with very competitive pricing, Ohio's patients are not purchasing all the inventory Ohio's cultivators and processors are producing today, and vaults are full. In fact, many Ohio license holders are halting production lines, discounting prices and initiating layoffs. Ohio's program started in January 2019, only has 163,849 active patients and 5-year cumulative sales of $1.14 billion[4]. For comparison, Pennsylvania's medical marijuana program, which started selling product only nine months earlier in April 2018, currently has 423,443 active patients, cumulative sales in excess of $6.3 billion[5], and Pennsylvania's price per gram is $3.46 per gram MORE than Ohio's. **The price of medical marijuana is clearly not the problem with Ohio's program.**

The Price of Trim - Stand-Alone Processors: Processors purchase biomass called "trim" from cultivators to produce oil they use to make edibles, vapes, or topicals. To justify their need for cultivation licenses, a couple of stand-alone processors have claimed there is no trim available in the market or the price of trim is too high. Neither of these claims are true. It costs the typical cultivator between $500 - $800 to grow a pound of trim or plant material. At the beginning of the program the price of trim was over $2,000 per pound. Today, the price of trim is around $150 per pound due to a significant oversupply. Ohio cultivators are already losing money on trim sales. The OMCIA has surveyed a number of stand-alone processors who have been adamant that biomass is plentiful.

MASSIVE PROGRAM EXPANSION . . . WITHOUT PATIENTS:

Operational Cultivation Area: There are currently around 460,000 square feet of cultivation actively producing medical marijuana for Ohio's 163,849 active patients. That's the equivalent of 2.8 square feet per patient in today's market, and those patients aren't purchasing all the medical marijuana existing operators are producing. **Cultivator and processor vaults are full.** Today, many licensed cultivators are scaling back their production by 30% - 50% due to lack of demand. Despite this, there are 150,000 sf[6] of additional capacity entering the market starting in February '23, equating to an additional 33% increase over current market capacity.

MMCP rules already allow for two expansions of the existing cultivators, each equaling the same amount of square footage that was originally brought online. The Department of Commerce began accepting applications from operating cultivators to initiate the first round of expansion authorized in rule on October 1, 2021. At the time, Ohio's market appeared to be flourishing, and eager cultivators lined up to submit expansion requests (four Level 1 and eight Level 2 expansions have been submitted and approved). By the time this round of expansions is complete the program will reach 1.23 million square feet of licensed cultivation area.

At a rate of 2.8 square feet of cultivation area per patient, Ohio would need to add 276,865 active patients (for a total of 440,714 active patients) over the next two or three years to purchase close to the amount of medical marijuana produced by 1.23 million square feet of cultivation area. In 2022 Ohio only added 30,000 patients. At this rate, it will take nine years to add the required number of patients necessary to support the expansion levels already approved by the Department of Commerce.

Table 1: CURRENT MEDICAL MARIJUANA PROGRAM CULTIVATION AREA			
	ORIGINAL	EXPANSION 1	EXPANSION 2
Cultivation Area	617,000 sf	1,234,000 sf	1,851,000 sf
Minimum Patients @ 2.8sf/patient	220,357 active patients	440,714 active patients	660,714 active patients

[4] MMCP Program Update 1-16, 2022

[5] Pennsylvania Medical Marijuana Advisory Board Presentation November 2022, Slide 10

[6] These cultivators were awarded licenses under the 119 appeals process.

SB 9 proposes to more than double the maximum square footage currently allotted to Level 2 cultivators and also proposes to give them future preference for Level 1 (L1) licenses, which could result in 1.27 million[7] additional square feet if they are all approved. It also increases the maximum capacity of a L1 cultivator from 75,000 sf to 100,000 sf, adding 575,000 square feet to the program, which is also an unnecessary expansion. The bill also gives some stand-alone processors[8] a level 2 cultivation license and all Level 2 cultivators a processing license. In other words, SB 9 could potentially add around 2 million square feet of cultivation to the program. All of these moves further saturate an already oversupplied market.

Table 2: IMPACT OF SENATE BILL 9 ON CULTIVATION AREA				
	CURRENT MAX	**SB 9[9]**	**SB 9 (Preference)[10]**	**TOTAL PROGRAM**
Cultivation Area	1,851,000 sf	809,000 sf additional	1,440,000 sf additional	**4,100,000 total square feet**
Minimum Patients @ 2.8sf/patient	660,714 active patients	288,928 additional patients	514,285 additional patients	**1,463,927 total patients**

More Dispensary Licenses: SB 9 awards more than 60 additional dispensary licenses to cultivators (2 each for L1 and 1 each for L2). SB 9 anticipates that L1 cultivators won't object to all the cultivation expansion awarded to L2 cultivators and stand-alone processors if they are also awarded cultivation expansion and dispensary licenses. In 2021 the Board of Pharmacy received 1,463 applications from hopeful dispensary operators who, combined, invested tens of millions to apply for a chance to win one of 73 licenses to be awarded in a qualified lottery. Now SB 9 proposes to give 60+ licenses away yet requires that all future rounds must be competitive. While the OMCIA supports competitive licensing, we don't support the handouts proposed in SB 9.

Unfortunately, the original premise that the market is already oversaturated holds true. **More dispensary licenses and additional cultivation square footage does not create more purchasing patients.** With 163,849 patients and only 61 operating dispensaries, Ohio's medical marijuana market is experiencing a downturn characterized by layoffs and unsustainable price reductions. We are in a race to the bottom to stay open.

The 1 dispensary per 1,000 patients ratio proposed in SB 9 is not sustainable. Ohio's 61 dispensaries are struggling stay open with only 163,849 active patients (a ratio of 1 dispensary per 2,686 patients). An additional 73 are due to come online in Q1 of 2023, and SB 9 would add another 60 to that list this year. Compare these numbers to neighboring Pennsylvania, which has 171 operating dispensaries and 423,443 active patients (a dispensary to patient ratio of 1:2,476). It is clear that Ohio has plenty of retail licenses in the pipeline without adding the 60+ new licenses SB 9 proposes to award to cultivators.

Processing Licenses for Level 2 Cultivators: SB 9 also awards processing licenses to any Level 2 cultivator without a processing license, **taking a huge area of business away from stand-alone processors that rely on biomass produced by these cultivators or who have developed white-labeling agreements with**

[7] 1.27 million square feet is for current Leve 2 only, not including potential stand-alone processing L2 licenses

[8] Note: It is difficult to confirm the number of stand-alone processor cultivation licenses that will be awarded. SB 9 only awards these cultivation license to stand-alone processors who were operational before October 1, 2021, and originally applied for a cultivation license on the same property. We estimate this provision may apply to 3 or 4 companies.

[9] Assumes all L2 move to 20,000 sf (minus 9,000 original) and all L1 move to 100,000 sf (minus 75,000 original) and that four L2 licenses are awarded to stand-alone processors.

[10] Assumes all L2 (18 including stand-alone) take first preference for future L1 @ 100,000 sf minus the 20,000 sf in SB 9.

independent cultivators. There is no shortage of processors in Ohio's market. The MMCP originally issued processing licenses to 48 operators. Today 44 are operational, two are pending and two have been relinquished.

Additionally, it is important to note that cultivators are farmers, and processors are chemists. Processing marijuana biomass into medicine is a highly technical and potentially dangerous area of the medical marijuana industry that regularly involves the use of hazardous and explosive materials like supercritical (liquid) carbon dioxide, liquid nitrogen, and pressurized butane, propane, and other hydrocarbons. Equipment used by processors (specifically for hydrocarbon extraction) is strictly regulated by the State Fire Marshal and required to be housed in explosion proof Class 1, Division 1 (C1D1) facilities. This equipment should only be operated by trained, experienced technicians.

Expansion Should Be Based on Actual Market Data: Furthermore, we believe any discussion of License size and type should remain in rule, where the Department of Commerce can continue to make adjustments based on *actual* market data. The arbitrary expansion provisions in SB 9 are not based on supply/demand data or an actual need for additional cultivation space or new dispensaries. Real-time market data from the Department of Commerce demonstrates that, while new licenses continue to come online and existing licenses continue to expand, the amount of flower and trim sitting unsold in vaults has continued to grow.

Ohio can learn from the oversupply problems in states like Michigan, Colorado, Oregon, Massachusetts, and Washington where cultivators are growing on average three times more plant material than dispensaries are able to sell. Unprecedented low prices mask the problems in these programs as regulators work to investigate operators cutting corners out of desperation. In Oregon, the oversupply of legally grown marijuana regularly makes its way into the illicit market and across state borders. Michigan has the opposite problem, as their new lead regulator struggles to crack down on the illegal marijuana that is being mislabeled and sold by licensed dispensaries to lower their operating costs. All of these programs are also dealing with business failures, layoffs, and legal marijuana sold into the illicit market falling into the hands of minors.

COMPLICATING AN ALREADY OVERREGULATED PROGRAM:

Creating a New Commission:
The foundation of SB 261 was a universal desire to move regulatory authority over the medical marijuana program to the Department of Commerce. Such a move was intended to streamline operations with regulators familiar with the program who also understand regulating businesses, and to eliminate unnecessary bureaucracy. SB 9 eliminates the primary goal of the original bill by creating an independent commission comprised of 13 lifelong political appointees to regulate all areas of the program. Essentially, the bill restarts the program from scratch with 13 unknown regulators who wield unlimited power over the program. The Commission is exempted from evaluation of usefulness, performance or effectiveness (standard oversight for Commissions in Ohio), and the appointments expire at death, resignation or removal by the appointing authority. In other words, these political appointees wield complete regulatory power and autonomy. **Do we really need another layer of government in the Ohio medical marijuana program?**

ADDING TESTING STANDARDS:

SB 9 incorporates a testing standards amendment that was originally added into Senate Bill 261 at the last minute in a committee hearing without notice or discussion with the state licensed labs or the medical marijuana industry as a whole. Six of the seven then-licensed testing laboratories reviewed the amendment and developed an extensive position paper documenting the problems with the amendment and its impact on testing costs for licensed cultivators and processors. *A copy of the position paper is included at the end of this document.* With the inclusion of this language in SB 9, all eight licensed laboratories have sent a letter to the bill's co-sponsors opposing the inclusion of the language and proposing alternative language.

The OMCIA strongly opposes the inclusion of the lab standards outlined in lines 2161 – 2176 of SB 9 that will increase the cost of testing by $40M - $50M a year for the industry.

ADDRESSING THE PATIENT COUNT:

Who is Going to Buy All of The Marijuana SB 9 Wants Ohio to Grow? Companies that stand to benefit from SB 9's massive expansion are promising the legislature the bill will add a million patients to Ohio's program. **This will not happen.** The half-hearted measures included in the bill to increase patient counts are nothing more than window dressings with very little ability to materially impact the program's patient count:

1) **Allowing physicians to recommend for any condition won't add many new physicians or patients to the program:**
   - **Many physicians are prohibited from recommending:** Most of Ohio's major hospital systems prohibit their physician's from writing medical marijuana recommendations for fear of losing federal funding. Only around half of the program's 656 registered physicians are currently writing recommendations and this number will not increase. New York State added this provision to their program projecting a jump from 105,000 patients to over 700,000 patients. A year later, the patient count is still low, at 124,000.
   - **Ohio Already has Chronic Pain:** Physicians are already allowed to write recommendations for chronic pain, a broad category that can capture most conditions that are not on the list of 25.
   - **Fear of Reprimand:** The OMCIA supports allowing physicians to use their discretion to recommend medical marijuana. However, we feel this provision will most likely be used to recommend medical marijuana to patients with rare debilitating diseases similar to those already on the list of approved conditions for fear their professional license will be jeopardized or sanctioned by the state medical board.

2) **Only Two New Conditions are Added:** SB 9 adds opioid use disorder and autism to the program, along with codifying other conditions that have already been approved by the State Medical Board like terminal illness, spasticity/chronic muscle spasms, arthritis and migraines. In states where autism is an approved condition, it only accounts for a small percent of the patient population (0.1% - 2%). In New York, opioid abuse disorder accounts for a little over 5,000 patients.

3) **The Foreign Patient Database is Set-Up to Fail:**
   - The foreign patient database requires pre-registration, a hurdle that will inhibit most out-of-state patients from participating. At best, we would capture a small number of patients on vacation from other states with the foresight to register in the database.

- *Suggestion*: Remove the database from the proposal or allow for dispensaries to enroll patients upon arrival. Out-of-state patients with a driver's license and a medical marijuana card issued by another state should be allowed to walk into any Ohio dispensary and purchase medical marijuana.
- *Expand this opportunity*: The language should be changed to allow qualifying patients in states without a medical marijuana program to participate in Ohio's program. For example, the Governor of Kentucky, which does not have a program, recently issued an executive order[11] allowing patients with one of 21 qualifying conditions to possess up to 8 ounces of marijuana with a letter from a physician and a receipt proving the product was legally purchased. Ohio's dispensaries could be serving these patients with minor revisions to the foreign patient registry language.

4) **Allowing Medical Directors to Recommend:** Physicians serving on medical marijuana company advisory boards are currently prohibited from recommending marijuana. SB 9 allows them to recommend. While this provision may add a few doctors, we don't anticipate a large jump in the patient count since most of these physicians already have medical practices or are affiliated with major hospital systems.

RECOMMENDATIONS

How Do We Increase Ohio's Patient Count?

If the Senate truly wants to expand access for patients, you should consider the price to enroll in the program and execute changes that may help to retain active patients, attract patients who have let their registrations lapse, and add new patients. To date 301,973 patients have registered for the MMCP and purchased medical marijuana from a dispensary at some point since January 2019. Only 163,849 of those patients still have an active card and can purchase medical marijuana today.

Patients are leaving the MMCP for a variety of reasons, including:

- Rampant availability of cheap intoxicating hemp derived products, like Delta-8 THC, which are readily available in gas stations, convenience stores and specialty shops across the state without any age restrictions;
- Fear of losing their jobs when they find out a patient card does not protect them from termination after a drug test;
- Fear of losing their right to purchase a firearm;
- The cost to renew a medical marijuana card is expensive (around $200 per year);
- Frustration with overly restrictive rules, arbitrary purchasing limits, and the perception they are being "shorted" because Ohio created its own daily increments that force operators to partially fill containers;

[11] Governor Beshear Executive Order Regarding Cannabis

- Access to lower priced adult use marijuana in bordering states;
- Ohio prohibits smoking, the least expensive form of marijuana consumption.

The OMCIA has developed a list of recommendations to increase Ohio's patient count. **These are changes the program needs to make today just to support the current plan outlined under OAC 3796, not including any of the expansion proposed by SB 9.**

1) Creating a category for patients with "life-long" conditions that are exempted from costly annual physician visits (like Illinois),
2) Replacing annual physician visits for other patients with visits once every three years (like Illinois),
3) Eliminating the $50 patient/$25 caregiver registration fee,
4) Adding anxiety, depression, and chronic insomnia as approved conditions,
5) Give medical marijuana patients equal rights afforded to patients with opioid prescriptions under the Americans with Disabilities Act,
6) Consider removing the prohibition on smoking due to the high cost/complexity of using vaporizers,
7) Expanding the Foreign Patient Registry to include patients in states without medical marijuana programs,
8) Prohibiting the sale of hemp-derived Delta-8 THC, Delta-9 THC, Delta-10 THC and other intoxicating cannabinoids in the unregulated market,
9) Eliminating state and local sales taxes on medical marijuana,
10) Exempting medical marijuana businesses and owners from state 280E taxes

SUGGESTIONS:

(1) Add "Lifelong Conditions": Patients pay, on average, $200 per year to participate in the MMCP before purchasing any medical marijuana ($150 to a recommending physician and $50 to the Board of Pharmacy for a card). Like Illinois, Ohio could allow patients suffering from incurable conditions like AIDS, Crohn's disease, Alzheimer's, Huntington's, etc. to visit a recommending physician only one time for a lifelong approval. These patients don't need to pay a recommending physician $150 per year and the state $50 per year to confirm they still have an incurable lifelong condition. We recommend the following language:

After line 1069, add " 'Life-long condition' means any qualifying medical condition that is incurable."

After line 2404, add "(3) A written recommendation issued to a patient for treating a life-long condition is valid for the patient's lifetime and does not expire."

In Line 2338, after "Revised Code," add "life-long condition,"

(2) Change Annual Physician Visits to Every Three Years:

Illinois also allows all patients (other than those enrolled under the "life-long" category) to renew their registration once every three years, significantly reducing the cost to participate in the program. To achieve this goal we recommend adding the following language:

In line 2399 strike "ninety days" and replace with "three years".

Strike lines 2400 – 2404.

In Line 2405 strike "Annually," and replace with "Every three years".

In line 2408 add "s" to the word "year".

(3) Eliminate the Annual Program Registration Fee: The bill should prohibit the Medical Marijuana Control Program from charging an annual fee to register a patient. The Board of Pharmacy currently charges patients $50 per year and caregivers $25 per year to register with the program. As of October 9, 2022, the MMCP is carrying an estimated cash balance of $39,259,000 and the loss of the revenue generated by patient and caregiver fees would not impact the operation of the program.

In Line 1349 , after "cards" strike ";" and add "for which the Division may not assess a fee.

(4) Adding specific diseases to the list of qualifying conditions may increase patient counts: The OMCIA supports the language allowing the physician to recommend at their discretion, although we feel this provision is most likely to add a small number of patients with very rare conditions to the program, where the physician feels they need to cautiously exercise their discretion. To capture larger groups of patients the program should cast a wider net by expressly including common conditions like anxiety, depression, and chronic insomnia. Like autism and opioid use disorder, the efficacy of medical marijuana for patients with anxiety, depression and chronic insomnia has been supported by medical evidence but the State Medical Board has repeatedly denied petitions to add them to the program.

While these conditions could add a good number of patients to the program, expectations must be tempered to align with the realistic adoption rate for a medical marijuana program. For example, Post Traumatic Stress Disorder (PTSD) is the second most common condition in the MMCP with 20,203 registered patients (total PTSD recommendations since 2019) according to the most recent Board of Pharmacy Director's Report[12]. According to the US Department of Veteran Affairs, PTSD affects 6% of the national adult population[13] (or approximately 507,888 people in Ohio's 8,464,801 adult population). The adoption rate of Ohio's population with PTSD registered with the medical marijuana program is around 4% of those who are eligible. Apply this adoption rate to new specific conditions like depression (22% of the national population[14]) and 74,490 new patients would enroll. For anxiety (31.1%[15] of the national population) a similar 4% adoption rate would add another 105,302 patients, and for chronic insomnia (10% - 15%[16] of the national population) a similar adoption rate would add another 50,788 patients. At that point, Ohio would be getting closer to the number of patients we need to support the first round of expansion the Department of Commerce has already approved in rule (L1 go to 50,000 sf and L2 go to 6,000 square feet). **These numbers are only projections and not a guarantee of the actual adoption rate.**

After Line 1103 add "depression, anxiety and chronic insomnia."

[12] January 2023 Board of Pharmacy Executive Director's Report page 5, data from November 2022.
[13] US Department of Veteran Affairs
[14] WKYC "Depression in Ohio Higher than National"
[15] National Institute of Mental Health, Any Anxiety Disorders
[16] Cleveland Clinic Chronic Insomnia Statistic

(5) **Protect Patients from Termination of Employment or Housing:** Many patients enroll in the MMCP to find out afterwards that they are not protected from termination by their employer if they test positive for marijuana and legitimately have a medical marijuana card. Yet, in Ohio, medical marijuana is a Schedule 2 drug like oxycodone, hydromorphone, methadone, codeine and hydrocodone and patients should be afforded equal protections. The legislature has previously offered no like protections for Ohioans who are medical marijuana patients, and SB 9 moves further in this direction by specifically exempting public and private payers operating in Ohio from ever having to cover healthcare expenses related to medical marijuana. Similarly, the legislature has also not afforded any protections from eviction for those Ohioans who rely on medical marijuana.

(6) **Consider Allowing Patients to Smoke Medical Marijuana:** The OMCIA understands and respects Senator Huffman and Senator Schuring's objections to smoking medical marijuana. We ask you to consider the issue from a different angle. Smoking medical marijuana is common because it is the most effective, simplest, least expensive form of marijuana used in any market. Ohio's law requires patients to "vaporize" plant material, adding significantly to the cost of a simple product that should be inexpensive. Vaporizing plant material requires the purchase of expensive equipment capable of heating to the point it vaporizes cannabinoids without combusting the plant material. Many patients can't afford these expensive devices and risk having their medical marijuana card revoked if they smoke the product to cut costs. The equipment is also complicated and confusing for many older patients who struggle to use the device correctly and quickly become frustrated.

(7) **Expand the Foreign Patient Registry**: The OMCIA supports SB 9's addition of a Foreign Patient Registry, with a couple minor changes. First, a patient that has a medical card from another state should be allowed to be added to the registry by a dispensary, rather than pre-registering. Second, the language should be changed to allow qualifying patients in states without a medical marijuana program to participate in Ohio's program. These patients should be allowed to apply for a medical marijuana card in Ohio to ensure they truly meet our program's requirements. The Governor of Kentucky, which does not have a program, recently issued an executive order[17] allowing patients with one of 21 qualifying conditions to possess up to 8 ounces of marijuana with a letter from a physician and a receipt proving the product was legally purchased. Ohio's dispensaries could be serving these patients with minor revisions to the foreign patient registry language.

(8) **Restrict the Sale of Intoxicating Hemp Derived Cannabinoids to the Regulated Market:** Members of the committee may have noticed neon signs hanging in windows in shopping centers, convenience stores and gas stations across the state advertising "We Sell Delta-8" and "No Medical Card Needed." Delta 8 THC and many other synthetic derivatives of hemp are intoxicating like marijuana. However, because they are derived from "hemp" these products are being sold across the country in states that have taken no action to regulate them due to a loophole that has been exploited in the 2018 federal Farm Bill. These products are not tested and often include dangerous contaminants such as lead, heavy metals, chemicals and pesticides. They also aren't subject to age restrictions. Children can legally walk into a store and purchase, without showing any identification, a Delta-8 THC vape cartridge that will get them high. The longer the legislature takes to address this issue, the more opportunities there are for the market to exploit it. There are

[17] Governor Beshear Executive Order Regarding Cannabis

currently new, hemp-derived, synthetic cannabinoids being legally sold in Ohio that are 30 to 40 times as potent as the main psychoactive ingredients in medical marijuana.

Regardless of the impact on the medical marijuana program, these products need to be regulated by the state similar to medical marijuana, alcohol or prescriptions drugs; but they are not.

The topic is relevant to this discussion because, for many patients, Delta-8 THC is a comparable alternative to medical marijuana (Delta-9 THC). Why would someone spend $200 annually to register with the medical marijuana program and subject their purchases to tracking in the state's prescription monitoring program (OARRS) when they can legally purchase highly intoxicating Delta-8 THC and other synthetic cannabinoid products at their local convenience store?

Again, states are being tasked with picking up the pieces where the federal government has failed to act. At least **22 states** have enacted legislation or regulations, or issued legal opinions over licensed hemp producers engaging in the manufacture or sale of intoxicating THC products. Many have banned the sale of Delta 8 and other hemp derived synthetic cannabinoids in the open market, relegating it to the regulatory oversight and testing of the state's medical marijuana control program. *Attached you will find a comprehensive document on the topic developed by the US Cannabis Council (Attachment 2).*

(9) Remove the Sales Tax of Medical Marijuana: Ohio's dispensaries are charging patients state sales tax on every purchase of medical marijuana. In his sponsor testimony before the Senate General Government Committee Senator Steve Huffman said *"The Ohio Constitution is quite clear, we can't tax medication."* Yet, Ohio does tax medical marijuana at the traditional sales tax rate of 5.75% plus any local or county sales tax (in some communities 2%). Medical marijuana should be taxed like any other schedule 2 medication in Ohio – at 0%.

(10) Business Costs are Patient Costs - State 280E Tax Relief: A very simple legislative fix to Ohio statute can create a subtraction for "ordinary and necessary business expenses" that are non-deductible under federal tax law for medical operators -- thus allowing licensed marijuana companies to take standard business deductions on things like payroll, employee benefits, construction costs, building rent and maintenance, and utilities as a tax deduction in computing state income taxes. This punitive tax structure inhibits Ohio medical operators from reinvesting into the state just like any normal business would, hampering job growth and infrastructure investment. It also contributes to the cost of medicine patients rely on.

This current tax penalty applied to medical marijuana businesses under federal law, which is compounded[18] in states like Ohio, results in an income tax bill that is often larger than a licensee's operating cash flow. As a result, most licensees operate at an after-tax deficit and require continual cash infusions to keep doors open, despite operating at a pre-tax profit. The growth, and even continued existence, of the industry is unsustainable without a tax system that allows ordinary and necessary business expense deductions.

[18] Currently, Ohio calculates its state corporate income tax starting with the company's federal taxable income, which incorporates the 280E federal tax penalty after standard ordinary and necessary business deductions have been disallowed.

Unfortunately, until the federal government reschedules medical marijuana there is nothing the state of Ohio can do to relieve the larger federal 280E tax burden.

However, Many states have changed their statutes to shield licensed medical marijuana operators from the state share of 280E taxes.

Add to: Ohio Revised Code 5747.01 Income Tax Definitions (A) Adjusted gross income . . .

(36) For taxable years commencing on or after December 31, 2021, deduct;

(i) the amount of ordinary and necessary expenses paid or incurred during the taxable year in carrying on a trade or a business as a medical marijuana cultivator, processor, dispensary, laboratory, or any other marijuana establishment licensed by the state, if the deduction for ordinary and necessary expenses is disallowed under section 280E of the internal revenue code.

(ii) the deduction allowed under paragraph (i) of this subsection includes a reasonable allowance for salaries or other compensation for personal services actually rendered during the taxable year.

These are changes the program needs to make today to support the current plan outlined under OAC 3796 (Table 1 on page 4), not including any of the expansion proposed by SB 9.

Chairman Rulli, we understand that this is a comprehensive memorandum, but these are the issues that our members have identified as changes that would positively improve the medical marijuana program, support our patients, and respect the corrective nature of the effort we began nearly two years ago. Our Association stands ready to discuss these issues and work with you to achieve these goals.

Please do not hesitate to contact me with any questions.

Matt Close
Executive Director

ATTACHMENT 1

Letter from State Licensed Labs

December 2, 2022

The Honorable Shane Wilkin
Chair, House Government Oversight Committee
77 South High Street, 13th Floor
Columbus, Ohio 43215

Re: SB261 AM_134_3736

Chairman Wilkin and Members of the House Government Oversight Committee,

On November 17, 2022 the House Government Oversight Committee accepted an amendment to Senate Bill 261 intended to ensure the integrity of medical marijuana testing in the Ohio Medical Marijuana Control Program (MMCP). Unfortunately, the Committee accepted this highly scientific amendment without hearing any testimony from individuals familiar with the standards, individuals familiar with testing cannabis, or the licensed testing laboratories that will be tasked with implementing these standards in the MMCP.

After learning of the adoption of the amendment, representatives from Ohio's licensed laboratories ACT Laboratories, CP Labs Ohio, North Coast Testing Laboratories, Pinnacle Testing and Specialty Lab, Midway Labs and Priority Labs (all signatories to this letter) conducted a collaborative review of the specific standards prescribed by this amendment.

As a result of that review, the undersigned have concluded that this amendment will:

- Severely diminish reliability of labeled THC potency values on medical marijuana products, potentially leading to inaccurate patient dosing.
- Increase testing costs by 300 - 500%.
- Increase the cost of medical marijuana for patients, due to added test costs.
- Double the time to provide results to cultivators and processors, therefore increasing carrying/inventory costs.
- Require labs to invest millions of dollars in unnecessary and redundant equipment and associated costs.
- Require each lab to adhere to conflicting testing standards and requirements.
- Impose undue regulatory burdens and costs on cannabis testing laboratories without adding value to the quality or integrity of laboratory test results.

While we support the Committee's efforts to improve the uniformity of test results across licensed marijuana testing facilities, we feel this amendment fails to address the issue it is intended to fix. We would like to take this opportunity to offer alternate suggestions, which we believe will achieve the goal of ensuring the integrity of Ohio's medical marijuana testing process without increasing the cost of testing or the price of medical marijuana for patients.

Recommendation #1: Expand Proficiency Testing within the MMCP

Rather than mandate a list of contradictory standards that do not address the committee's concerns regarding the accuracy of medical marijuana potency results, the committee could require proficiency testing in statute.

The Department of Commerce has already implemented many accountability measures and subjected operational labs to multiple types of proficiency testing to determine the uniformity of test results. The use of testing lab accountability measures in the MMCP was highlighted in multiple public presentations to the Medical Marijuana Advisory Committee since 2020 and includes the use of various approaches to proficiency testing including mandatory blind testing and voluntary testing through third party administrators.

Proficiency testing typically includes portioning a representative sample of medical marijuana among the laboratories for testing. The Department of Commerce, through its new Division of Medical Marijuana Control ("the division"), would review test results in the state's tracking system, comparing the results across labs to ensure the licensed laboratories are testing products consistently by establishing an acceptable margin of error between labs. We recommend using multiple methods of proficiency testing, including a form of blind testing in which laboratories would not be aware of the intentions of these samples.

Laboratories are required to be accredited to the ISO 17025 standard as a condition of licensure. This adds an additional requirement for all licensed laboratories to participate in proficiency testing, in which labs receive blind samples and are required to report results for verification of accuracy.

Recommendation #2: The Division of Marijuana Control Should be Responsible for Identifying a Uniform System of Standards

As the agency tasked with regulating the MMCP, the Department of Commerce has the most knowledge and experience related to testing standards for medical marijuana. The division should be responsible for identifying the universal standards for testing laboratories that can be implemented without increasing testing costs while allowing for nimble adjustment when newer, better approaches to cannabis testing are established.

The amendment identifies a mixed list of testing standards between two organizations, the American Society of Testing & Materials (ASTM) and the Association of Official Analytical Collaboration International (AOAC), resulting in redundant, contradictory and sometimes inapplicable requirements. Generally, these testing standards are scientifically inferior to testing methods that have been optimized and are currently used in licensed Ohio laboratories.

The amendment locks into statute the use of already outdated standards (for example: ASTM D8196-18 has already been replaced by ASTM D8196-22) and nonapplicable standards, like AOAC SMPR 2019.003, which is specific to low-THC hemp that is not typically grown in the medical marijuana program.

The amendment requires testing for THC using not one but *three* different methods, one of which (ASTM 8375-22) would require every laboratory to purchase at least one additional instrument that could cost around $500,000 and which only achieves accuracy of 90.9%, as stated in ASTM 8375-22 itself (specifically, see Table 10). This is significantly lower accuracy than universally achieved on current instrumentation used by every testing laboratory in Ohio (High Pressure Liquid Chromatography, abbreviated HPLC; at a minimum of 97%), and commonly accepted as the industry standard across the United States.

We caution the committee that requiring a method that can only achieve 90.9% accuracy by definition means underreporting the concentrations of THC – introducing a new and significant risk to Ohio's

medical marijuana patients, who very likely would unknowingly and unintentionally consume significantly greater amounts of THC than stated on the label.

Finally, it is important to remember that we collectively operate in a high volume "production" environment. On top of being more expensive and less accurate than current equipment, this new piece of equipment is also much slower, and labs may be forced to purchase one or more units in order to meet demand.

Likely Impact of the Amendment

In addition to requiring testing labs to outlay millions of dollars to purchase new equipment, the ongoing unnecessary costs include regular maintenance of equipment and the hiring of additional staff including a chemist with specialized experience to operate and maintain the new equipment.

We project that these expenses have the potential to cause some licensed testing laboratories to withdraw from the industry if they are not able to afford to hire additional staff or purchase new equipment. The MMCP recently approved Certificates of Operation for multiple new labs. It is highly concerning that these labs would have to re-outfit their facilities and revalidate all of their methods, only months after receiving their Certificates of Operation.

Additionally, to meet these significant financial and operational burdens, these costs will be passed along to cultivators and processors, along with the cost to perform repetitive and unnecessary tests prescribed by the amendment. We estimate the cost of regular compliance testing for cultivators and processors will increase by potentially three to five times[1]. Inevitably, these costs will be passed on to patients, significantly increasing the price of medical marijuana products at Ohio's dispensaries. In summary, these proposed changes do not materially improve the overall accuracy and reliability of the testing results generated within Ohio which is a goal that we all share, ensuring patient safety.

Conclusion

On behalf of Ohio's licensed medical marijuana testing laboratories, ACT Laboratories, CP Labs, North Coast Testing Laboratories, Pinnacle Testing and Specialty Lab, Midway Labs and Priority Labs, we ask you to remove this amendment from SB 261. We are very willing to partner with you to ensure we develop a robust, cost-effective program within the state while ensuring patient and product safety. We are available to answer questions and provide any supplemental information that the Committee may find helpful.

Sincerely,

North Coast Testing Laboratories
Ryan Randolph, Scientific Director

CP Labs
Scott Jared, CEO

ACT Laboratories
Dr. Robert Miller, COO/Chief Scientific Officer

Midway Labs
Amber Lindsay, Scientific Director

Priority Labs
Gregg Hasman Jr., Laboratory Director/Chief Science Officer

Pinnacle Testing & Specialty Lab
Dr. Jean Boutros, Laboratory Director

[1] Estimate includes additional laboratory overhead comprised of equipment costs (one or multiple units), supplies, consumables, floor space, rent and lease-hold improvements, and additional staffing (from 1 - 5 staff members depending on lab throughput), as well as the cost to run additional redundant tests beyond those currently required in rule, and the cost to inventory larger samples on-site.

ADDENDUM - SUPPORTING INFORMATION

The standards prescribed in the amendment can generally be organized into 3 primary categories: 1) Standard Methods of Analysis, 2) Method Validation Performance Requirements, and 3) Standard Policies for Laboratory Operations. The following paragraphs discuss the specific standards within each of these categories and provide consensus opinions from participating laboratories regarding the anticipated impacts on testing laboratory operations, as well as the broader medical marijuana industry in Ohio.

Standard Methods of Analysis

The amendment specifies six standard methods of analysis. Three of which relate to testing for cannabinoid potency, while the others relate to pesticides, water activity and heavy metals testing.

Cannabinoid Potency Standard Methods:

Methods for cannabinoid potency include ASTM D8375-22, AOAC OMA 2018.10 and AOAC OMA 2018.11. None of these methods are applicable to cannabinoid determinations in the wide variety of infused products frequently submitted for cannabinoid potency testing. All three methods would significantly increase operational costs compared to existing validated methodologies; none more so than ASTM D8375-22, which requires use of advanced instrumentation that costs nearly $500,000 per system. That compares to $80k - $90k for the type of instrumentation currently in use at all licensed labs in Ohio, and which is widely accepted among cannabis testing laboratories as the most effective tool for this test. **All participating laboratories agree that implementation of these methods, at significant cost in terms of both capital expense and operating costs, would diminish reliability of potency test results due to inferior performance in terms of both accuracy and precision.**

Pesticides: ASTM D8399-22:

This method only applies to plant material and cannot be used for the wide variety of cannabis concentrates and infused products that must be screened for pesticide contamination. **Thus, testing laboratories would be forced to maintain multiple analytical workflows with different methods in order to provide comprehensive pesticide testing for all applicable products.**

Water Activity: ASTM D8196-18:

This is a simple method which generally reflects current methodology in place at participating laboratories. **We have no objections to implementation of this standard method for water activity.**

Heavy Metals, AOAC OMA 2021.03:

This method is generally recognized by all participating laboratories as inferior to proprietary methodology currently in use at each laboratory. It should be noted that the method lacks specific step-by-step procedures, which would allow for significant variations in how the method is applied in each laboratory, and in this regard, does not achieve the stated goal of uniformity among testing labs. **Although the method has been endorsed by AOAC, validation results are not available to allow evaluation of the method's performance characteristics.**

Method Validation Performance Requirements

Rather than specifying the exact procedure for a particular test, method validation performance requirements establish acceptance criteria for important characteristics of analytical method performance, such as accuracy, precision, dynamic range, sensitivity, and specificity. Standardizing method performance requirements rather than prescribing standard methods of analysis encourages innovation to develop more effective and efficient proprietary methodologies while maintaining uniform quality criteria across the industry. Ultimately, competition on this basis reduces costs and improves quality of service to the industry.

AOAC has established several Standard Method Performance (SMPR) documents related to test methods for the cannabis industry. Three of those were specifically identified in this proposed amendment to SB261.

Aspergillus, AOAC SMPR 2019.001:

While Ohio currently does not require *Aspergillus* testing, it is assumed that this SMPR is referenced in anticipation of future mandatory testing for *Aspergillus.* It is important to recognize that AOAC SMPRs for microbiological methods are developed with the intention of being applicable to manufacturers who develop test kits, which are then purchased and used by testing laboratories to complete those tests. **Thus, any regulatory requirement for testing laboratories to comply with this SMPR should allow for use of methods which have been validated by test kit manufacturers rather than by the testing laboratories themselves**.

Residual Solvents, AOAC SMPR 2019.002:

This SMPR includes method performance criteria for recovery that become increasingly narrow at higher analyte concentrations. **The consensus among laboratories is that these criteria are not realistically achievable by any known methodology.** Thus, any regulatory implementation of this SMPR should allow for considerable flexibility, allowing laboratories to use methodologies which may not meet the listed criteria. In fact, it is not uncommon for AOAC to designate Official Methods of Analysis (OMAs) which also fail to meet all the criteria listed in the respective SMPRs. OMA 2018.10, which is listed in this amendment, is one such example where the validation results did not meet all requirements listed in the applicable SMPR, 2017.002.

Cannabinoid potency, AOAC SMPR 2019.003:

This SMPR is written specifically for low-THC varieties of cannabis (e.g. hemp). **Thus, it is not applicable to the majority of THC-dominant products produced and sold within the Ohio Medical Marijuana program.** We recommend elimination of SMPR 2019.003 in deference to more appropriate SMPRs: 2017.001 for cannabis concentrates, 2017.002 for dried plant materials, 2017.019 for infused chocolate, and 2022.001 for infused beverages.

Laboratory Policies

The proposed amendment to SB261 includes reference to three ASTM standards for laboratory operational policies. These include D8222-21a, D8244-21a, and D8334/D8334M-20.

Quality Management Systems, ASTM D8222-21a:

This standard specifies particular elements of Quality Management Systems (QMS) as they relate to production of Cannabis/Hemp products for consumer use. Importantly, this document was not developed for use in laboratory operations. Nonetheless, there are several concepts presented in this standard which are consistent with requirements already established for laboratory accreditation under ISO 17025. **Since all licensed marijuana testing laboratories are already required to meet ISO 17025 accreditation as a condition of licensure, mandatory compliance with this standard would be redundant to existing requirements.**

Laboratory Operations, ASTM D8244-21a:

The recommendations outlined in this standard are well-aligned with existing practices for ISO 17025. Compliance with this standard may imply compliance with several additional ASTM standards referenced therein. These include:

- D8229-19 - Guide for Corrective and Preventive Action for the Cannabis Industry

- D8245-19 – Guide for Disposal of Resin-Containing Cannabis Raw Materials and Downstream Products
- D8282-19 – Practice for Laboratory Test Method Validation and Method Development
- D8334M-20 – Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analysis

The requirements of this standard, and the additional standards referenced therein, are essentially redundant to requirements already in place for ISO 17025 accreditation. Therefore, this will force testing laboratories to undergo a significant amount of additional administrative work to ensure compliance with a significant expansion of regulatory requirements, without providing additional value in terms of improving quality and integrity of laboratory testing results.

Sampling: ASTM D8334/D8334M-20:

Adherence to this standard would add substantial time to sampling events in terms of non-value documentation and collection of excessive material, will increase the costs of transportation and sample storage, and will increase the amount of product collected without scientific benefit relative to current practices.

Summary Table

Standard	Description	Position	Comments
Standard Methods of Analysis			
ASTM D8375-22	LC-MS/MS based method for cannabinoid potency	Opposed	● Requires multi-million dollar capital investment by labs ● Estimated cost increase up to 5X over current methodology ● Diminished accuracy and precision of results
AOAC OMA 2018.10	Cannabinoid potency in flower and oils	Opposed	● Not validated for >25% potency in flower ● Cannot measure >5% potency in oils ● Not applicable to infused products ● >2 fold increase in run time cuts lab capacity in half
AOAC OMA 2018.11	Cannabinoid potency in dried plant materials, concentrates and oils	Opposed	● Exceedingly complex sample prep scheme will: ○ require significant staffing increase ○ increase frequency of lab errors ● Uses ethanol for extraction solvent: excise taxes will increase cost significantly
ASTM D8399-22	Pesticides in dried cannabis/hemp	Opposed	● Not applicable to concentrates and infused products, additional methods would be required for all sample types
ASTM D8196-18	Water Activity	Acceptable	● This method is consistent with water activity methods already in use
AOAC OMA 2021.03	Heavy Metals	Opposed	● Inferior to existing methodology in terms of method performance characteristics ● Non-specific methodology allows significant flexibility for interpretation
Method Validation Performance Requirements			
SMPR 2019.001	*Aspergillus*	Conditionally acceptable	● Not intended for method validation in testing labs. SMPRs for microbiological methods are intended for test kit manufacturers
SMPR 2019.002	Residual Solvents	Opposed	● Method performance criteria for recovery not achievable by any known methodology
SMPR 2019.003	Cannabinoid potency in hemp	Opposed	● Not applicable to the majority of products in the OH Medical Marijuana market, which are THC-dominant
Laboratory Operational Policies			
ASTM D8222-21a	Quality Management Systems (QMS)	Opposed	● Intended for "…activities associated with processing, packaging, labeling, quality control, and distribution." ● Duplicative of ISO standards already in place
ASTM D8244-21a	Lab Operations	Opposed	● Compliance with this standard may imply compliance with several other standards referenced therein, including: D8229-19, D8245-19, D8282-19 and D8334M-20. ● Most requirements within this standard are already required for ISO 17025 accreditation

Standard	Description	Position	Comments
ASTM D8334/ D8334M-20	Sampling Plan for Cannabis/hemp	Opposed	• Requires collection of 3X the amount of sample needed for testing. Will increase cost to producers (product lost) and labs who will have to provide additional space to store test samples • Excessive/redundant documentation requirements will significantly impede sampling process without adding value to sampling event records

ATTACHMENT 1

US Cannabis Council White Paper on Delta-8 THC

Delta-8 THC Table of Contents

US CANNABIS COUNCIL

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 adenyl 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 (THCA x .8777 + THC Delta 9 = 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.

US CANNABIS COUNCIL

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.

US CANNABIS COUNCIL

Delta-8 THC Independent Test Results

Background

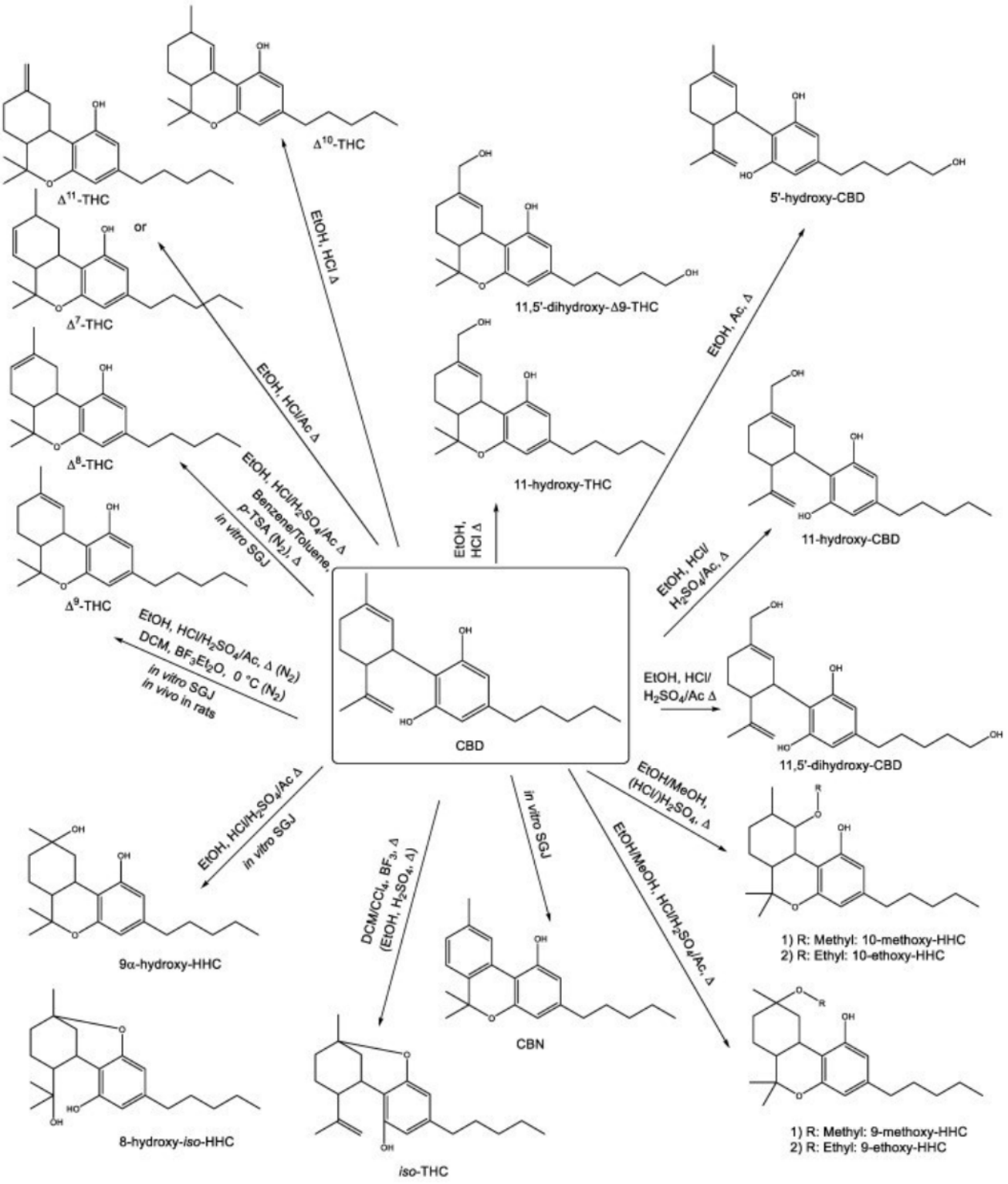
The legal hemp industry has been coexisting with the regulated cannabis industry for a number of years on a state-by-state basis. However, the passing of the 2018 Farm Bill by the USDA accelerated the entry of new hemp cultivators, processors, manufacturers, and retailers eager to profit off the newly 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 that 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.

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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	MoonWlkr	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	DABS 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 #	Tes tDate	Brand	Product	State	Matrix	Al	As	Ca	Cd	Cr	Cu	Fe	Hg	K	Mg	Mn	Mo	Ni	P	Pb	S	Sn	Zn	Zr
94183	4/30/2021	High Life	Gorilla Glue	MA	Vape Oil	0.182	0	9.011	0	0.404	0.455	4.085	0	3.479	0	0	0	0.593	8.201	0	4.384	0	0.068	0.007
94184	4/30/2021	3CHI	Caribbean Dream	IN	Vape Oil	0.128	0	7.849	0	0	0.554	0.883	0	2.396	0	0	0	0.14	6.966	0	2.864	0	0.141	0.017
94185	4/30/2021	Organic CBD Nugs	Grape Ape	TX	Vape Oil	0.226	0	5.819	0	0	4.973	1.725	0	3.052	0	0	0	1.409	5.042	0.342	3.253	0	5.334	0.005
94186	4/30/2021	EightySix	Blue Dream	CA	Vape Oil	158.77	0	6.011	0	0.099	0.358	5.704	0	2.292	0	0	0	0.465	3.331	0	7.067	0	0	0.434
94187	4/30/2021	Chill Plus	Pineapple Express	FL	Vape Oil	2.018	0	6.74	0	0	2.321	2.641	0	2.438	0	2.616	0	1.353	4.395	0.303	3.373	0	2.146	0.036
94188	4/30/2021	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	1.64	0.324	3.84	0.91	51.578	0.006
94189	4/30/2021	Treetop Hemp Co	Skywalker OG	CA	Vape Oil	0	0	6.339	0	0.072	3.187	2.18	0	2.574	0	0	0	0.895	2.946	0.076	4.326	0	3.196	0.03
94190	5/6/2021	MoonWlkr	Strawberry Gelato	NV	Vape Oil	0.438	0	1.919	0	1.419	0	5.044	0	0	0.677	0.124	190.729	0.884	0	0	1.345	0	0.39	0.022
94191	5/6/2021	VIIA	Lemon Diesel	CA	Vape Oil	0.17	0	0	0	0	0	0.575	0	0.835	0.303	0	357.248	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	10.979	0	17.362	2.753	0.244	803.303	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	0.692	0.115	0.007
94301	5/7/2021	Urb Delta8	DABS 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	0.234	0.007
94302	5/7/2021	Moon Men	Delta8 Shatter	FL	Vape Oil	0.547	0	9.863	0	0	0.971	6.418	0	6.488	1.28	0	10.662	0	3.472	0	0	0	0.345	0.056
94303	5/7/2021	Privada RUNTZ	RUNTZ Delta8 DAB DART	??	Vape Oil	0.735	0	9.457	0	0	0.086	0.629	0	6.922	1.581	0	12.517	0	4.147	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	0.836	0	3.681	1.127	0	21.936	0	5.386	0	0	0.557	0.183	0.021
94305	5/7/2021	Palm Treez	Delta8 Disidos	FL	Vape Oil	0.447	0	3.2	0	0	0.788	1.435	0	10.934	2.383	0	5.873	0.363	1.991	0	0	0	0.359	0.039
					USP Limit	-	0.2	-	0.2	0.3	3	-	0.3	-	-	-	-	0.5	-	0.5	-	6	-	-

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	MoonWlkr	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	1.32	0	0	0	0	0	0	1.13	0	0	0	0	0	0	0	0
94301	5/10/2021	Urb Delta8	DABS 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

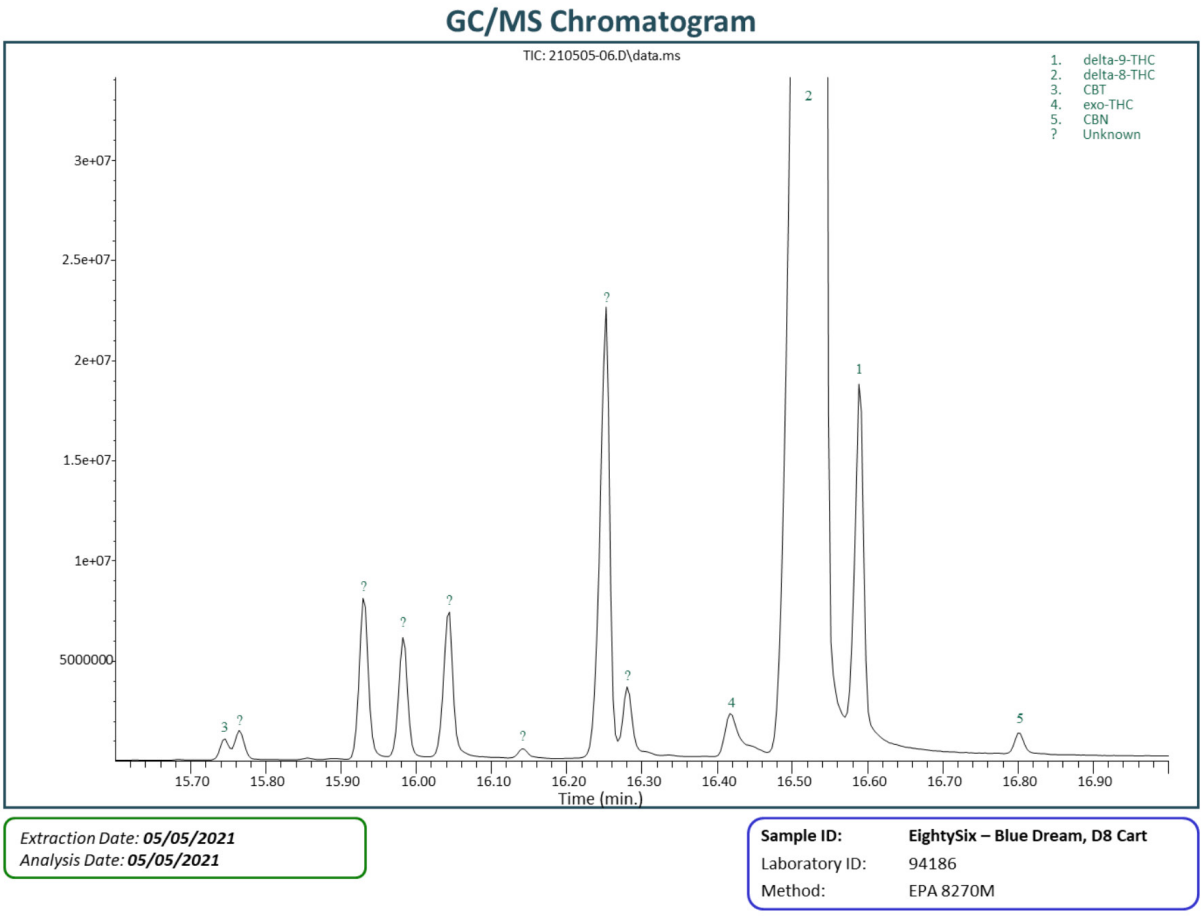
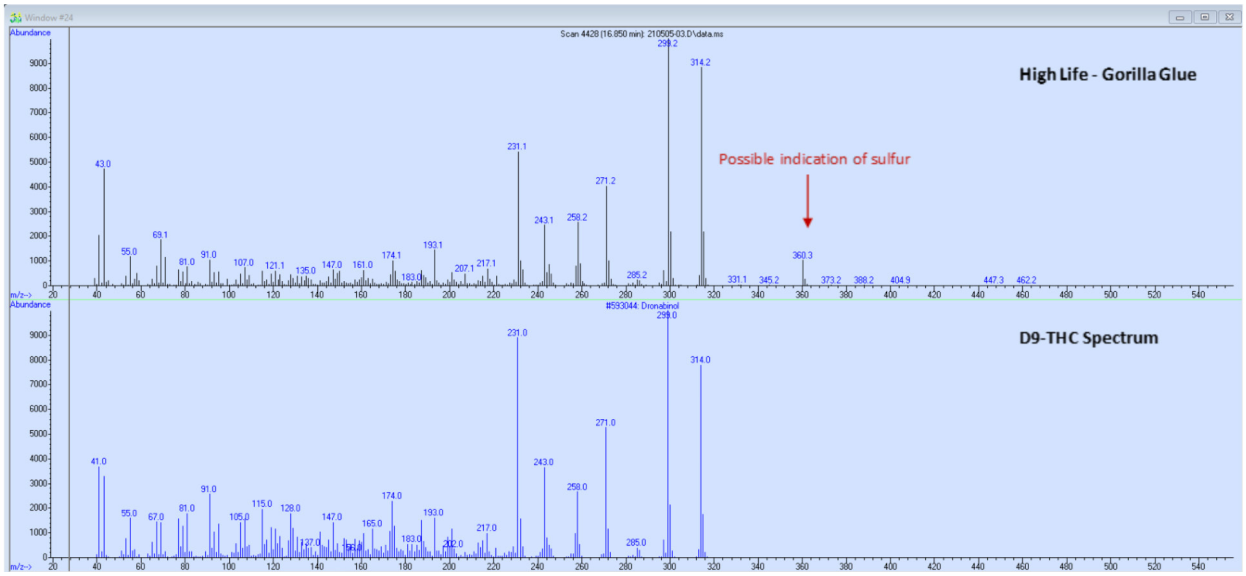


Figure 3. High Life - Gorilla Glue – Mass Spectral Comparison to D9-THC (as Dronabinol)



US CANNABIS COUNCIL

Federal Memorandum

CADWALADER

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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-psychotropic, Delta-8 is being marketed as a "legal" high with less potent, but similar effects to Delta-9-Tetrahydrocannabinol, the primary psychotropic 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

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[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

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[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/

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

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.

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[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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Related Media Coverage of Delta-8 THC

Title	Publication	Editor	Link	Date
Is Delta-8 THC A Controlled Substance?	AboveTheLaw.com	Nathalie Bougenies	https://abovethelaw.com/2021/05/is-delta-8-thc-acontrolled-substance/	5/6/21
Amendment potentially harmful to hemp industry removed by Senate	Alabama Political Reporter	Brandon Moseley	https://www.alreporter.com/2021/04/27/amendmentpotentially-harmful-to-the-hemp-industry-removed-bysenate/	4/27/21
Delta-8 THC Jumps Thru Legal Loopholes	Cannabis Tech	KARHLYLE FLETCHER	https://www.cannabistech.com/articles/delta-8-thc-jumps-thru-legal-loopholes/	11/16/20
An unregulated, weed-like drug dubbed 'CBD on crack' has spiked in popularity. Now the legal pot industry is calling for a crackdown.	Chicago Sun Times	Tom Schuba	https://chicago.suntimes.com/cannabis/2021/4/12/22378819/delta-8-thc-wake-bakery-canna-cafe-marijuanacannabis-botanic-alternatives-dispensary-cbd	4/13/21
Delta-8 THC Offers A Legal High, But Here's Why The Booming Business May Soon Go Up In Smoke	Forbes	Will Yakowicz	https://www.forbes.com/sites/willyakowicz/2021/03/12/delta-8-thc-offers-a-legal-high-but-heres-why-the-booming-business-may-soon-go-up-in-smoke/?sh=58aa0a5d5b3d	3/12/21
Vermont Joins List of States to Ban Delta-8 THC	Ganjapreneur	Cara Wietstock	https://www.ganjapreneur.com/vermont-joins-list-ofstates-to-ban-delta-8-thc/	4/28/21
Alabama Senate Committee Passes Bill to Ban Delta-8 and Delta-10 Products	Ganjapreneur	TG Branfalt	https://www.ganjapreneur.com/alabama-senate-committee-passes-bill-to-ban-delta-8-and-delta-10-products/	4/6/21
Oregon Targets Delta-8 THC With New Regulations	Ganjapreneur	TG Branfalt	https://www.ganjapreneur.com/oregon-targets-delta-8-thc-with-new-regulations/	3/24/21
Delta-8 THC Is the Next Big Thing in Weed, and We Tried It	GQ	Chris Cohen	https://www.gq.com/story/delta-8-thc-is-the-next-bigthing-in-weed	4/20/21
The Advanced Guide to Delta-8 THC Flowers	Green Market Report	N/A	https://www.greenmarketreport.com/the-advanced-guide-to-delta-8-thc-flowers/	4/16/21
Delta-8 legality map	Greenway Magazine	Brandon Dunn	https://mogreenway.com/2021/05/03/delta-8-legality-map/	5/3/21
States Begin Implementing Delta-8 THC Bans	Hemp Grower	Douglas Brown	https://www.hempgrower.com/article/states-ban-delta-8-thc-industry-organizations-weigh-in-hemp-industries-association/	4/23/21
U.S. Hemp Roundtable Warns Against Marketing Psychoactive Properties of Delta-8	Hemp Grower	Teressa Bennett	https://www.hempgrower.com/article/us-hemp-roundtable-warns-against-marketing-psychoactive-intoxicating-properties-delta-8-thc/	3/9/21
More states banning delta-8 THC as regulators clarify its legality under federal law	Hemp Industry Daily	Laura Drotleff	https://hempindustrydaily.com/more-states-banning-delta-8-thc-as-regulators-clarify-its-legality-under-federal-law/	5/4/21
What's Up With the Sudden Delta-8 THC Craze?	Inside Hook	Logan Mahan	https://www.insidehook.com/article/health-and-fitness/what-is-delta-8-thc	5/5/21
What to know about Delta-8 THC, the legal-ish weed compound that gets you high	Insider	Andrea Michaelson	https://www.insider.com/what-is-delta-8-thc-does-it-get-you-high-2021-4	4/20/21
Omaha police: 3-year-old hospitalized after getting into mom's Delta 8 THC gummies	KETV Omaha	N/A	https://www.ketv.com/article/omaha-police-3-year-old-hospitalized-after-getting-into-thc-gummies/36365122#	5/7/21
Explainer: How Oregon lawmakers plan to address Delta-8 THC	KOIN Portland	Kelcie Grega	https://www.koin.com/news/oregon/explainer-how-oregon-lawmakers-plan-to-address-delta-8-thc/	5/2/21

Title	Publication	Editor	Link	Date
DELTA-8 THC -> EFFECTS TOLD BY USERS	LA Weekly	N/A	https://www.laweekly.com/delta-8-thc-%E2%86%92-effects-told-by-users/	4/13/21
Delta-8 Craze Puts Pot Attorneys On The Spot	Law360.com	N/A	https://www.law360.com/articles/1377167/delta-8-craze-puts-pot-attorneys-on-the-spot	4/29/21
How long will delta-8 remain legal?	Leafly	Bruce Kennedy	https://www.leafly.com/news/politics/how-long-will-delta-8-remain-legal	4/27/21
What is Delta-8?	Leafly	N/A	https://www.leafly.com/news/science-tech/what-is-delta8-thc	3/31/21
What Is Delta-8 and Is It Legal?	MG Magazine	N/A	https://mgretailer.com/cannabis-news/what-is-delta-8-and-is-it-legal/	4/13/21
CBD store raided in Menomonee Falls after two small children had a nonfatal overdose, sheriff says	Milwaukee Journal Sentinel	Cathy Kozlowicz	https://www.jsonline.com/story/communities/northwest/news/menomonee-falls/2021/04/03/menomonee-fallscbd-store-allegedly-sold-products-illegal-thclevels/7073054002/	4/3/21
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