



Doctors for Drug Policy Reform

A D4DPR Position Paper

Recommendations for Regulating Intoxicating Cannabinoids
Chemically Synthesized from Hemp

April, 2024

Subject

Recommendations for Regulating Intoxicating Cannabinoids Chemically Synthesized from Hemp

Summary

The U.S. 2018 Farm Bill may have inadvertently legalized the chemical conversion of hemp-derived cannabidiol (CBD) and other phytocannabinoids (those derived directly from the plant) into intoxicating minor cannabinoids like delta-8 tetrahydrocannabinol ($\Delta 8$ -THC), leading to a booming industry without adequate regulatory oversight. Our stance at D4DPR is that all intoxicating cannabinoids should be subject to a regulatory framework to ensure public safety.

Background

In recent decades, numerous U.S. states and many countries worldwide have legalized various aspects of cannabis, including possession, cultivation, distribution, and sale, under regulatory statutes. These regulations typically include laboratory testing, package and labeling requirements, supply chain traceability (e.g. track-and-trace), licensing of outlets, age restrictions, marketing limitations, and penalties for illegal sales. While compliance with these regulations has been challenging and costly for the cannabis industry, it has also generally proven effective in limiting underage cannabis use and eliminating the harms of prohibition. No jurisdictions with legal medical or adult use cannabis have rescinded their laws and every year new jurisdictions recognize the value of legal cannabis and pass laws supporting these regulations.

The cannabis plant is botanically identical to the hemp plant, but for regulatory purposes hemp has been defined in the U.S. as having less than 0.3% $\Delta 9$ -THC by weight. (1). In 2018, the U.S. Congress passed a Farm Bill (2) that legalized the cultivation, distribution, and sale of hemp and hemp products, declassified hemp as a Schedule I controlled substance, and allowed for its legal transfer across state lines. By descheduling hemp products, regulatory responsibility shifted from the Drug Enforcement Agency (DEA) to the Department of Agriculture (USDA). It also explicitly preserved the authority of the Food and Drug Administration (FDA) to regulate consumer products as defined in the Food Drug & Cosmetic Act. The Farm Bill thus

allowed the unrestricted use of hemp in textiles, fiber, seed oil, biocomposite plastics, building material, biofuel, and other purposes.

Presumably as a consequence of the enthusiasm surrounding the potential of hemp and CBD products upon its descheduling, an oversupply of hemp following the 2018 Farm Bill's passage resulted in the cost of CBD decreasing from \$25,000 to \$500 per kilogram (1). However, savvy hemp cultivators and processors, assisted by chemists, recognized that it was now economical to convert the low-priced CBD into the intoxicating cannabinoid Δ^8 -THC (3). The resulting cannabinoids are commonly referred to as "semi-synthetic cannabinoids." (In both naturally-occurring hemp and cannabis, Δ^8 -THC is found in trace amounts but is not in near enough quantities for commercialization). According to the Controlled Substance Act (CSA), all tetrahydrocannabinol isomers (code 7370) specifically list Δ^8 -THC along with its isomeric cousin Δ^9 -THC as a Schedule 1 substance (4). But apparently Congress, DEA, USDA, FDA, and hemp proponents and opponents alike had not considered that the 2018 Farm Bill was written such that the semi-synthetic production of Δ^8 -THC and other minor cannabinoids from descheduled CBD was not expressly prohibited (5). And, really, why would they?

Taking advantage of this opportunity, Δ^8 -THC (chemically synthesized from hemp CBD) quickly became available in various retail outlets such as gas stations, CBD shops, convenience stores, smoke shops, and online platforms. Several states have now either banned or imposed regulations on its sale. However, in 22 states (as of November 2023) (6, 7), Δ^8 -THC remains legal and unregulated, with limited laboratory testing and taxation, lacking warnings about its intoxicating effects, without dosing limits, and easily accessible to minors. Moreover, numerous new "minor cannabinoids" have been synthesized from CBD, including Δ -10 THC, tetrahydrocannabinol (THC-O), hexahydrocannabinol (HHC), tetrahydrocannabiphoral (THCP), and tetrahydrocannabivarin (THCV). Unless restricted by state regulations, these compounds are also unrestricted and readily available. Our understanding of these compounds is limited; many have never been observed in nature and their toxicology is unknown. Additionally, chemists have reported the presence of unknown THC isomers and other undesirable compounds in these products due to inadequate cleaning of reaction products (including strong acids and residual metals), posing potential health risks to consumers (7, 8).

Whether these products are federally illegal or not remains uncertain. In correspondence with the Arkansas Department of Agriculture, the DEA unequivocally stated that “Arriving at delta-8-THC by a chemical reaction starting from CBD makes the delta-8-THC synthetic and therefore, not exempted by the AIA [Agricultural Improvement Act, or Farm Bill]. Any quantity of delta-8-THC obtained by chemical means is a controlled substance” (9). In 2023, the DEA further determined that “delta-9-THCO and delta-8-THCO do not occur naturally in the cannabis plant and can only be obtained synthetically, and therefore do not fall under the definition of hemp” and are controlled substances (10). On the other hand, in 2022 the 9th Circuit Court of Appeals ruled that as the Farm Bill was “silent” on the semi-synthetic production of cannabinoids from hemp, it was not illegal. And if “Congress inadvertently created a loophole legalizing vaping products containing delta-8 THC, then it is for Congress to fix its mistake” (11). Further, lawyers Matt Zorn and Shane Pennington have advised that the “DEA has historically used statutory language that broadly prohibits derivatives and extracts. The fact that DEA has authority to answer questions like this one under the CSA doesn’t mean it always answers them correctly. [In this case] we’re fairly sure the DEA is wrong.” (9).

Regardless of their legal status, there has been a relative absence of federal and, in many parts of the country, state oversight and/or enforcement of hemp-derived semi-synthetic cannabinoid production and sale. These products are typically marketed as safe and comparable to CBD. However, there are significant risks associated with them. Urine drug tests may mistakenly identify these minor cannabinoids as $\Delta 9$ -THC, potentially jeopardizing child custody and professional careers. $\Delta 8$ -THC has been implicated in 183 cases reported to the FDA Adverse Event Reporting System (FAERS), showing a two-fold increase from 2019 to 2021 (12). Common adverse events included dyspnea, respiratory disorders, and seizures. (It is important to note that $\Delta 8$ -THC involvement was self-reported by patients, and other substances or pre-existing illnesses may have contributed to these events.) And over a one-year period in 2021-2022, there were 2362 calls to poison control related to $\Delta 8$ -THC, 41% among minors (7). However, as the widespread use of these minor cannabinoids is relatively new, most toxicity reports are based on news and anecdotal sources, which lack scientific rigor. This uncertainty underscores the need for comprehensive research and regulatory measures to effectively address the potential risks associated with these products.

In this unregulated environment, producers of these products have achieved significant economic success. The U.S. market for $\Delta 8$ -THC and other hemp-derived cannabinoids has skyrocketed by over 1200% in just three years, with estimated sales between 2019 and 2022 reaching approximately \$20 billion in the U.S. alone (13). This financial success has translated into political influence, leading legislators in many states to hesitate in implementing regulations on these products. This reluctance is particularly notable in states with limited medical cannabis programs. For instance, despite Texas maintaining stringent regulations on THC concentration in its medical cannabis program (limiting it to no more than 1%) and continuing to impose onerous penalties for cannabis possession, the state has allowed the production and sale of hemp-derived semi-synthetic cannabinoids to continue unabated. This disparity highlights the complex interplay between economic interests, political dynamics, and regulatory frameworks within the cannabis industry.

D4DPR Recommended Policy

- Implement a regulatory framework for all intoxicating cannabinoids, regardless of their source (hemp, cannabis, laboratory synthesis, or via bioreactors/fermentation). This framework should include:
 - Licensing requirements for dispensaries selling intoxicating cannabinoids.
 - Appropriate taxation to fund regulatory oversight and public health initiatives.
 - Prohibition of sale to minors and packaging that does not appeal to children.
 - Childproof containers and clear labeling of intoxicating effects with the International Intoxication Cannabinoid Product Symbol (ASTM D8441).
 - Mandatory laboratory testing with required Certificate of Analysis (CoA) to assure purity and potency.
 - As many of these minor cannabinoids are newly described and difficult to detect, research into toxicology, clinical safety, and laboratory testing standards must be conducted.

- Align regulations for minor cannabinoids with those in place for cannabis in states with legal medical and/or adult use programs.
- Encourage states without a regulatory framework for minor cannabinoids to develop such a framework as soon as possible.
- Recommend that in states developing a regulatory framework for semi-synthetic cannabinoids but without legal medical or adult use cannabis, $\Delta 9$ -THC should be included in this framework.
- Call for the descheduling of cannabis at the federal level to eliminate the confusion between hemp and cannabis and establish a minimal regulatory structure that can be adapted by individual states.
- Recognize that an outright ban on minor cannabinoids (rather than their regulatory control) will result in a continuation of the drug war, leading to negative outcomes on public health.

This policy stance reflects our commitment to safeguarding public health while ensuring reasonable access to cannabis- and hemp-derived products within a responsible regulatory framework.

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See also

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