

FORENSIC SCIENCE REVIEW

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Objectives and Scope

The discipline of forensic science has nurtured many publications oriented toward research and case reports, as well as broad-based formal treatises. Rapid advances in forensic science have created a need for a review journal to bridge the gap between research-oriented journals and reference volumes.

The goal of *Forensic Science Review* is to fill this void and provide a base for authors to extrapolate state-of-the-art information and to synthesize and translate it into readable review articles. The addition of this journal extends the spectrum of forensic science publications.

Articles bring into focus various narrowly defined topics whose literature has been widely scattered. Articles are presented to stimulate further research on one hand and worthwhile technological applications on the other. The publisher's aim is to provide forensic scientists with a forum enabling them to accomplish this goal.

Technological applications based on basic research are emphasized. Articles address techniques now widely used in forensic science as well as innovations holding promise for the future.



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The 2018 Agricultural Improvement Act and Δ^8 -Tetrahydrocannabinol

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Mahmoud ElSohly and Donald Stanford have worked together for 45 years, first at the University of Mississippi's (UM) Research Institute of Pharmaceutical Sciences (RIPS), then at ElSohly Laboratories, Inc. (ELI), and now at the National Center for Natural Products Research (NCNPR), where they are embarking on a new avenue to share their expertise with cannabis researchers at the Resource Center for Cannabis and Cannabinoid Research (R3CR), an NIH endeavor to improve and advance cannabis science.

Now serving as Research Professor and Professor of Pharmaceutics, Mahmoud ElSohly's decades of work at UM involving the science of natural products, with an emphasis on cannabis and cannabinoids, has led to many advances in the fields of isolation, synthetic, analytical, and forensic chemistry. He holds over 40 patents and has authored over 400 publications in these areas of science. He has provided research-grade cannabis plant material, cannabis extracts, and purified cannabinoids to other investigators through the National Institute on Drug Abuse (NIDA) Drug Supply Program, including clinical-grade research materials. In 1985, he founded ElSohly Laboratories, Inc. (ELI) as an analytical testing company for drugs of abuse, which has grown into a nationally recognized commercial research organization that provides standardized testing products to research and forensic laboratories. He was recognized in the Journal of Analytical Toxicology as being one of the top ten most cited authors and most prolific authors in the journal between 1981 and 2003, and recognized by The Scientist and Science Watch as the second most cited author in forensic sciences in the world for the period 1981–1993.

Now serving as UM School of Pharmacy's Assistant Director of RIPS, Donald Stanford has been involved in various support capacities at UM's long-standing "Marijuana Project" that is best known for the work of numerous colleagues such as Mahmoud ElSohly and others. However, cannabis-related activities in the school are much broader than the NIDA contract work, such as development of cannabis-derived drugs, plant cultivation technologies, analytical methods, and cannabinoid isolation techniques. His primary focus has been quality assurance and regulatory compliance for various programs in the School of Pharmacy. His current professional services include consulting with the Council on Governmental Relations (COGR), Marijuana/Hemp Research Group; and the United Natural Products Alliance (UNPA), Hemp Extract/Cannabinoid Committee.

Introduction

The multitude of hemp-based products now available everywhere is a very confusing situation for consumers, health professionals, lawmakers, and scientists. This com-

mentary will explore the many ambiguities concerning the regulatory status of these products that soon developed after enactment of the 2018 Agricultural Improvement Act, the extensive legislative measure colloquially known as the "Farm Bill" [1]. We will elucidate the paradox of how certain hemp-based products, those that contain Δ^8 -tetrahydrocannabinol (or delta-8) as the major active ingredient, have become potent psychoactive preparations that are widely available to consumers without medical supervision.

^aThe views expressed are those of the authors and do not necessarily reflect the view, the position, or the policy of *Forensic Science Review* or members of its editorial board.

Our roles as scientists for many years at the University of Mississippi's National Center for Natural Products Research (NCNPR) involved in both cannabis and botanical dietary supplements research gives us and our colleagues insight into the many facets of this delta-8 paradox, such as regulatory issues, cannabinoid chemistry, plant biology, and truth in labeling. Although we have advised federal agencies, lawmakers, and health professionals on these matters for many years, our sage advice has been appreciated but not always followed.

Past Regulations

In 1970, Congress enacted the Controlled Substance Act (CSA) [2] to make practically all cannabis materials strictly controlled. The oversight of the development of botanically derived cannabis-based drugs by the US Drug Enforcement Administration (DEA) and the US Food and Drug Administration (FDA) has changed significantly over the past twelve years. Prior to that, it was easy to understand the regulations, as marijuana plants, extracts, and purified cannabinoids were all DEA Schedule I (C-I), except roots and stems which were specifically excluded from the prescribed definition (also known as "marihuana" by the DEA). Regulatory status was clear to scientists and governmental bodies:

- All forms of cannabis materials were DEA Schedule I (C-I) controlled substances that required a DEA C-I Researcher registration to acquire and possess;
- Pure cannabinoids, such as THC and cannabidiol (CBD), could be obtained from commercial sources or at no cost from the National Institute on Drug Abuse, Drug Supply Program (NIDA DSP);
- Cannabis plant materials, including cigarettes, could only be obtained from the NIDA DSP;
- Cultivation of *Cannabis sativa* plants for research, including the hemp varieties, was not allowed, except by the contractor engaged by NIDA to produce materials for the DSP; and
- There was no sanctioned pathway to develop FDA-approved botanical-based drugs, such as cannabis extracts for oral administration.

Complications Arise

In the 1990s, cannabis proponents in several states who had experienced relief from various ailments through the use of cannabis for medical reasons began to also seek relief from the legal consequences of the same. In 1996, California voters passed Proposition 215 to form the first state-sanctioned cannabis program for medical purposes [3]. Taking California's lead, within three years five other states adopted their own programs which gave

qualifying patients and caregivers some immunity from prosecution for cultivating or possessing cannabis for medical use. Eight more states adopted medical cannabis programs over the following decade, but with innovative approaches that solidified the progressive movement that has led to state-sanctioned cannabis use in all but three states today. Each state, however, has its own set of rules and regulations that may be very different from those of other states, and certainly conflict directly with federal laws, a situation that creates confusion over the legal status of cannabis manufactured under state jurisdiction ever since quasi-legal products became available to patients seeking alternative therapies. These uncertainties also opened doors for recreational users seeking to reduce their risk of retribution.

"Hemp" by Any Other Name

Hemp production for industrial products, such as textiles, building materials, and biofuels, as well as consumable hemp products such as hemp seeds and hemp seed oil, has spawned diversified agricultural industries in most states. At first, those consumable seed products were touted for health benefits not related to cannabinoid content, as those products only had trace amounts of those compounds due to contamination during processing. Later, though, the term "hemp seed oil" became confused with "hemp oil" products, as the latter contain extracts of cannabis plants specifically intended for oral or topical administration of cannabinoids.

The term "industrial hemp" arose in 2009 when the state of Oregon began issuing licenses to cultivate fiber-type cannabis plants within the state [4]. However, like medical cannabis programs, hemp production was also at odds with federal law until the passage of the 2014 Farm Bill that legitimized industrial hemp research. That year, Kentucky's universities and Department of Agriculture began to launch a statewide program to develop agricultural methods to produce industrial hemp for fiber and seed oil. The passage of the 2014 Farm Bill allowed "institutions of higher education" to grow hemp varieties of cannabis under pilot programs. Having industry funding, Kentucky's hemp program rapidly went forward, as the bill established a definition of "industrial hemp" which could be cultivated without a DEA registration. However, certain aspects of hemp production were subject to DEA oversight, including the importation of seeds. Kentucky's program came quickly to a halt when DEA agents seized 250 pounds of seeds that were to be planted at a ceremony to launch the program. Kentucky Agriculture Commissioner James Comer told the press that state officials are perplexed by

the DEA's interpretation of the newly enacted Farm Bill: "They're interpreting the law a hundred different ways. The only way they're not interpreting it is the way it actually reads" [5].

The state eventually prevailed in court to allow the Kentucky hemp program to proceed, but lawmakers who had supported the bill realized that more explicit language was required due to the inherent complexity of activities involving cannabis in the US. The 2018 Farm Bill [1] did just that by removing hemp from the list of DEA controlled substances, utilizing a definition that would have significant consequences:

The term "hemp" means 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.

The year 2019 was a pivotal time for our NIDA work when the 2018 Farm Bill became effective, now defining hemp as cannabis plants and all derivatives containing less than 0.3% delta-9 THC based on dry weight. Frankly, we were a bit skeptical of the new law and not certain how the DEA may apply the regulations to the unique cannabis supply program at NCNPR. This seminal regulatory development occurred during one of our outdoor cultivation seasons in which we were contracted by NIDA to grow three varieties on the UM campus: high-THC drug-type plants, high-CBD plants having low levels of THC, and an intermediate variety, all inventoried under our C-I Bulk Manufacturer DEA registration. To develop new procedures for handling hemp outside of our DEA registration, that same season we cultivated cannabis plants at a site off campus for the first time since 1968. We cultivated these off-campus plots not to supplement our supplies but to prove to UM administrators, as well as to ourselves, that we now have other options for cannabis research. UM administrators were hesitant about the legality and optics of hemp cultivation, even though the Mississippi Department of Agriculture and Commerce sanctioned our experimental plot that first season.

It was not until 2020, when the DEA published in the Federal Register the notice of interim final rule "Implementation of the Agricultural Improvement Act of 2018" (IFR) [6], that we perceived the procedural changes we needed to make in our activities. We immediately sought guidance from the DEA on our interpretation of the new regulations regarding specific cannabinoids — *such as delta-8*.

The 2018 Farm Bill also changed the C-I listing of "tetrahydrocannabinols" in the CSA by excluding tetra-

hydrocannabinols in hemp. Therefore, in its IFR the DEA verified that tetrahydrocannabinols that occur naturally in the plant are no longer controlled if the materials containing the compounds have a delta-9 THC concentration no greater than 0.3%, unless a particular tetrahydrocannabinol is controlled elsewhere in the CSA. This development was very significant for us to continue our cannabinoid isolation and synthetic activities as we could not afford to go afoul of federal law. The list of cannabinoids continuing under C-I status seemed to us to now be unfathomably limited.

The Delta-8 Paradox

Inevitably, this precise legal definition of hemp opened the doors for a flood of cannabis-based products to appear on the consumer market. As authors we take the liberty here to coin a new phrase for this commentary, "non-industrial hemp", with which we will refer to the subcategory of hemp intended for cannabinoid production rather than the traditional industrial hemp uses. The production of non-industrial hemp requires not just specific cultivation and processing methods but also requires specific chemovars of plants having the genetic predisposition to yield high concentrations of various cannabinoids, such as cannabidiol (CBD) or cannabichromene (CBC) but, of course, with no more than 0.3% delta-9 THC. And, to our knowledge, *high delta-8 chemovars do not exist*.

Predictably, the first hemp-based cannabinoid products to appear on the market were CBD preparations, as this cannabinoid was well characterized for its therapeutic properties and low potential for abuse as well as its physical and chemical properties for stability and potential purity [7]. Because products containing CBD were sought by consumers, the hemp companies responded with diverse selections of oils and tinctures, capsules, edibles, topicals, transdermal patches, and vape products for humans, as well as foods and oils for pets.

Perhaps the most difficult question faced by scientists and lawmakers is how the synthetic versions of cannabinoids fit the regulations that are based on those that occur naturally in the cannabis plant. A product containing CBD as the major active ingredient fits nicely under the definition of hemp if the delta-9 THC level is no more than 0.3% by dry weight, such as oils and tinctures prepared from dried hemp plants. However, CBD derived through total chemical synthesis used in a preparation would likely contain a barely detectable amount of delta-9 THC due to inevitable byproducts of the synthetic process. By the DEA's strict interpretation of the 2018 Farm Bill in its IFR, the synthetically derived product would be C-I as it

was not prepared from hemp plants and contains a minute amount of delta-9 THC. A synthetic CBD product totally devoid of all delta-9 THC, however, would not be a DEA controlled substance because the molecular structure of CBD excludes it from the “tetrahydrocannabinols” class of compounds. The delta-9 THC impurity in a synthetic CBD product triggers the C-I status regardless of the THC amount.

Inevitably, following the success of non-intoxicating CBD products manufactured from non-industrial hemp, the hemp industry utilized the language of the 2018 Farm Bill to justify marketing *intoxicating* hemp products, such as those containing substantial concentrations of delta-8.

In this commentary we will not dwell on the public health hazards associated with the use of delta-8 products other than to direct our readers to the FDA website that warns the public on this matter [8]. The agency warns that delta-8 products have not been evaluated or approved and may be marketed in a way that puts the public’s health at risk. Both FDA and national poison control centers have received numerous adverse event reports in both adult and pediatric patients through both intentional and unintentional exposure to delta-8, many of those events requiring intervention or hospital admission. The FDA also advises that the synthetic conversion of CBD to delta-8 often introduces potentially harmful chemicals into the products.

Studies with our colleagues at NCNPR have characterized many impurities found in commercially available delta-8 products through GC/MS analyses and NMR spectra of isolates [9,10]. Knowing that no cannabis chemovar exists that contains enough delta-8 that could be readily isolated on a commercial scale, we were certain that commercially available delta-8 must be either totally synthetic or a semisynthetic product. That is, manufactured from scratch, using olivetol and a monoterpene along with an acid catalyst, or by acid cyclization of CBD obtained from hemp. We therefore embarked on a study to examine the composition of delta-8 available on the commercial market. A large quantity of delta-8 isolate was purchased and subjected to both analytical and phytochemical investigations. By analysis, we found that at least 12 contaminants were present in that product and that the delta-8 purity was less than 90 percent. Through phytochemical investigation of the product we isolated 16 different compounds, some obviously from cannabis (possibly due to the CBD isolated from hemp) while others being the side products of the acid catalyzed reaction.

When we analyzed 21 different vape products labeled as containing delta-8, we found that they all contained numerous contaminants. We also found that some prod-

ucts contained olivetol, which suggests that the delta-8 ingredient in those was produced totally synthetically rather than semi-synthetically from hemp. Our greatest concern, however, was our determination that although all the products claimed to contain less than 0.3% delta-9 THC to meet the criteria as hemp, all were found to contain much more than the claim, as high as ~5% delta-9 THC, and thus, not legally hemp.

We are continuing our work to explore possible health implications and to possibly unravel the complexities of these hazardous products through toxicity studies of delta-8 contaminants.

An additional facet of the delta-8 paradox is a comparison of the FDA regulatory status of CBD to that of delta-8. Because CBD is a drug substance approved by the FDA in the product Epidiolex[®], that agency makes it very clear that the sale of products containing CBD may be in violation of the Food and Drug Act which prohibits the addition of an approved drug to foods or dietary supplements [11]. However, because delta-8 is not an approved drug, its regulatory status as an ingredient in any type of product is somewhat difficult to ascertain.

While delta-8 occurs naturally in many *Cannabis sativa* chemovars, due to the plant’s metabolism delta-8 levels cannot exceed delta-9 levels regardless of the cultivation practices or environmental conditions that affect the cannabinoid profile in plants which may be intended for commercial production of naturally occurring delta-8. So why do delta-8 products so proliferate in the hemp industry? The answer is simple: delta-8 may be readily and economically prepared via a synthetic chemical process using CBD as the starting material isolated from hemp. The language of the 2018 Farm Bill’s definition of hemp precisely includes “all derivatives” — *the key to the delta-8 paradox*. If delta-8 could not be economically manufactured in a manner that still fits the definition of hemp, the proliferation of delta-8 products would not likely have occurred.

For some time we had maintained that delta-8 was indeed a C-I controlled substance in all cases, due to the amended 21 CFR Part 1308 “Schedule of Controlled Substances” [12] which clearly states that tetrahydrocannabinols of similar structure and pharmacological activity are C-I, except those that fall within the definition of hemp. A legal case, however, caused us to reconsider.

In 2022, a delta-8 vaping product manufacturer sued another manufacturer for copyright infringement [13]. The defendant, Boyd Street Distro, ironically argued that a copyright on an illegal product is not valid. The opinion issued by the Honorable D. Michael Fisher in the Ninth Circuit Court of Appeals touched on the very doubts in our

minds about the legal status of delta-8. Judge Fisher stated that the only statutory metric distinguishing controlled marijuana from legal hemp is the delta-9 THC level, and the definition of hemp extends beyond just the plant to all derivatives, extracts, and cannabinoids. He concisely sums up the vexing issues that demonstrate the root of the delta-8 paradox: “If Boyd Street is correct, and Congress inadvertently created a loophole legalizing vaping products containing delta-8 THC, then it is for Congress to fix its mistake.”

Concluding Remarks

To conclude, we suggest that the proliferation of consumer products containing delta-8 resulted from a somewhat coincidental confluence of the intrinsic characteristics of the delta-8 molecule that give it both therapeutic and psychoactive properties, along with the unanticipated language of a US law that allows delta-8 products to be excluded from a class of compounds historically controlled under DEA C-I status. It seems that the paradoxical qualities of this potent cannabinoid have led to the development of a highly marketed product without the regulatory pathway that would have established the safety parameters required to protect public health before a product like this would be available to patients.

Many state legislators also recognize the serious health hazards directly related to delta-8 being widely available without medical supervision. A number of states have enacted laws to prohibit those products in their states. During the 2025 Mississippi session, our legislators debated a bill to establish a state hemp production program which would require the manufacture and sale of certain products, such as those containing delta-8, to be regulated through licensure, quality and labeling standards, and restricting sales to adults [14]. Although the measure failed to be approved, we commend our state leaders for their concerns and efforts in the matter.

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