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Time for a Cannabis Health and Education Act:

How Regulation, Product Definition and In-House Testing will Influence Future Litigation

Executive Summary

As the legal cannabis industry gains legitimacy on an international level, new regulations are changing the marketplace. While the regulated sale of cannabis creates myriad business opportunities, those same regulations lay the groundwork for new scrutiny and, undoubtedly, class action litigation against suppliers.

Much of the legal scrutiny in cannabis' future hinges on the definition of the drug. Cannabis sativa meets the description of a pharmaceutical drug, as per the United States Food and Drug Administration. Although cannabis is federally illegal in the United States, as of this publication, both tetrahydrocannabinol (THC) and cannabidiol (CBD) fulfill the definition of a medicinal drug. However, at the same time, the cannabis flower might also be classified as a dietary supplement because it is a biological matrix with myriad undocumented and unregulated compounds.

By reflecting on the regulations, definitions, and litigation of the dietary supplement and pharmaceutical industries, cannabis product suppliers can anticipate problems. Furthermore, in-house testing can mitigate legal and consumer health risks by facilitating quality control and documentation, particularly by increasing the number of samples analyzed during the process.

Defining Pharmaceuticals and Dietary Supplements

According to the United States Food and Drug Administration (FDA), pharmaceutical drugs and dietary supplements are categorically different. In the case of pharmaceutical drugs,[1] a specific chemical compound is tested in clinical trials performed by the manufacturer. Then, the FDA's Center for Drug Evaluation and Research (CDER) reviews the manufacturer's evidence before approving a drug for sale. CDER assesses the proposed drug's known risks in consideration of its confirmed benefits. If the drug is approved, the FDA suggests labeling practices to explain its benefits and risks.

Unlike dietary supplements, pharmaceutical drugs are assumed to be unsafe by the FDA until proven otherwise; thus, the burden of proof falls on the drug manufacturers. Vitamins, minerals, amino acids, enzymes, botanicals, and botanical extracts, however, are defined as dietary supplements.[2] As such, the FDA regulates them as food products; therefore, these supplements are considered safe until proven otherwise. The burden of disproving the safety of supplements is on the FDA. Until incidents of harm arise from a dietary supplement, the FDA allows its sale. Because dietary supplements are untested, any claims that they can treat or cure a disease are prohibited. However, some vitamin supplements may claim disease prevention, like in the case of folic acid that has been shown to help prevent birth defects.[3]

Yet, some naturally occurring botanical extracts such as morphine, which occurs in the opium poppy, may be classified as drugs rather than as dietary supplements. This is because such drugs are a proven treatment for specific conditions or diseases.

Additionally, some natural substances (e.g., morphine, psilocybin) may present dangers involving intoxication, overdose, or abuse. This, too, is a reason for a substance's classification as a drug rather than as a dietary supplement. Undoubtedly, cannabis fits this profile as an intoxicant.

Classifying Cannabis as a Pharmaceutical Drug

If the medicinal benefits of cannabis are validated for specific conditions, then cannabis – or its constituent cannabinoids – will necessarily be considered a drug or drugs, per the FDA. Furthermore, tetrahydrocannabinol (THC) is an intoxicant, which doubly confirms the need for THC's classification as a drug rather than as a dietary supplement. If THC-containing cannabis is legalized on a federal level in the United States, the U.S. Drug Enforcement Administration (DEA) will reassess its abuse potential and regulate its pharmaceutical distribution accordingly. THC – when isolated from the rest of the plant – is clearly a drug.

Cannabidiol (CBD) is also clearly a drug. In 2018, the DEA reassessed the legality of CBD medicines – but only for specific CBD products pre-approved by the FDA on a case-by-case basis.[4] According to the DEA's tiered system of pharmaceutical drug classification, CBD – long an illegal, Schedule I drug – is now a Schedule V drug, which indicates a low potential for harm or abuse.

Cannabinoids are not cannabis. Cannabis is not a cannabinoid.

Therefore, CBD and THC, the two major cannabinoids in cannabis, align well with the FDA's definition of a drug. The cannabis plant, however, is not so simple or easily classified. The plant itself is a complex botanical matrix, completely unlike a single-compound pharmaceutical, such as Prozac or Oxycontin.

Classifying Cannabis as a Dietary Supplement, Not Just a Drug

The cannabis flower is a not a single drug; it is a matrix of dozens of bioactive compounds that may have medicinal benefits or other effects. The plant contains no fewer than 113 cannabinoids and dozens of other compounds, including terpenes, flavonoids, waxes, and plant metabolites.[5]

As a botanical matrix, the cannabis plant is similar to an herbal supplement that contains many presumably safe compounds. The dietary supplement saw palmetto, which is believed to benefit men with prostate conditions, can serve as a paralleling example.

The constituents of saw palmetto fruit that provide the purported benefits have not been verified, although researchers speculate that the plant's combination of fatty acids, phytosterols, and other bioactive compounds play a role.[6] Yet, because saw palmetto is classified as a dietary supplement rather than a drug, defining the active ingredient is unnecessary. In addition, because clinical trials have not proven that saw palmetto is an effective treatment, supplement manufacturers may not make direct efficacy claims.

In the case of cannabis, the FDA will not have the capacity or resources to assess or regulate the dozens of cannabinoids that may be present in any given sample. Furthermore, naturally occurring compounds may not be patented, so it would not be sensible for any individual business to fund the clinical trials necessary to classify minor cannabinoids as drugs. This will likely mean that these less understood, anecdotally safe compounds will be considered dietary supplements without confirmed medical benefits.

Minor Cannabinoids as Contaminants?

Medicinal cannabis, when sold as an intact flower, does not fit the delivery format of existing pharmaceutical drugs. While dietary supplements may be sold in whole plant form, drugs are plant isolates or synthetic compounds bound in an approved delivery vehicle, such as a tablet or an oral solution.

So, if THC and CBD are the cannabinoids listed on the label of retail cannabis – and the cannabis product as a whole is considered to be a pharmaceutical drug – the other cannabinoids and natural compounds may fit the definition of contaminants. Yet in the case of cannabis, the incidental compounds are beneficial. Major and minor cannabinoids have been found to provide benefits that surpass the effects of any single cannabinoid alone, a phenomenon labeled the 'Entourage Effect.' This is why cannabis straddles the definition of drug and dietary supplement, and why a new definition is needed to regulate cannabis when federal legalization occurs.

Defining Cannabis

To avoid litigation and increase consumer awareness, a formal definition of cannabis is required. The Dietary Supplement Health and Education Act 1994 (DSHEA) provided such a definition for the dietary supplement industry in the United States.[7] It also outlined the regulatory statutes that govern the supplement industry today. Therefore, the DHSEA may serve as an example for cannabis.

The Dietary Supplement Health and Education Act:

- Defined "dietary supplement"
- Classified supplements as food, rather than drugs
- Prohibited claims of disease treatment
- Required manufacturers to use Current Good Manufacturing Practices (cGMP)
- Established the FDA's regulatory authority to remove products from the market in incidents of harm.

A definition of cannabis as a botanical matrix of many compounds, along with standardized labeling, would help consumers and it might also prevent suits against cannabis suppliers. Similar to the DHEA, a Cannabis Health and Education Act would mandate cGMP and establish the testing protocols that are critical for quality control. This would build the confidence of prescribing physicians and consumers unfamiliar with cannabis, improve the consistency of patient outcomes, increase safety, and legitimize the industry.

A Health and Education Act for cannabis products might:

- Define cannabis as a collection of compounds that may – or may not – be present in a particular cultivar or product
- Establish potency labeling standards for the most prevalent cannabinoids (e.g., THC, CBD)
- List all known cannabinoids, cannabis terpenes, and flavonoids
- Require testing and the implementation of cGMP
- State the precautions for using high-THC cannabis

Class Action Lawsuits and Cannabis

The dietary supplement industry is rife with lawsuits and recalls, both in the form of class action suits from consumers and suits from the FDA. As the cannabis industry evolves, it may be subject to this scrutiny or, worse, legal discrimination by anti-cannabis groups.

Class litigation is often driven by opportunistic attorneys and prompted by recalls or cautionary notices from the FDA. Once a problem is identified, attorneys will assess the sales volume of the product in question and the extent to which it harmed consumers. If the case is profitable – and supported by consumer complaints – it is likely to proceed. Even a successful defense will create sizable legal fees for the product manufacturer.

In the dietary supplement industry, three types of suits arise most frequently against product manufacturers and retailers, and these themes are likely to occur in the cannabis businesses also.

False Claims

False advertising is the most common claim of loss or injury against dietary supplement manufacturers. Because health benefits are the presumed value of supplements, companies walk a fine line between promotion and penalty.

Improper claims in the cannabis industry are already drawing the scrutiny of the FDA. The FDA has – on three occasions – threatened CBD companies for making illegal health claims.[8] The companies had listed specific conditions in their marketing materials, prompting regulators to issue warning letters that threatened product seizure if the claims continued.

In the dietary supplement industry, the success of the 2007 suit against Dannon Yogurt acted as a floodgate for class litigation. Dannon's Activa and DanActive branded yogurts claimed to help regulate digestion with beneficial bacteria. However, after consumer complaints, tests showed that the products were no different than other yogurts and that the claims were exaggerated. Dannon accepted a settlement that reimbursed consumers $35 million and required modification of their advertising. The size and scope of the Dannon suit legitimized class litigation for false claims and brought a wave of lawsuits in its wake. A similar cannabis-related case could do the same.

Purity

Because dietary supplements are unregulated, they are not tested prior to sale. Therefore, adulterated or contaminated products frequently enter the market without notice. The term adulteration refers to the intentional substitution of an active ingredient for a less costly one; contamination, by contrast, occurs accidentally.

Cannabis companies are liable to experience fallout over contamination. Mold is the most common contaminant and, in emerging markets without testing laws, aspergillus mold could prove lethal to immunocompromised patients.8 Steep Hill Laboratories, a leading cannabis testing firm in California, estimated that 20%-30% of the flower they tested in 2017 contained significant mold contamination.[9]

The FDA has banned companies from the market on the grounds of adulterated product and mislabeling, and also for the failure to establish testing procedures for active ingredients.[10] Testing verification and adherence to cGMP are seen as critical by the FDA, even in the less-regulated dietary supplement industry.

Potency

The variable potency of cannabis is well-documented. Potency varies between crops and between individual buds from the same plant. Additionally, potency decreases as plant material ages. Some extract products may even experience an eight-month half-life, meaning 50% of the potency is lost every eight months.[11]

In the dietary supplement industry, potency degradation has proven troublesome. A 2017 lawsuit against Nutraceutical Corporation claimed that the levels of its B12 liquid vitamins were rendered negligible and ineffective due to the instability of the formulation. In 2015, the New York State Attorney General demanded recalls of herbal products sold at Target, Walgreens, WalMart, and GNC due to a lack of the labeled ingredient or an absence of the ingredient altogether. In 2017, a class action suit was filed against Costco when its fish oil supplements were found to contain significantly less omega-3 fatty acid than advertised.

Class action lawsuits attract many plaintiffs. This is because anyone who has purchased the product in question may sign on to receive part of a damage award. When cannabis – possibly aged several months – tests below the stated cannabinoid percentage, consumer suits become viable.

Cannabis is overdue for class litigation. Since 2015, the FDA has issued warning letters to dozens of CBD manufacturers whose products have tested below the labeled quantity of the drug. Potency variance or claims of harm stemming from a false advertising claim will eventually trigger a wave of class action litigation in the cannabis industry.

In-House Testing for Preparedness and Propriety

Ultimately, chemical analysis is the only means to address the quality control issues of cannabis medicines. The objectivity brought by testing is, in fact, the cornerstone of consumer safeguards brought by legalization.

While many of the testing requirements of cannabis will need to be fulfilled by laboratories (e.g., residual solvents, heavy metals, pesticides), in-house testing is becoming increasingly popular with cannabis companies. Forward-thinking businesses are using small testing units to refine their products, increase quality control, and create an extra line of defense against regulatory and legal problems.

In-house testing units can provide valuable data logging. For instance, the GemmaCert portable testing unit stores testing data on a secure server for easy download. Such documentation is a powerful tool against claims of negligence or poor quality control. Voluntary testing creates an image of propriety that impresses regulators and customers.

Testing allows retailers to create objectivity-based customer loyalty. When customers are better informed about the potency issues that affect their cannabis – and when they see testing in action – they trust the retailer providing the education. Testing with GemmaCert is non-destructive to the cannabis flower; therefore, retailers can test the actual product the customer is purchasing in front of the customer, if desired. This satisfies customer curiosity and engages them in conversation on a deeper level. Public understanding of potency variance, degradation, and the struggle for representative sample selection help prevent litigation as well.

Quick, inexpensive testing with units such as those offered by GemmaCert make possible what laboratories cannot: a better assessment of potency variance with more frequent sample analysis. Because THC and CBD content can vary widely from flower-to-flower, selecting a representative sample is difficult. Testing multiple samples – even with a testing unit slightly less accurate than conventional laboratory equipment – provides a far better understanding of the potency of a crop. A representative assessment of potency with multiple tests is more relevant to quality control than a highly-accurate test from a single specimen.

Quick potency testing complements the role of laboratories. Some tests must be performed with resource-intensive laboratory technology, such as pesticide analysis. A single sample from a crop satisfies a pesticide or heavy metal inquiry because pesticides and heavy metals are present throughout the crop. Cannabinoids, however, vary between plants and between flowers from the same plant. Testing multiple times for cannabinoids makes sense to resolve this variance. Conventional laboratory tests, which require thirty minutes and the use of costly solvents, are ill-suited to this task. GemmaCert technology requires no solvents, measurements, or specially trained personnel, and it requires only a few minutes to complete. The ability of the unit to test more frequently greatly benefits quality control throughout the supply chain.

Cultivators, distributors, and processors benefit from frequent testing, too. Beyond compliance and legal defense, testing allows transactions to be fair and objective. Superior cultivators and processors find that testing improves their bargaining position,[12] with more potent products fetching higher prices than average fare. Testing units like the GemmaCert are accurate for transactional and comparative purposes, and they offer in-the-moment information that a third-party laboratory cannot. In the future, point-of-sale testing will prove standard for business-to-business cannabis transactions.

In Conclusion

Regulation brings litigation. While class action suits have yet to affect cannabis, the legal environment of the dietary supplement industry affirms that they will. The reasons for oncoming litigation will be determined, in part, by how regulators classify cannabis medicines. Whole flower cannabis is a novel drug delivery medium, unlike capsules, solutions, or intravenous drugs.

The cannabis flower may be best described as a dietary supplement that contains a regulated drug. This definition applies because of the numerous compounds that cannabis contains in addition to those considered to be the active ingredients. Regardless of the definition of cannabis medicines or attorneys' approaches to litigation, in-house testing will serve as a tool against large settlements and damage awards. Testing improves consumer safety and satisfaction while advancing the legitimacy of legal cannabis.

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Company Bio

GemmaCert is a biotechnology company, based in Israel since 2015, aiming to become a market leader in medicinal plant composition and potency analysis, starting with cannabis.
GemmaCert's skilled team of chemists, molecular biologists, biotechnologists, data scientists and programmers work tirelessly to advance cannabis analytical solutions.
In the long run, GemmaCert's breakthrough technology will enable patients and doctors to correlate cannabis composition with specific health conditions, significantly enhancing therapeutic treatment by cannabis and transforming the medical cannabis industry.

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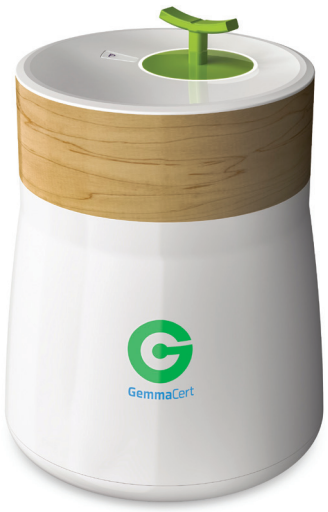

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