Prominence and Risks Related to New, Highly Concentrated Marijuana Products

Data Science Solutions, LLC
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BACKGROUND

Marijuana companies have been known to make false, misleading, or unproven claims about the therapeutic benefits of their products, which violates the Food, Drug, and Cosmetics Act (FDCA) and poses serious threats to public health and safety. Vulnerable patients suffering from conditions such as pain, mental illness, or cancer deserve access to accurate, evidence-based information so they can make the best possible health decisions. False or misleading claims about cannabinoid treatments, on the other hand, could lure patients away from FDA approved treatments and toward unproven, ineffective, and potentially unsafe products.

False and misleading marketing is particularly concerning in the context of new, highly concentrated marijuana products. In recent years, marijuana companies have developed several new product lines – such as concentrates and vapes – which often have exceptionally high concentrations of tetrahydrocannabinol (THC) and other cannabinoids.

Little is known about these new cannabis products, but the risks are substantial. Higher concentration of cannabinoids could increase the risk of worsening or exacerbating existing health conditions, inducing harmful drug interactions, and/or causing unintended **side effects**. Further, many such products are adulterated with potentially **dangerous residual solvents** leftover from the manufacturing process. While little systematic evaluation has been conducted on the consequences of highly concentrated marijuana product use, case reports suggest the possibility of severe neurotoxicity and **cardiotoxicity**. If vulnerable patients with preexisting health conditions are misled into using these unproven products as treatments, potentially to the exclusion of proven treatments, the consequences could be disastrous.

MARIJUANA AND MISLEADING CLAIMS

Pharmaceutical development is extremely complex, and patients – particularly those who suffer from a serious medical condition – do not have the time, resources, or education to adequately research their treatment options. In an ideal world, patients could rely upon well-intentioned experts to both provide accurate, evidence-based information about the available treatment options and guide them to an optimal treatment plan. However, this ideal situation is broken down when bad actors – whose incentives don't align with patient health optimization – abuse patients' lack of scientific understanding. The consequences of such a misalignment can be disastrous if patients are led away from proven treatments and toward dangerous products.

The solution is existing government regulation contained in the FDCA, which in the past has successfully ensured virtually every class of pharmaceutical drug in the U.S. is safe and effective. According to the FDCA, it is illegal for companies to claim that their products prevent, treat, or cure diseases before undergoing thorough scientific review and receiving FDA approval. Through this and related consumer protection regulation, pharmaceutical companies are deterred from making false or misleading statements about their products and violations are quickly enforced. Consequently, patients can rest assured that the drugs they are prescribed are safe and effective.

Cannabinoid-based drugs, however, have become the exception in this otherwise successful system.

Their outlier status among drug classes likely derives from the complex and often contradictory legal landscape governing cannabinoids, which also leads to a willingness among manufacturers to abuse the law. Marijuana use and sale is federally illegal under the Federal Controlled Substance Act, but several states have individually adopted legislation that allows for the sale of marijuana for medical and/or recreational purposes. Federal law technically overrides state law, but federal law enforcement agencies have allowed these state marijuana marketplaces to continue unabated.

Marijuana sales, thus, exist in limbo in several states between legal and illegal. Meanwhile, the FDCA and related regulations ban companies from claiming that their products prevent, treat, or cure disease without FDA approval. Because none of the marijuana products available in these state marketplaces have received FDA approval, such claims are illegal. This places federal FDA regulators in the contradictory position of regulating claims on products that are, according to federal legislation, technically illegal to use or sell in the first place.

In the midst of all this confusion, cannabinoids have become vastly underregulated by the FDA posing a major threat to consumers and patients. None of the products available in marijuana dispensaries and retail stores have undergone the rigorous, scientific testing needed for their safety and efficacy in treating medical diseases, and so the therapeutic profile of these drugs is unknown. Nevertheless, marijuana companies regularly make false, misleading, or unproven claims about the therapeutic value of these products. These claims lead patients towards unproven treatment options – even where proven treatment options exist – in order to bolster corporate revenues.

This research team aims to first describe the market size, popularity, and growth trajectories of highly concentrated marijuana products. This analysis will demonstrate the prominent role highly concentrated products (concentrates and vapes) now play in the marijuana marketplace and illustrate that highly concentrated marijuana products deserve attention from policymakers and regulators. The use of potential health claims in public-facing product descriptions for highly concentrated marijuana products was also investigated. This analysis will highlight marijuana companies' misleading marketing practices and the potential for patient harm, underscoring the need for enhanced regulation.

METHODOLOGY

HEADSET SALES DATA AND ANALYSIS

To provide context for the project, the research team analyzed sales trends for marijuana product categories that tend to contain high-potency products: concentrates and vapor pens using aggregate sales data from Headset. Headset data contains sales, in both units and dollars terms, by product category for nine states since June 2020 (CA, CO, IL, MD, MA, MI, NV, OR, WA), as well as Arizona since January 2021 and Florida since August 2021. The team then analyzed and visualized sales trends by product categories.

LEAFLY PRODUCT DATA

The main data source for this project comes from Leafly, a popular online directory for licensed marijuana businesses. Thousands of dispensaries across the United States and Canada voluntarily post a profile on Leafly. As part of their profile, many of these dispensaries also post their product catalog, containing the name, description, price, and other useful information for their products. Collectively, these catalogs serve as a nearly comprehensive source of producer-prepared, consumer-facing statements linked to specific marijuana products.

Leafly's data is organized as two related datasets: menu items and products. Menu items are specific items sold at specific dispensaries. Products, on the other hand, link the same item sold across dispensaries. These two datasets are not mutually exclusive: some items are only menu items (i.e., items not linked across dispensaries), some are only products (i.e., items not currently available on any dispensary menu), and some items are both products and menu items. Only menu items can be linked with specific dispensaries and only products can be linked with product reviews.

The research team used a complex web scraping strategy to collect both datasets, including information on product name, description, price, type, and listed THC content for all concentrate and vape products. The core strategy involved searching for products and dispensaries at the latitude and longitude of the centroid of every zip code in the United States and then using dispensary identifiers to search for each dispensary's full catalog of menu items.

ASSESSING PRODUCT POPULARITY

Sales volumes are not available in Leafly data. However, items in the Leafly "product" dataset are linked to customer reviews, which can be used as a reasonable proxy for popularity in the marketplace. We collected all such publicly available customer reviews. To give a broad view of the most popular brands and products on the market, we reported the top 25 products based on the number of reviews using a maximum of five products per brand on the list. These products are then used in a case series to better understand which highly concentrated marijuana products are among the most popular in the marketplace and how they are marketed to consumers.

ASSESSING POTENTIAL HEALTH CLAIMS

The team also investigated how highly concentrated marijuana products are marketed using their product descriptions. Product descriptions are producer-generated, public-facing marketing content and are thus representative of how marijuana companies intend their products to be perceived.

The team iteratively developed a keyword search algorithm to identify product descriptions that contain "potential health claims" related to five medical condition categories: mental health, pain, gastrointestinal disorders, oncology/cancer, and other medical conditions. We applied this algorithm to the corpus of product descriptions in the Leafly "menu item" dataset for all items available at medical or dual license dispensaries. We quantify, in aggregate and by medical condition category, how many product listings contain potential health claims. Note that one product sold at multiple dispensaries will be represented as several different "menu items", reflecting the user's experience of viewing the menus at different dispensaries.

LIMITATIONS

Leafly is an extremely popular directory of cannabis products in the United States and Canada, but its data is not entirely comprehensive. Not all cannabis dispensaries have a Leafly profile, and not every dispensary with a Leafly profile lists its full menu on Leafly. Further, these results reflect the data available on Leafly at the time it was scraped (October 2023 to January 2024). Much of the data is self-reported, and so it is possible that some product types were miscategorized. Nevertheless, these data reflect the content shown to Leafly users searching for highly concentrated marijuana products and constitute perhaps the largest analytical sample of cannabis products and product descriptions to date.

We use product reviews as a reasonable proxy for product popularity under the assumption that products that are purchased more often will receive more consumer reviews. It is possible, however, that the number of consumer reviews is not perfectly correlated with popularity or sales.

Our keyword search algorithm detects the presence of strings in product descriptions related to medical condition categories. While the search algorithm was iteratively developed to reduce classification errors, misclassification for some product descriptions is still possible.

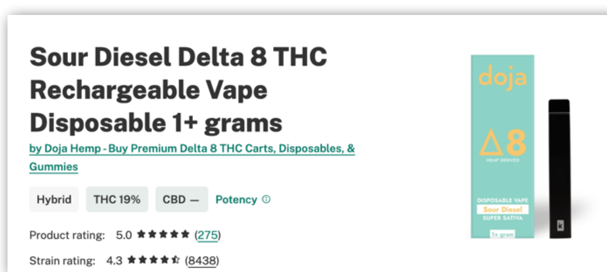
KEY FINDINGS

SALES GROWTH ANALYSIS

According to Headset sales data, concentrates and vapes are a large and growing share of the marijuana market. Sales growth for concentrates and vapor pens have significantly outpaced that of flower products since 2020. In dollar terms, concentrates and vapor pens have grown by 55.5% between June 2020 and May 2023, while flower sales have only grown 22.0%. In terms of units, the disparity in growth trajectories is even more stark. Concentrates and vapor pens have grown by 93.6% over the sample period, compared to 38.1% for flower. These results suggest that highly concentrated marijuana products – in particular, concentrates and vapor pens – are an increasingly important part of the marijuana marketplace. While flower is still more popular than concentrates and vapor pens in raw terms, that gap is closing. According to Headset estimates, the market for concentrates and vapor pens reached $490 million, while the flower market was $640 million. The tremendous sales growth of concentrates and vapor pens suggests that further investigation of this market is merited.

PRODUCT POPULARITY

The research team found 47,303 product reviews across all highly concentrated marijuana products identified in the Leafly "product" dataset. Many of the products with the most customer reviews contained descriptions explaining both their high THC concentration and their potential therapeutic benefit. For example, the Sour Diesel **Rechargable Vape** (right) is marketed as "one of the most potent



disposables on the market" with a concentration of 93% delta-8 THC. The description states that "Delta THC cannabinoids have been identified as an effective reliever of stress and anxiety" and that "Delta-8 THC can suppress nausea and improve appetite".

POTENTIAL HEALTH CLAIMS

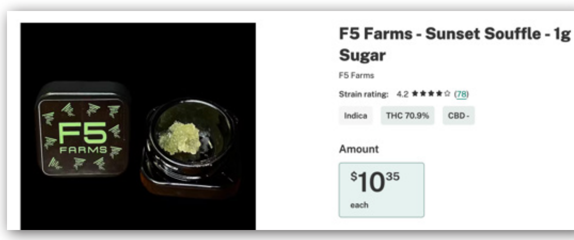
The research team found over 24,000 product listings in the Leafly "menu item" dataset that contain one or more potential health claims.

Among these, over **14,000** contain keywords related to each of the mental health and pain categories. **Over 5,000** contain keywords related to **gastrointestinal conditions, such as lack of appetite**. **Nearly 400** contain keywords related to **cancer**. **Over 6,000** contain keywords that pertain to other health conditions (Note that categories are not mutually exclusive as one product listing can contain keywords for multiple categories).

Category	Number of Product Listings
Mental Health	14,311
Pain	14,138
Gastrointestinal	5,589
Oncology/Cancer	398
Other	6,117
Any	24,102

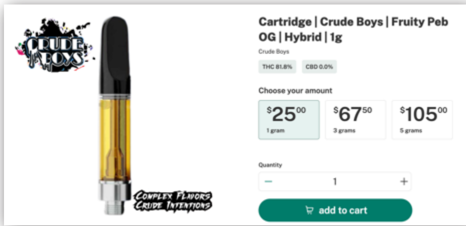
In one example, **this cartridge** for sale in Oregon with over 70% THC is included in both the oncology/cancer and mental health categories due to its product description, which included, "...that may have anti-inflammatory benefits...commonly believed to provide anxiety and stress relief...may have the ability to help fight cancer."

An Oklahoma "sugar" **product** *(right)* with over 70% THC includes in its description the ability to "relieve anxiety chronic pain depression insomnia mood swings stress"



This Alaska **product** *(left)* notes in its description it is "typically used for instances involving serious pain, sleep disorders, cancer and/or epilepsy..."

A popular "**Grand Daddy Purp**" Missouri product *(right)*, containing over 80% THC, claims it is "for consumers looking to combat pain, stress, insomnia, appetite loss, and muscle spasms."



Massachusetts based "**Crude boys**" fruity pebble flavored vape cartridge *(left)* with over 81% THC claims the product "May Relieve: ADD/ADHD, Anxiety, Arthritis, Bipolar Disorder, Chronic Pain, Depression, Headaches, Loss of Appetite, Stress."

Michigan's **Nature's Remedy oil** *(right)* has in its description, "THC is known to provide relief from neuropathic (nerve) pain1, stress relief, insomnia treatment, and reduction in the number of spasms for those suffering from multiple sclerosis. It can also help manage depression and anxiety, reduce cancer-related symptoms, and have neuroprotective properties. THC can stimulate appetite while CBN can reduce it. CBN, often referred to as the 'mother of all cannabinoids', has potential benefits such as pain relief, decreasing inflammation, relieving anxiety and depression, possibly inhibiting cancer growth, and is shown to have antibacterial, anti-inflammatory, antidepressant qualities, and may help with bladder dysfunction and act as a neuroprotectant."

One **product** in Maine even claims its ability to treat "patients suffering from a variety of conditions including chronic stress, depression, chronic fatigue, mood swings, headaches or migraines and Bipolar Disorder."

See below for additional examples of products making multiple health claims:

THC product description examples checklist						
Product Name	**State**	**Mental Health**	**Pain**	**Gastrointestinal**	**Cancer**	**Other**
NU Phoenix Tears	AK	1	1	0	1	1
Gorilla Punch Crumble	MT	1	0	1	0	1
GDP Disposable Vape	MO	1	1	1	0	0
AfterGlow- Grape-Alicious Cartridge	OR	1	1	1	0	0
Delta Oil Co - Granddaddy Purp	OK	1	1	1	0	0

THC product description examples checklist						
Product Name	**State**	**Mental Health**	**Pain**	**Gastrointestinal**	**Cancer**	**Other**
Synergy Moonlight Cartridge	IL	1	1	1	0	0
Cartridge | Crude Boys | Fruity Peb	MA	1	1	1	0	1
High Coast GMO Distillate Cartridge	ME	1	1	1	0	0
Pomegranate Oil	ME	1	1	1	1	1
In The Flow: Vape	MO	1	1	1	0	0
Alien Haze Shatter	CO	1	1	0	0	1
Bangerang Bubble Hash	MT	1	1	1	0	1
Cloud Z Bigfoot Glue	OK	1	1	1	0	0
Blue Dream Cartridge	NJ	1	1	1	0	0
Blue Hashplant Cartridge	ND	1	1	1	0	1
Burnwell Live Resin Cartridge Cookies & Cream	WA	1	1	1	0	0
Cream and Cheese Cartridge	ND	1	1	1	0	1
Dosi Cookie Cartridge	ND	1	1	0	0	1
Harle-Tsu Tincture	OR	1	1	0	0	1
Charlotte's Web Full Spectrum	OR	1	1	0	0	1
Sauce: Koffee Breath	CA	1	1	0	0	1
Mango Punch Wax	OR	1	1	0	0	1
Watermelon Syrup	MA	0	1	1	0	1
Tangerine Dream Cartridge	ND	1	1	1	0	1
Purple Urkel Shatter	MT	1	1	1	0	1
Illicit Cookies Cartridge	MO	1	1	0	0	1
Infused Pre-roll Super Lemon Hazee	WA	1	1	1	0	1
Lill Disposable	CA	1	1	1	0	0
MED ONLY - SunMed Labs Double Cross Cured Resin Shatter	MD	1	1	0	0	1
Rove - Blue Dream - Live Diamonds	OK	1	1	1	0	1
Rove - Pineapple Express - Live Resin	OK	1	1	1	0	0

Reminder: Examples were pulled between October 2023 to January 2024 and are subject to change as companies update their product descriptions, websites, etc.

CONCLUSION AND RECOMMENDATION

As discussed previously, the incentives of patients and marijuana companies are misaligned. Enhanced regulation is needed to realign these interests and better protect consumers. Although FDA warning letters have called out false health claims and have influenced marijuana companies' marketing efforts in retail spaces, a similar crackdown on misleading social media marketing should be implemented to better protect consumers.

In addition to enhanced enforcement of existing laws and regulations, regulators should devote more resources to monitoring social media posts from medical marijuana - this is particularly important to address the health claims being made for high-potency products that pose significant public health risk.

We recommend the FDA begin using automated tools to monitor marijuana companies' social media posts efficiently and effectively.

We recommend that Congress encourage FDA and FTC to expand their enforcement against therapeutic claims made by cannabis companies and provide the necessary resources for the FDA to conduct effective oversight of marijuana-related health claims on social media platforms.