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Health Claims About Cannabidiol Products: A Retrospective Analysis of U.S. Food and Drug Administration Warning Letters from 2015 to 2019

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Abstract

Background: Cannabidiol (CBD) products are increasingly available to consumers in the United States and are subject to regulation by the U.S. Food and Drug Administration (FDA). CBD products cannot be marketed as unapproved new drugs with claims of therapeutic benefit. In addition, because CBD is the active ingredient in a FDA-approved CBD product, Epidiolex, CBD cannot be marketed as, or in, food products or dietary supplements. The FDA has issued Warning Letters to promote voluntary regulatory compliance. These letters provide insights as to the types of violations for CBD products detected in the U.S. market.

Objective: The goal of this retrospective study was to content analyze Warning Letters issued by the FDA to identify illicit marketing of CBD products.

Design: Warning Letters issued by the FDA between 2015 and 2019 were content analyzed using a deductive approach. We extracted year of issuance, issuing office, and claim types that are currently prohibited by the FDA, including (i) unapproved new drug, (ii) misbranded drug, (iii) false and/or misleading, (iv) FDA-approved/endorsed, (v) dietary supplement, and (vi) adulterated food product. In addition, we documented the disease or conditions the product claimed to affect, pharmacological effects, and location of violation.

Results: Of the 39 Warning Letters issued, 97% were for violations made on company websites and 56% were for social media accounts. Almost all letters (97%) cited violations of marketing CBD as an unapproved new drug. These illicit therapeutic claims were made for >125 unique health problems, including cancer (87.2%), diabetes (71.8%), inflammation (66.7%), pain (66.7%), and arthritis (66.7%). The majority of letters (79.5%) also cited illicit marketing of CBD as a dietary supplement or food product. CBD was promoted as having 16 unique pharmacological effects, including anti-inflammatory (53.8%), anticancer (43.6%), and antipsychotic (30.8%).

Conclusions: CBD products have been unlawfully advertised online as unauthorized drugs with health claims that promote therapeutic benefits and as dietary supplements. Efforts are needed to regulate and monitor illicit advertising so consumers are not misled about the risks and benefits of CBD use.

Keywords: cannabidiol; CBD; marketing; regulation

Introduction

Cannabis sativa is one of three primary species of cannabis and contains over 100 cannabinoids.[1] The two most prevalent cannabinoids are delta-9-tetrahydrocannabinol (THC), the main psychoactive constituent in cannabis, and cannabidiol (CBD) that has no intoxicating effects to users.[2] Hemp and marijuana are two varieties of *C. sativa* that have different chemical compounds: hemp contains an abundance of CBD, but no more than 0.3% of THC, whereas marijuana contains both compounds, with levels of THC reaching concentrations of >30%.[3–6] The Agriculture Improvement Act

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of 2018 (a.k.a. Farm Bill)[3] removed hemp from the Controlled Substance Act and preserved the U.S. Food and Drug Administration's (FDA) authority to establish and enforce regulations on CBD under the Federal Food, Drug, and Cosmetic Act (FD&C Act).[7] This resulted in a proliferation of CBD-infused consumer goods readily available, both online and in brick and mortar stores, which are subject to the same laws as other FDA-regulated consumer products.[8]

The FDA is currently evaluating the regulatory framework for cannabis-derived products, including CBD, and determining if new regulations are appropriate.[9] Until then, CBD products fall under FDA's jurisdiction that mandates that products containing CBD cannot (i) be marketed for therapeutic purposes or benefits without prior approval from the FDA's Center for Drug Evaluation and Research (CDER)[7]; (ii) use false and/or misleading information; or (iii) convey the product is approved or endorsed by the FDA, without FDA approval.[7] In addition, CBD cannot be (iv) marketed as a dietary supplement or (v) food additive, because it is an active ingredient in an approved drug product, Epidiolex, to treat specific epilepsy syndromes.[10]

CBD's anti-inflammatory and antioxidant properties, as well as its tolerability profile,[11] make it a potential candidate for a range of medical uses beyond epilepsy, spurring new research to determine its effectiveness in treating a variety of conditions. Although there is strong evidence for CBD's beneficial role in treating seizure disorders,[12,13] the current evidence is much weaker for other conditions for which CBD is marketed, including pain, psychosis, and anxiety due to small sample sizes and a limited number of studies.[14–17]

Nevertheless, approximately 26% of U.S. adults have tried CBD, and about 14% report daily use.[18] Nearly 40% of users are ages 45 and over,[18] likely due to the perception that CBD can alleviate, cure, or reduce symptoms of a variety of medical conditions.[18] The majority of users (62%) report using CBD to treat medical conditions, most commonly chronic pain.[19] In a recent study, 30% of CBD users reported taking CBD in addition to an existing prescription or over-the-counter medication,[18] raising concern for drug interactions or other unintended consequences.[20,21]

Use of CBD, potentially without clinical oversight, could place consumers at increased risk of unintended consequences,[21] as studies have shown CBD products can contain pesticides, heavy metal contaminates, and be adulterated with synthetic cannabinoids.[22] In clinical trials, CBD has been shown to produce adverse effects, including gastrointestinal disturbances (e.g., diarrhea and decreased appetite), skin reactions, an increase in liver enzymes, and general weakness, fatigue, and malaise.[23,24] Nearly half of CBD users in one study experienced adverse drug events such as transaminase elevation, sedation, sleep disturbances, infections, and anemia.[25] Furthermore, the lack of product standards allows products to be mislabeled regarding the CBD content, making it impossible to know the exact dose of CBD a person has ingested.

The FDA is concerned about the quality of CBD products and how they are marketed to consumers. It determines through its own inspections, as well as evidence submitted by states, when a violation of regulatory significance has been made.[26] Warning Letters are issued that provides information about the type of violation and directions for voluntarily correcting the issue and complying with the law. In recent years, the FDA has issued Warning Letters to multiple companies for CBD product marketing violations.[27] The goal of this study was to content analyze Warning Letters issued to companies between 2015 and 2019 to determine the types of illicit marketing for CBD products intended for human consumption. Synthesizing the types of violations for which CBD companies are cited could provide evidence about target audiences and marketing strategies used by CBD companies to persuade consumers to use these products.

Materials and Methods

We used a deductive approach for the content analysis,[28] using the existing FDA-prohibited claims and the current literature as a framework for the initial coding categories. This approach allowed for the quantification of illicit marketing violations across numerous letters and exploration of the specific conditions the products claimed to benefit.

Sample

Warning Letters are available to the public on the FDA website.[29] The website was searched for letters with issue dates between January 1, 2015 and December 31, 2019 using the keywords Cannabidiol and CBD. Letters were downloaded and manually screened for CBD or cannabidiol in the "Subject" heading. Letters issued to companies for illicitly promoting CBD products for humans and animals were included; however, claims specific to animals were excluded from analyses since the study is focused on claims related to products intended for human consumption. Duplicate letters, identified as having the same company name, issue date, and issuing office, were excluded.

Content analysis

Before coding, the research team developed a codebook based on the existing literature, the FD&C Act and FDA guidance documents.[7,30] The team of two coders tested the codebook on two letters; the first author reviewed the coding and identified discrepancies, which were verified using the original source. The codebook was updated with any changes. Each Warning Letter was double coded. For each letter, we extracted the date of issue and issuing office, reviewed the narrative descriptions of the violations and coded for claim types that are currently prohibited by the FDA, including (i) unapproved new drug, (ii) misbranded drug, (iii) false and/or misleading, (iv) FDA-approved/endorsed, (v) dietary supplement, and (vi) adulterated food product. Each letter could be coded for multiple claim types. To determine if Warning Letters were targeting illicit marketing made online (i.e., website and social media) versus offline (e.g., in-store, product literature/pamphlets, and product label) we recorded the location of the violation. Finally, because CBD is primarily used by consumers to treat medical conditions,[18] we recorded the specific medical condition or disease (e.g., cancer and pain) the product claimed to affect and the pharmacological properties it claimed to have (e.g., antibacterial and anti-inflammatory). After coding was completed, the first author identified and resolved discrepancies using the original Warning Letters. Descriptive statistics were performed using SPSS.

Results

A total of 39 Warning Letters were issued to companies for illicitly promoting CBD products for human benefit between 2015 and 2019. Warnings were often issued from multiple offices, including from the FDA's CDER (59%) and Center for Food Safety and Applied Nutrition (56%). Almost all letters referred to online violations found on the company's website (97%), Facebook (41%), Twitter (18%), Instagram (18%), and/or another online site (10%). Offline violations addressed issues with manufacturing, product labeling, and product literature (i.e., pamphlets) (Table 1).

Warnings were issued for many violations ranging from illicit promotion and distribution of unapproved new drugs to illegally marketed food. Almost all (97.4%) companies illicitly promoted CBD as an unapproved new drug. These claims indicated that CBD could be used in the "diagnosis, cure, mitigation, treatment, or prevention of disease" without evidence of safety or efficacy reviewed by the FDA's CDER. Under the FD&C Act, many companies had "misbranded" products (94.9%) without adequate directions for use, illegal promotion of products as dietary supplements (79.5%), and violated interstate commerce regulations (46.2%).

CBD claims were made for over 125 unique health problems, including symptoms or diseases of multiple human body systems (e.g., immune and nervous). Unsubstantiated claims were identified for a median of 18 unique health problems per letter (range = 0–44, mean = 19.4, and standard deviation = 9.5) The most prevalent unauthorized CBD claim across companies was for cancer (87.2%). More than two-thirds of companies warned made claims about the prevention or treatment of diabetes (71.8%), inflammation (66.7%), pain (66.7%), and arthritis, including rheumatoid arthritis and rheumatism (66.7%). The majority of the companies in violation also included illicit CBD indications for anxiety (59.0%), Alzheimer's disease (59.0%), depression (56.4%), post-traumatic stress disorder (53.8%), schizophrenia (53.8%), multiple sclerosis (51.3%), and Parkinson's disease (48.7%). CBD products were promoted as having 16 pharmacological effects, including anti-inflammatory (53.8%), anticancer (43.6%), antipsychotic (30.8%), and antibacterial (25.6%). More than half of the companies (79.5%) were also in violation for labeling products that contained CBD as a dietary supplement or food additive.

Table 1. Claim Type by Year

	Total *N*	2015 *N* (%)	2016 *N* (%)	2017 *N* (%)	2018 *N* (%)	2019 *N* (%)
Number of warning letters issued	39	4	8	4	1	22
Unapproved new drug	38 (97.4%)	4 (100%)	8 (100%)	4 (100%)	1 (100%)	21 (95.5%)
Dietary supplement	31 (79.5%)	0 (0%)	6 (75%)	3 (75%)	1 (100%)	21 (95.5%)
Adulterated foods	12 (30.8%)	0 (0%)	0 (0%)	1(25%)	0 (0%)	14 (63.6%)
FDA approved/endorsed	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
False and/or misleading	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Misbranding	38 (94.9%)	4 (100%)	8 (100%)	4 (100%)	1 (100%)	20 (90.1%)

Warning Letters could contain more than one claim type.
FDA, Food and Drug Administration.

Discussion

Between 2015 and 2019, the FDA issued numerous Warning Letters for illicitly marketing CBD online through company websites and social media accounts. Notably, no warnings were issued for claims of the product being approved or endorsed by the FDA. Even though a variety of illicit claims about CBD products were found, the most salient violations were illicit therapeutic claims and marketing as a dietary supplement or food product. These findings suggest that CBD producers utilize a marketing strategy directed to the health market divided in two fronts, the dietary supplement market for healthy individuals and the therapeutic market for patients suffering different diseases. From these groups the most at risk segment is undoubtedly patients suffering conditions for which there are limited FDA-approved drugs.

Unapproved new drug claims, or claims that promise to prevent, treat, or cure medical conditions without the FDA's approval, were the most common type of claims for which Warning Letters were issued. Products were marketed for a variety of medical conditions, most often cancer, diabetes, dementia, pain, inflammation, and arthritis. From these medical conditions there are two distinct clinical features that reflect the nuances in the marketing strategy of these products: these conditions are chronic (e.g., cancer, diabetes, dementia, and arthritis) and/or painful/incapacitating (e.g., pain, inflammation, and arthritis). For some of these conditions, the available FDA-approved treatments are scarce, or they are largely ineffective and produce limiting side effects. Thus, the types of claims made about CBD make it an attractive alternative for patients with debilitating conditions and limited therapeutic options. Accordingly, the current literature on CBD use indicates that chronic pain and arthritis are the two most common reasons of use.[19] More research is needed using national samples to better understand how consumers with chronic conditions are using CBD, including replacing prescribed medications or using them in addition to their existing treatments. It is also worth exploring if these types of claims may influence consumers to postpone seeking medical care, including diagnosis and treatment for medical conditions.[6,13]

This study also highlights that CBD is often illicitly marketed as a dietary supplement and in foods, targeting a vast food and health supplement market composed of avid consumers. The carefully portrayed safety profile of CBD and hemp makes CBD products attractive as a food and health supplement, reflective in the multiple Warning Letters (i.e., 79.5%) that were issued by the FDA citing these reasons. As mentioned earlier, this type of marketing is not allowed since CBD is an active ingredient in an FDA-approved drug. It is important to note that the large variability in CBD formulations, the inaccuracy in their content of active ingredients, and their quality or potential contaminants make the consumption of these products very risky even for healthy individuals who use them as dietary or health supplements.[31]

The number of Warning Letters for illicitly marketing CBD experienced a marked increase in 2019 compared with previous years. There are multiple reasons that could explain this sharp increase, including the surge of new CBD products that came to the market as a result of the Farm Bill,[3] as well as new cannabis legal programs that were enacted in multiple states since 2015. Whether FDA's strategy of issuing Warning Letters will persuade manufacturers to stop illicit marketing, or whether this action prevents other producers from making similar illicit claims remains to be seen. However, the analysis of these letters provide context on the CBD market, including the identification of the most likely targeted users.

Our study shows that the FDA issued numerous Warning Letters to companies for making illicit claims about CBD, primarily online. However, the brick and mortar retail environment, where the 74% of users report purchasing CBD,[18,32] has been largely ignored. No warnings have been issued to brick and mortar CBD retailers for illicit health claims. A handful of studies have focused on advertising for cannabis dispensaries.[33–35] Notably, one study found 67% of dispensaries made claims pertaining to medical conditions that could be treated with cannabis.[36] Future research should assess brick and mortar retailers that sell CBD.

Limitations

This study did not link health claims to specific products and did not assess if companies successfully addressed violations outlined in the letters. Future research should assess consumer perceptions of illicit claims such as those highlighted in this study, as our content analysis only categorized the claims identified in the letters.

Conclusions

Understanding the type of health claims that are being marketed to consumers about CBD is important, as these types of illicit claims may mislead consumers about the risks and benefits of CBD. This analysis allows us to identify key components of the CBD market

and the strategies used to promote their products, including sector (e.g., health and supplements), segments (e.g., preventive and therapeutic), main medical conditions, and patient populations. Our results provide a clearer picture of the marketing strategies for CBD products and could guide efforts to protect consumers by informing specific regulations.

Author Disclosure Statement

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Abbreviations Used

CBD = cannabidiol
CDER = Center for Drug Evaluation and Research
FDA = Food and Drug Administration
THC = tetrahydrocannabinol