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Ask The Pharmacist

To suggest a topic, send an email to: AskThePharmacist@cvty.us.com

How safe and effective are the CBD oil products marketed to the public for purchase?

With the legalization of marijuana in the majority of states across the country, cannabidiol (CBD) products have become all the rage, and the market has seen an influx of multiple preparations including oils, tinctures, creams, and supplements that are touted for a variety of conditions ranging from anxiety to inflammation to sleeplessness and seizure control. However, both limited evidence of established safety and efficacy as well as a lack of regulations related to CBD products have led to questionable quality and benefit vs. risk concerns.

Today, the only CBD product with U.S. Food and Drug Administration (FDA) approval is Epidiolex, a cannabidiol oral solution indicated in the treatment of seizures associated with Lennox-Gastaut or Dravet syndrome in patients two years of age and older. The label includes recommended dosing starting at 5 mg/kg/day with increases advised based on individual clinical response and tolerability up to a maximum recommended maintenance dose of 20 mg/kg/day. Established safe and effective dosing and monitoring guidance are some of the components lacking with other CBD products that are not approved by the FDA.

In fact, the FDA has issued more than 90 warning letters in the past 10 years to CBD companies over fraudulent product and health claims made on websites, social media, and in physical store locations. The letters advise the makers of these CBD products that they are considered unapproved new drugs and are also misbranded under the Federal Food, Drug and Cosmetic Act (FFDCA), meaning essentially that they do not meet the requirements for labeling, including adequate directions for use, and should not be used to treat diseases without the supervision of a licensed practitioner. The FDA further asserts that it has tested the chemical content of these cannabidiol-related products, and the results indicate that many of the products do not contain the amounts of CBD that they claim.

A 2017 study by Bonn-Miller et al published in JAMA examined the "Labeling Accuracy of Cannabidiol Extracts Sold Online." Their test results showed that nearly seven out of every 10 CBD products did not contain the amount of cannabinoid touted on the label. Further, the study revealed that approximately 43% of the products contained less CBD than they claimed, while about 26% contained more than the label indicated. Even more concerning were the findings that one in five "CBD-only" products also contained THC, the constituent of marijuana that can lead to euphoric effects and that would potentially show up on a urine drug test (UDT). This could be of particular concern when considering the ill or injured worker population who may be turning to such products for a multitude of symptoms, as often a positive UDT for THC could preclude that individual from working depending on the policy of his or her employer.

The evidence indicates that without clear regulations and oversight of such products, an individual can never really be sure of what he or she is getting, and without the oversight of a health care provider who is knowledgeable about CBD and its effects and potential for drug-drug interactions, safety and efficacy concerns tip the scales disproportionately on the risk-benefit scenario toward risk. If one wishes to circumvent such concerns and limit exposure to unknown additives with CBD products, the most advisable thing to do is to avoid use until such products are able to be manufactured under consistent and well-established quality guidance and regulatory oversight and are backed with adequate, large-scale clinical scientific evidence supporting their safety and efficacy.

That being said, today, CBD products are legal and available for use in states where medical and/or recreational marijuana (30 states) or CBD-specific laws (17 states) are in place. The FDA's guidance to the consumer is "buyer beware" any time one is considering purchasing and using CBD products not approved or regulated by the agency. In the end, it is the consumer's choice, and injured workers should be advised that strong consideration ought to be given to the possible risks, unwanted effects, and potential impacts on workplace drug testing prior to use of unregulated CBD products.

Lower Cost Generic of Evzio® Available in 2019

Kaléo® Inc. has announced their subsidiary, IJ Therapeutics, will produce a lower cost generic of Evzio® (naloxone auto-injector), an opioid overdose antidote. A kit containing two doses will cost $178 (AWP), while Kaléo® Inc.'s brand-name naloxone auto-injector, Evzio, costs a staggering $4,100 per dose (AWP). The generic will be the same formulation and design, and meets the same standards of quality as the brand, just with a different label. The anticipated new generic and pricing will be available mid-2019.

Drug of the Month

Ajovy™ (fremanezumab-vfrm)

Ajovy (fremanezumab-vfrm) was approved by the FDA on September 14, 2018, for the preventative treatment of migraine in adults. The injectable biologic agent produced by Teva Pharmaceuticals USA, Inc. is another among similar products developed by Amgen (Aimovig™ [erenumab-aooe]) and Eli Lilly (Emgality™ [galcanezumab-gnlm]), which were both approved earlier this year. Like Aimovig and Emgality, Ajovy works by blocking the activity of calcitonin gene-related peptide (CGRP), one of the molecules involved in migraine attacks.

Ajovy is available in two different dosing options as either a once monthly or once quarterly (every three months) injection. The formulation is contained in a single-dose prefilled syringe with 225 mg/1.5 mL solution for subcutaneous use. The approved recommended dosing for Ajovy is for 225 mg to be administered once monthly or for 675 mg (three consecutive injections of 225 mg each) to be administered once quarterly. The product is intended for self-injection into the abdomen, thigh, or upper arm.

Clinical studies shown that Ajovy is generally well-tolerated with the most commonly reported adverse effects being injection site reactions. Ajovy is not yet addressed in the Official Disability Guidelines (ODG); however, it is comparable in pricing to another injectable migraine product supported as a second-line treatment option for chronic migraine sufferers: Botox® (onabotuinumtoxinA). According to Medispan, the cost (based on AWP) for a single-dose Ajovy product (pre-filled syringe) is $690 (the same as Aimovig and Emgality). First-line oral preventative migraine medications including select antidepressants, anticonvulsants, or antihypertensive agents are recommended to be a part of the patient's regimen before consideration for Ajovy.

Furthermore, biologic medications like Ajovy fall in the "specialty" drug category, and additional oversight is recommended due to the complex or costly nature of these types of drugs. The appropriateness for use of Ajovy in relation to the work injury, as well as prior treatment history, should be determined prior to coverage consideration.

Reference: https://www.accessdata.fda.gov/scripts/cder/daf/

Regulatory Update

ODG Guideline for Dsuvia: Not Recommended

On November 2, 2018, the FDA announced the approval of Dsuvia (sublingual sufentanil) for the management of acute pain in adults that is severe enough to require an opioid analgesic in medically supervised settings. Sufentanil is a synthetic opioid analgesic that is five to ten times more potent than fentanyl and estimated to be 1,000 times more potent than morphine.

The ODG recommendation statement for Dsuvia is: Not recommended as a first line therapy for acute or chronic pain. That means that Dsuvia will be an N Drug in the ODG Drug Formulary. Detailed guidance, including patient selection criteria for inpatient settings, black box warnings, dosing information, and a full-text clinical evidence summary is also included in the ODG guideline update.

Colorado

Effective January 30, 2019, Rule 17 regarding medical treatment guidelines adds new guidelines for Mild Traumatic Brain Injury and Moderate/Severe Traumatic Brain Injury. Changes include indications that medication and medical management review may be required more frequently for changes in medications.

Illinois

Senate Bill 904 adopts various reimbursement changes to 820 ILCS 305/8.2 and 820 ILCS 305/8.2a of the Workers' Compensation Act regarding fee schedule and electronic claims. The bill was adopted on November 27, 2018 and has an effective date of June 1, 2019.

Wyoming

Effective December 11, 2018, new rules WCWR 059-0002-6 and WCWR 059-0002-8 adopt partial fill and pharmacists, practitioners and appointed delegate rules. Some changes include prescriptions for controlled substances to be issued by registered or exempted practitioners, and additional requirements for partial fills of controlled substances.