

Virtual Meeting & Expo

OCTOBER 12 - 13, 2020



Handling CBD and Medical Marijuana in Non-Acute Settings

T.J. Griffin, RPH
Chief Pharmacy Officer. PharMerica

Soumi Saha, PharmD, JD

Vice President of Advocacy, Premier, Inc.



Disclosures

- T.J. Griffin is the Chief Pharmacy Officer for PharMerica and Soumi Saha is the Vice President of Advocacy for Premier, Inc. They have no relevant or apparent financial interests or relationships to disclose.
- This continuing education activity is managed by Innovatix* and AffinityCE. Innovatix* is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
- Innovatix* and AffinityCE as well as planners and reviewers have no relevant financial interest or relationships to disclose. Neither Innovatix* nor Affinity CE support or endorse any product or service mentioned in this activity. Disclosure will be made when a product is discussed for an unapproved use. T. J. Griffin will be covering off-label use of FDA approved products and use of non-FDA approved products
- The material presented for this session has been reviewed by the Innovatix* Institute CE Committee and AffinityCE and has been found to be free of any content influence or commercial bias.
- Commercial Support was not received for this activity.

^{*}Innovatix now operates under *Premier Alternate Site Programs*



Learning Objectives

- 1. Discuss legislative and regulatory proposals to legalize medical marijuana in the United States.
- 2. Identify risks to non-acute providers associated with medical marijuana.
- 3. Explain the challenges and opportunities CBD decriminalization poses on a non-acute provider.

Agenda

Cannabis Characteristics & Background

Legal & Regulatory Infrastructure

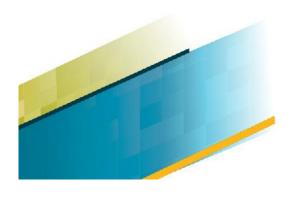
Question & Answer



Virtual Meeting & Expo

OCTOBER 12 - 13, 2020

Cannabis Characteristics & Background





Virtual Meeting & Expo

OCTOBER 12 - 13, 2020







































Pharmacist Formulated CBD





PHYTOCANNABINOIDS

PHYTOCANNABINOIDS, OR EXOGENOUS CANNABINOIDS, ARE PLANT-DERIVED CANNABINOIDS PRODUCED BY GLANDULAR TRICHOMES COVERING THE SURFACE OF THE CANNABIS PLANT, MORE THAN 100 CANNABINOIDS HAVE BEEN DISCOVERED IN THE CANNABIS PLANT.

Phytocannabinoids 🗼



The cannabis plant and other plants produce cannabinoids, which interact with our body's receptors. These plant cannabinoids are known as phyto-cannabinoids. Phyto is a prefix that means "pertaining to derived from plants". They are categorized as any plant-derived natural product with the capability to directly interact with the body's cannabinoid receptors or share chemical similarity with cannabinoids.

Furthermore, phytocannabinoids from cannabis have significantly influenced research on the endocannabinoid system. So far, they have become widely known for their medicinal properties in recent years. In particular, the cannabis plant contains over 400 chemical entities, and more than 60 of them are cannabinoid compounds, which have varying effects.











Cannabidivarin

Cannabidiolic acid Cannabichromene

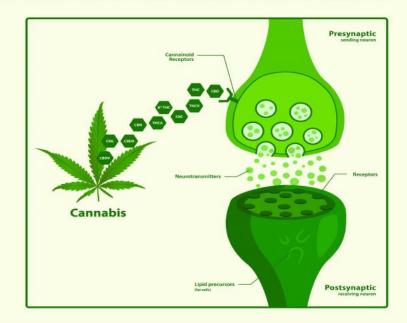








Cannabinol





Definitions

- Cannabidiol (CBD): The non-psychoactive component of cannabis
- Cannabidiolic Acid (CBDA): Acidic precursor to CBD. Converts to CBD through decarboxylation.
- Nabiximols: A herbal preparation containing a defined quantity of specific cannabinoids. Contains a standardized extract of tetrahydrocannabinol (THC), cannabidiol (CBD), other minor cannabinoids, flavonoids, and terpenes from two cannabis plant varieties.
- Tetrahydrocannabinol (THC): main psychoactive compound in marijuana
- Tetrahydrocannabinol acid (THC-A): non-intoxicating precursor that becomes THC molecules as they are exposed to heat over a prolonged period of time, often by way of smoking.
- Terpenes: aromatic organic hydrocarbons found in cannabis



FDA Approved Formulations

Product	Indication
Dronabinol (Marinol/Syndros) – CIII Synthetic THC	 Anorexia associated with weight loss in AIDS patients CINV failed to respond adequately to conventional antiemetic treatments
Nabilone (Cesamet) – CIII Synthetic THC	- Refractory CINV nausea and vomiting
Cannabidiol (Epidiolex) — Federally descheduled 4/6/2020 CBD (>99%)	 Seizures associated with Lennox-Gastaut Syndrome or Dravet Syndrome in patients 2YO



Hemp vs Marijuana

HEMP vs MARIJUANA

HEMP AND MARIJUANA BOTH DERIVE FROM THE CANNABIS SATIVA FAMILY, THEY DO SHARE CERTAIN SIMILARITIES, HOWEVER, DUE TO EACH PLANT'S BIOLOGICAL STRUCTURE, THEY HAVE SEVERAL VERY DISTINCT AND CRUCIAL DIFFERENCES.



HEMP

Low THC content (<0.3%)

Non-psychoactive

Adaptable growing

Used for clothing, body care, hemp oil, CBD oil



MARIJUANA

Higher THC content (5-35%)

Psychoactive

Careful growing

Used for medical and recreational purposes



Hemp vs Marijuana Based Products

Hemp Seed Oil	Hemp Based CBD	Marijuana Based CBD/THC-A (VA)	
Trace amounts CBD	Typically contains approx. 3.5% CBD	prox. 3.5% CBD Oil: ≥15% CBD; ≤ 5% THC (from extract) ≥5mg/ml CBD, ≤ 5% THC (from resin)	
0% THC	Must contain < 0.3% THC (dry weight)	THC-A Oil: >15% THC-A; < 5% THC (from extract) >5mg/ml THC-A, < 5% THC (from resin)	
	Few terpenes	More terpenes	
Typically utilized in food products	Effective December 2018, legal in US in dosage forms other than supplements and food	Considered CI at federal level. Medical use legalized/decriminalized at state level (including VA)	



Hemp vs Marijuana Based Products

Hemp Seed Oil	Hemp Based CBD	Marijuana Based CBD/THC-A (VA)	
Manufacturing not regulated	Manufacturing not regulated	Regulated at state level (Board of Pharmacy)	
Often contain pesticides, heavy metals, petroleum based products	Often contain pesticides, heavy metals, petroleum based products	Labeling must include whether product passed/failed microbiological, mycotoxin, pesticide and toxic metal testing (Arsenic, Cadium, Lead, Mercury)	
Rarely includes ingredients on label	May include ingredients on label	Must include ingredients on label: THC THC-A CBD CBDA Any other active ingredients comprising >1% of batch	

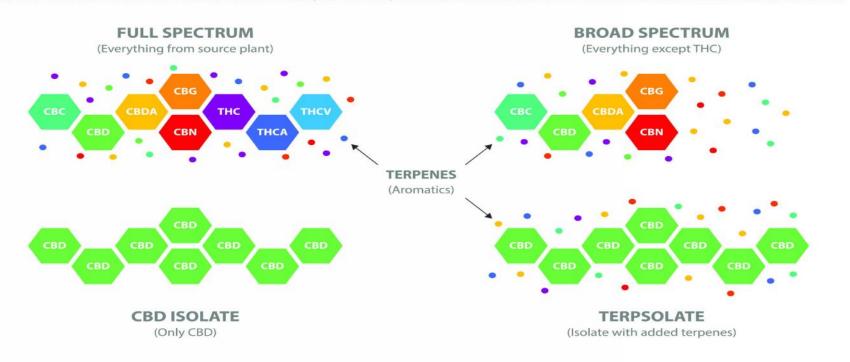


The Difference of Cannabinoids Spectrum Options

THE DIFFERENCE OF CANNABINOIDS SPECTRUM OPTIONS



THERE ARE DIFFERENT CANNABINOID SPECTRUM OPTIONS TO CHOOSE FROM WHICH ARE FULL-SPECTRUM, BROAD-SPECTRUM CBD, CBD ISOLATE AND TERPSOLATE, WHILE THESE FOUR TYPES OF PRODUCTS MAY SOUND SIMILAR BUT THERE ARE ACTUALLY APART FROM EACH OTHER.





Hemp-Based CBD

- Hemp-based CBD Products
 - Full Spectrum is unmodified hemp extracts with <0.3% THC
 - Broad Spectrum is nearly identical but with ZERO THC
 - Lack of state and federal oversight of formulations, potency, harmful compounds
 - Louisiana requires CBD products to have a scannable QR Code linking the product to a Certificate of Analysis
 - COA show test results identifying the cannabinoid profile by percentage of dry weight, solvents, pesticides, microbials and heavy metals
 - FDA has officially classified CBD as a drug, so it cannot be used in dietary supplements under existing legislation. HR5587 would amend FDCA would allow FDA to regulate CBD that comes from Hemp as a dietary supplement
 - Oral formulation currently a violation of FDA regulation



Labeling Accuracy of Cannabidiol Extracts Sold Online

https://jamanetwork.com/journals/jama/article-abstract/2661569

Research Letter

November 7, 2017

Labeling Accuracy of Cannabidiol Extracts Sold Online

Marcel O. Bonn-Miller, PhD; Mallory J. E. Loflin, PhD; Brian F. Thomas, PhD; Jahan P. Marcu, PhD; Travis Hyke, MS; Ryan Vandrey, PhD;

Author Affiliations

JAMA. 2017;318(17):1708-1709. doi:10.1001/jama.2017.11909

There is growing consumer demand for cannabidiol (CBD), a constituent of the cannabis plant, due to its purported medicinal benefits for myriad health conditions. Viscous plant-derived extracts, suspended in oil, alcohol (tincture), or vaporization liquid, represent most of the retail market for CBD. Discrepancies between federal and state cannabis laws have resulted in inadequate regulation and oversight, leading to inaccurate labeling of some products. To maximize sampling and ensure representativeness of available products, we examined the label accuracy of CBD products sold online, including identification of present but unlabeled cannabinoids.

- · Study with 84 products purchased and analyzed from 31 companies
- THC detected (up to 6.43 mg/mL) in 18 of 84 samples tested

Accuracy, %	CBD Oil (n = 40)	Tincture (n = 20)	Vaporization Liquid (n = 24)	Total (N = 84)
Accurate	45	25	12.50	30.95
Under	25	40	75	42.85
Over	30	35	12.50	26.19

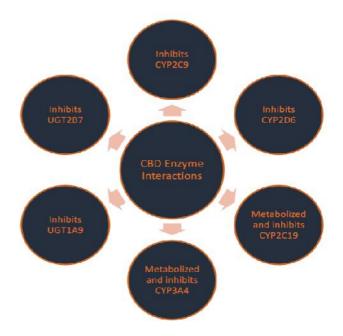
JAMA vol. 318, 17 (2017). 1708-1709



Potential Safety Concerns

- Drug Interactions
 - Hepatic metabolism pathway (CYP450)
- Low blood pressure
- Dry mouth
- Increase in tremors
- Sedation
- Lightheadedness
- Variable potency/components/contaminants
- (hemp based)
- Very little clinical research exists

CBD INTERACTIONS



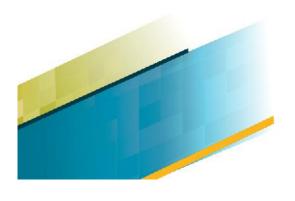


Polling Question

Which of these FDA Approved Formulations is **Not** a DEA Schedule Product?

- A. Dronabinol (Marinol)
- B. Cannabidiol (Epidiolex)
- C. Hydrocodone/Acetaminophen (Vicodin)
- D. Nabilone (Cesamet)
- E. Dronabinol (Syndros)

Legal & Regulatory Infrastructure





Virtual Meeting & Expo

OCTOBER 12 - 13, 2020

Illegalization at the Federal Level



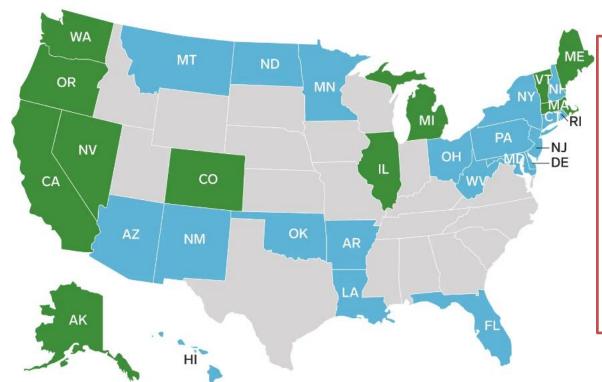
1937 – Congress passed the Marijuana Tax Act and officially made the use of marijuana illegal in all forms.

1969 – The US Supreme Court essentially determined that the Marijuana Tax Act was unenforceable.

1970 – Existing drug laws were consolidated, and cannabis was classified as a Schedule I substance under the Controlled Substances Act confirming its illegal status in all forms.

Legalization at the State Level





Legalization by the numbers:

33 states + DC – legalized medical marijuana

11 states + DC – legalized recreational marijuana & decriminalized

11 states – fully illegal

Source: Business Insider. As of December 2019.



Legalization at the State Level

- Medical marijuana laws differ greatly from state to state
- In general, recreational marijuana laws are more uniform and patterned after retail sale and use of alcohol
 - The purchaser must be at least 21 years of age;
 - The amount that can be possessed in public is generally around one ounce;
 - Retailers must be licensed by the state;
 - Driving under the influence of marijuana is prohibited;
 - Use in or near schools and other public locations is prohibited;
 - Local municipalities can prohibit use and sale;
 - Open container laws pertain; and
 - Most states permit purchases by nonresidents.

State vs Federal Law



The Doctrine of Preemption – If a state or local law is inconsistent with federal law, the state or local law may be declared unconstitutional. The federal law will preempt, or supersede, the state or local law.

State vs Federal Law



The Doctrine of Preemption – If a state or local law is inconsistent with federal law, the state or local law may be declared unconstitutional. The federal law will preempt, or supersede, the state or local law.

If federal law supersedes state law, then how is marijuana legal in some states?



2005 – US Supreme Court decision in *Gonzalez vs Raich* ruled that under the Commerce Clause of the US Constitution, Congress may criminalize the production and use of homegrown cannabis even if state law allows its use for medicinal purposes. Confirmed that federal law supersedes state law.

2009 – DEA announced that it would deprioritize marijuana prosecutions of persons complying with existing state laws for the use of medical marijuana

"(a)s a general matter, pursuit of these priorities should not focus federal resources in your States on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana. For example, prosecution of individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable state law, or those caregivers ... who provide such individuals with marijuana, is unlikely to be an efficient use of limited federal resources."



2012 – Colorado sought an advisory opinion from the Justice Department prior to legalizing recreational marijuana.

"The Department will continue to enforce the CSA but will not challenge the state's ability to regulate the retail marijuana industry under state law, based on the expectation that state and local governments would implement strong, effective regulatory and enforcement systems to address public safety, public health and other public interest.

The Justice Department, however, maintained eight enforcement priorities:

1) Preventing distribution of marijuana to minors; 2) Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels; 3) Preventing the diversion of marijuana from states where it is legal under state law in some form to other states; 4) Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity; 5) Preventing violence and the use of firearms in the cultivation and distribution of marijuana; 6) Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use; 7) Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and 8) Preventing marijuana possession or use on federal property.



2018 – US Attorney General Jeff Sessions issued a memorandum

CSA and other statutes "reflect Congress's determination that marijuana is a dangerous drug and that marijuana activity is a serious crime" and that "previous nationwide guidance specific to marijuana enforcement is unnecessary and is rescinded, effective immediately"

2018 – Congress passed the Agriculture Improvement Act (Farm Bill) removing hemp containing <0.3% THC from the Controlled Substances Act. This legalized hemp-derived products (e.g. CBD) *if and only if* the hemp is produced in a manner consistent with the Farm Bill, associated state and federal regulations, and produced by a licensed grower.



2019 – House Judiciary Committee passed the MORE Act. The bill would remove cannabis from the Controlled Substances Act, expunge past federal convictions related to cannabis, establish a Cannabis Justice Office, implement a 5% federal tax on sales, permit loans through the Small Business Administration, and permit VA physicians to prescribe medical marijuana.

 The House was scheduled to vote on the MORE Act in September 2020 but opted to delay the vote until after the Presidential election

2020 – House passed the SAFE Banking Act. The bill would allow banks and insurance companies to offer their services to marijuana-related businesses without running afoul of federal law.

The bill now goes to the Senate for consideration



Will federal non-enforcement of state marijuana laws continue?





FDA Regulation of Marijuana

- The FDA does not regulate cannabis with >0.3% THC as it is federally illegal
- With the passage of the Farm Act, FDA is technically tasked with regulating hemp containing <0.3% THC, including CBD
 - The FDA has approved only one CBD product, a prescription drug product to treat two rare, severe forms of epilepsy.
 - It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement. The FDA has issued warning letters to companies illegally selling CBD products in interstate commerce that claimed to prevent, diagnose, mitigate, treat or cure serious diseases, such as cancer, or otherwise violated the FD&C Act.
 - The FDA is continuing to evaluate the regulatory frameworks for products containing cannabis and cannabis-derived compounds.
 - The FDA has stated that CBD is not generally recognized as safe.



FDA Regulation of Marijuana

- FDA recently said it could not issue a final response to a petition filed by the Consumer Healthcare Products Association seeking regulations to allow CBD products to be marketed as dietary supplements
 - FDA maintains that CBD cannot be marketed as a food or supplement because it is an active ingredient in Epidiolex, an FDA-approved drug for treating pediatric epilepsy
 - CHPA petition also requested:
 - A statement that hemp-derived CBD is lawful under the Food, Drug and Cosmetic Act.
 - FDA maintain new drug application protections for CBD medicines
 - FDA increase enforcement actions against "unscrupulous manufacturers."
- Potential FDA action on vaping devices may also impact marijuana and CBD vaping



Polling Question

Which of the following statements is true?

- A. The FDA has approved only one CBD product, a prescription drug product to treat two rare, severe forms of epilepsy.
- B. It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement.
- C. The FDA is continuing to evaluate the regulatory frameworks for products containing cannabis and cannabis-derived compounds.
- D. The FDA has stated that CBD is not generally recognized as safe.
- E. All of the above



CMS Regulation of Marijuana

- As long as marijuana is federally illegal, federally funded health programs cannot cover it even if state laws permit it. This includes Medicare, Medicaid, the Veterans Administration, and Obamacare plans.
- CMS can take action against hospitals, health systems, providers, pharmacies, non-acute facilities, etc. for violation of the Controlled Substances Act and revoke participation in CMS programs.
 - Thus far, CMS has not taken action against healthcare entities.



Polling Question

To date, how many healthcare entities has CMS acted against for violation of the Controlled Substances Act and revoked participation in CMS programs?

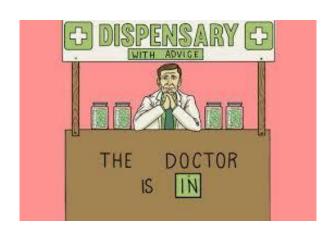
- **A**. 0
- B. 10
- C. 50
- D. 100
- E. 100+



Personnel Considerations

The role of a medical professional vs a budtender?

- Most states do not require the involvement of a medical profession in the selection or dispensing of marijuana.
- Most states permit physicians to recommend marijuana for medicinal use, not prescribe it.
- Medical professionals involved in the prescribing, dispensing, sale or other activities involving marijuana can face criminal charges for violation of the Controlled Substances Act. States may also take action on professional licenses.
- Some states have passed laws to protect hospital staff from criminal punishment if they allow patients access to marijuana.
- Budtenders have limited requirements for education and training.





Additional Legal Considerations

Americans with Disabilities Act (ADA) - Marijuana use is not protected under the ADA and employers may still require drug tests and can make employment decisions based upon the results.



Financial - Banks are subject to Federal regulations and there are restrictions on credit card use and banks can be prosecuted for providing accounts to marijuana related businesses. The IRS also has restrictions on deductible business expenses for marijuana sellers.

Personal Possession - Possession is limited to a private residence or establishment. In most states, possession in a leased property is subject to the terms of the lease and the landlord's permission.

TSA - If marijuana is found in someone's belongings, they can be asked to dispose of the material and can face arrest.

Postal Service - Marijuana cannot be mailed and individuals attempting to send marijuana through the mail can face federal charges.



Handling Marijuana & CBD in Non-Acute Facilities?

› Marijuana

- Remains federally illegal and therefore should NOT be permitted into facilities or administered due to risks associated with potential loss of federal funding for the non-acute facility
- Exception: FDA approved drugs containing THC

> CBD

- Now legal at the federal level if it contains <0.3% THC and therefore can be permitted into facilities and administered.
- Note: There is a gray area right now as FDA has yet to publish regulations. Therefore, this may change in the future and additional restrictions may be placed on CBD in the future.



Handling Marijuana & CBD in Non-Acute Facilities? Marijuana

- Remains federally illegal and therefore should NOT be permitted into facilities or administered due to risks associated with potential loss of federal funding for the non-acute facility
- Exception: FDA approved drugs containing THC

> CBD

- Now legal at the federal level if it contains <0.3% THC and therefore can be permitted into facilities and administered.
- Note: There is a gray area right now as FDA has yet to publish regulations. Therefore, this may change in the future and additional restrictions may be placed on CBD in the future.

As a best practice, non-acute facilities should consider implementing policies and procedures outlining how it will handle marijuana & CBD in the healthcare setting.



Notable Trends

- In states that have legalized marijuana for recreational use, most dispensaries have shifted business models from a medicinal dispensary to a recreational dispensary. Most patients have also foregone obtaining marijuana via medicinal routes and instead opt to purchase it recreationally.
- Things to consider:
 - Does this create challenges and limit access for patients under 21?
 - Does this create challenges for medical professionals to track which patients are or are not using marijuana as part of their healthcare regimen?
 - In states where marijuana remains illegal, will they skip legalization for medicinal purposes and instead go straight to recreational legalization?



Marijuana is federally considered illegal.



Marijuana is federally considered illegal.

Several states have passed laws legalizing marijuana for medicinal and recreational use.



Marijuana is federally considered illegal.

Several states have passed laws legalizing marijuana for medicinal and recreational use.

Federal enforcement of marijuana state laws has been passive and hands-off in recent years. However, this may change at any point.



Marijuana is federally considered illegal.

Several states have passed laws legalizing marijuana for medicinal and recreational use.

Federal enforcement of marijuana state laws has been passive and hands-off in recent years. However, this may change at any point.

The FDA is developing a framework for regulating CBD.



Marijuana is federally considered illegal.

Several states have passed laws legalizing marijuana for medicinal and recreational use.

Federal enforcement of marijuana state laws has been passive and hands-off in recent years. However, this may change at any point.

The FDA is developing a framework for regulating CBD.

Non-acute facilities can lose CMS funding for violation of the Controlled Substances Act.



Marijuana is federally considered illegal.

Several states have passed laws legalizing marijuana for medicinal and recreational use.

Federal enforcement of marijuana state laws has been passive and hands-off in recent years. However, this may change at any point.

The FDA is developing a framework for regulating CBD.

Non-acute facilities can lose CMS funding for violation of the Controlled Substances Act.

As a best practice, non-acute facilities should consider implementing policies and procedures outlining how it will handle marijuana in the healthcare setting.

Key References

- https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476
- Andre C. M., Hausman J.-F., Guerriero G. (2016). Cannabis sativa: the plant of the thousand and one molecules. Front. Plant Sci. 7, 19. 10.3389/fpls.2016.00019
- https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms
- https://www.epidiolex.com/sites/default/files/pdfs/0820/EPX-03645-0820 EPIDIOLEX %28cannabidiol%29 USPI.pdf
- Devinsky O., Cross J. H., Laux L., Marsh E., Miller I., Nabbout R., et al. (2017). Trial of cannabidiol for drug-resistant seizures in the dravet syndrome. New Engl. J. Med. 376 (21), 2011–2020. 10.1056/NEJMoa1611618
- https://anandahemp.com/pages/what-are-cannabinoids
- https://www.dementiacarecentral.com/assisted-living/cbd-usage
- > https://anandahemp.com/blogs/news/cbd-vs-thc-exploring-the-differences
- Cannabidiol Drugs Clinical Trial and Outcomes and Adverse Effects; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7053164/
- https://www.cbdcentral.com/most-compelling-cbd-studies/

Question & Answer



Thank you!

T.J. Griffin, RPH
Chief Pharmacy Officer,
PharMerica

Soumi Saha, PharmD, JD Vice President of Advocacy, Premier, Inc.