#### Medical Cannabis & Mito Disease

Mechanism of action, legalities and other need to knows

#### Fran D. Kendall, M.D.

Clinical Biochemical Genetics Metabolic, Mitochondrial & Inherited Disorders

VMP Genetics - Founder, Managing Director University of Georgia - Adjunct Assistant Professor

### Disclaimer

Dr Kendall and VMP Genetics have no financial interest in any laboratory.

Dr Kendall is a paid consultant to Stealth BioTherapeutics, Inc.



# Warning

The following information is not meant to be recommendations or a substitute for professional advice and services rendered by qualified doctors, lawyers, allied medical personnel, and other professional services. The responsibility for any use of this information, or for proper medical treatment or legal advice, rests with you.

### Historical Perspectives of Marijuana

- Antiquity references dating to Chinese in 1500 BC, Greeks and Egyptians
- Brought to North American via Jamestown settlement in early 1600's
- Addition to US pharmacopia in 1850 with subsequent removal in 1942
- Criminalization with Boggs Act in 1952 and Narcotics Control Act in 1956
- Identification of psycho-active ingredient of Cannabis, Delta-9 tetrahydrocannabinoid or THC in mid 1960's
- Legalization of medical marijuana in California in 1996
- Colorado legalizes both medical and recreational use of marijuana in 2012
- Legalization of medical marijuana in Georgia on April 16, 2015 for use in 8 diseases, including mitochondrial disease.

### Mechanism of Action of Marijuana

- Human body contains two forms of receptors for cannabinoids, CB1 and CB2
- We have several naturally occurring cannabinoids known as endocannibinoids to include anandamide, that stimulate these receptors.
- Over 80 cannabinoids, known as phytocannabinoids, are found in the cannabis plant. Including the best known and most psychoactive, THC.
- THC, THCa and CBD are the most widely used cannabinoids for medicinal purposes.
- THC has been used medicinally as a muscle relaxant, pain reliever, appetite stimulant and anti-emetic.
- THCa is a non-pyschoactive form of THC and is used for anti inflammatory, antiproliferative and antispasmodic effects.
- CBD, or cannabidiol, is used for seizure control. It has no psychoactive properties.

## **CBD** and Seizure Management

- Evaluation of 213 children and adults with 12 different forms of severe epilepsy including Dravel syndrome and Lennox-Gastaut treated for 12 weeks with daily CBD.
- 137 completed the study with a 54% reduction in seizure activity.
- Convulsive seizures fell by 53% in the 23 patients with Dravet syndrome.
- Atonic seizures were diminished by 55% in the 11 patients with Lennox-Gastaut.
- 12 patients discontinued the cannabis due to intolerance citing drowsiness (21%), diarrhea (17%), fatigue (17%) and decreased appetite (16%) as the primary causes.

#### Mito and Medical Cannabis

- Most data is anecdotal but it appears to improve seizure control, pain relief and GI functionality.
- A recent German study suggests that exposure to cannabis can improve mitochondrial function in rodent models.
- The activation of the brain's cannabinoid systems triggers the release of antioxidants and may eliminate the brain inflammation seen with a number of neurodegenerative disorders, potentially including mitochondrial disease.

## **Dosing and Safety Information**

- Dosing of cannabis is based on patient weight and type of cannabinoid to be used.
- Cannabinoids are typically administered several times per day.
- Drowsiness, fatigue, agitation and diarrhea are the most common side effects although 10% of patients on high dose THC can experience seizures.
- Cannabinoids can be administered by smoking or using edibles, oils, tinctures and topicals in the form of a patch, gel or salve/cream.

## General Legalities

- Cannabis is still a schedule I substance
- 23 states have comprehensive medical marijuana programs
- 13 states have limited programs which restrict the amount of THC allowed in available products and limit the mechanism of delivery to oil.
- In these 13 states with restricted programs, patients can only acquire their cannabis out of state or risk prosecution under federal law. However, some companies are shipping their products to other states but they may face prosecution by the DEA if they elect to enforce the law.

## The New Georgia Law

- Haleigh's Hope Act, consisting of three components, was signed into law on April 16, 2015
- Part one includes participation in the Epidolex trial which is evaluating effectiveness of highly purified CBD in liquid form created by GW Pharma in seizure patients.
- Part two allows possession of up to 20 ounces of cannabis oil with no more than 5% THC with at least the same amount of CBD for patients with one of eight qualifying conditions, including mitochondrial disease.
- Part three legislates the creation of an in depth plan by December 31, 2015 for the development of a GA instate cannabis cultivation and distribution program.

### CARERS Act of 2015

- There is no unifying Federal law regarding the medicinal or recreational use of marijuana.
- The CARERS (Compassionate Access Research Expansion and Respect States) Act of 2015 was recently introduced into the House of Representatives (H.R. Bill 1538).
- The bill would allow states to legalize marijuana for medical use without federal interference, permit interstate commerce in CBD oils, reschedule marijuana to a schedule II substance, allow banks to provide checking accounts and other financial services to marijuana dispensaries, allow VA physicians to recommend medical marijuana to vets, and eliminate barriers to medical research.

### Procuring a Safe Cannabis Product

- Find a legitimate vendor
- Know the lab that is testing the cannabis product
- Know which laboratory tests are needed to ensure a safe product

# **Product Testing**

- Potency testing how concentrated is the product?
- Microbial testing is there fungus, mold, bacteria or yeast in your product?
- Residual solvent testing does any ethanol, butane or hexane remain in your cannabis?
- Heavy metal testing if grown outdoors does your cannabis product have residual arsenic, mercury or lead in it?

#### Thank You!

Follow the latest at facebook.com/vmpDrKendall



Fran D. Kendall, M.D.

www.vmpgenetics.com

info@vmpgenetics.com

404.720.0820 voice | 866.744.5665 fax