



COMPASSIONATE MEDICINE

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Medical Cannabis Education



## “Cannabinoids as antioxidants and neuroprotectants”

“The **cannabinoids** are found to have particular application as **neuroprotectants**, for example in **limiting neurological damage** following ischemic insults, such as **stroke** and **trauma**, or in the treatment of neurodegenerative diseases, such as **Alzheimer's disease**, **Parkinson's disease** and **HIV dementia**. ”

<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetacghtml%2FPTO%2FSrchnum.htm&r=1&f=G&l=508&s1=6630507.PN.&OS=PN/6630507&RS=PN>

“ We have some preliminary data showing that for certain medical conditions and symptoms, that **marijuana can be helpful.** ”

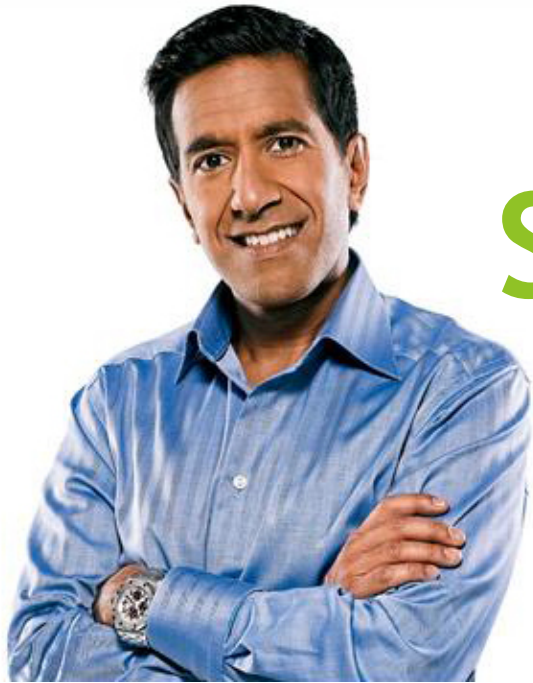
“ I think that we have to use that data to drive policymaking ”

“CBS This Morning” February 4<sup>th</sup> 2015



**Dr. Vivek Murthy**

**U.S. Surgeon General**



# Sanjay Gupta

Medical Doctor & Host of CNN's "Sanjay Gupta, M.D."

“ Marijuana doesn't have a high potential for abuse, and there are very legitimate medical applications. In fact, sometimes marijuana is the only thing that works... It is irresponsible not to provide the best care we can as a medical community, care that could involve marijuana. **We have been terribly and systematically misled for nearly 70 years in the United States, and I apologize for my own role in that.** ”





# Raphael Mechoulam

Israeli Chemist & Professor of Medicinal Chemistry at  
Hebrew University of Jerusalem in Israel

“The work on the plant has now led to the identification of a major physiological system (the endocannabinoid system), which seems to be involved in many human diseases.”

**40+** years of **US Taxpayer funding** allowed **Dr. Mechoulam** to discover:

- ▶ **THC (1964)**  
(Tetrahydrocannabinol)
- ▶ **Anandamide**  
(Cannabinoid produced within human body)
- ▶ **Endocannabinoid system (1992)**

# Why is the Endocannabinoid System Important?

- **Stanford University** study on mice found that disruptions in the endocannabinoid system may lead to autistic like behaviors.



Meet **Alex**  
**Parents gave up** until another asked if they had tried cannabis. Now look at that smile again. Things are not perfect, but they're better.

[http://www.huffingtonpost.com/2012/09/27/marijuana-chemical-autism-fragile-x\\_n\\_1920320.html](http://www.huffingtonpost.com/2012/09/27/marijuana-chemical-autism-fragile-x_n_1920320.html)  
<http://www.alexneedshelp.com/about-alex#.Vj78kq6rSDU>

# Federal Medical Cannabis Program

*Ole Miss.*

University of Mississippi

- ▶ Sole provider of cannabis to **Federal medical cannabis program** & studies **since 1968**
- ▶ Administered by the National Institute Drug Abuse (NIDA)



## **Dr. Mahmoud ElSohly**

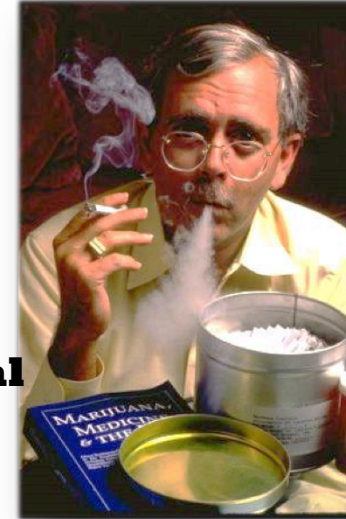
- ▶ Head of cannabis program since **1981**
- ▶ Contracted through NIDA to cultivate & study cannabis @ the University of Mississippi



# Federal Cannabis Patients

**1976 Federal Judge** James Washington: “While blindness was shown by competent medical testimony to be the otherwise inevitable result of the defendant's disease, no adverse effects from the smoking of marijuana have been demonstrated...**Medical evidence suggests that the medical prohibition is not well-founded.**”

**1976** Robert Randall became **1<sup>st</sup>** legal **federal medical cannabis patient.**



**1991** Barbara Douglass has MS & receives 9oz every 25 days

**1990** George McMahon has nail patella syndrome & receives 8oz every 25 days

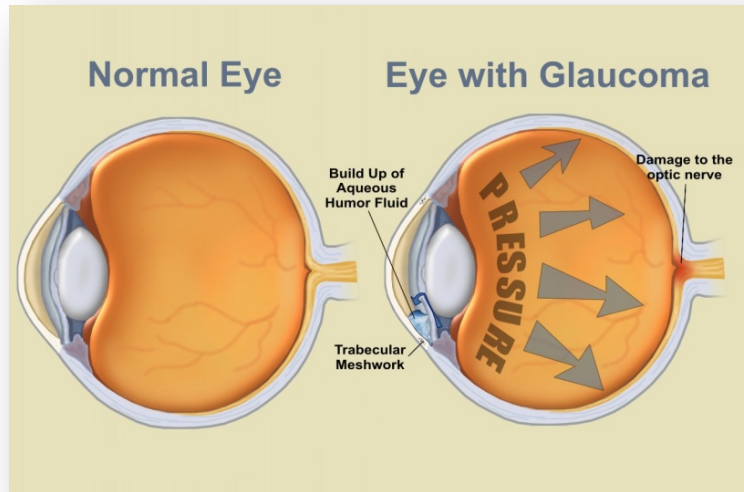


**1988** Elvy Musikka has glaucoma & receives 8oz every 25 days



**1982** Irvin Rosenfeld has hundreds of tumors & receives 9oz every 25 days. Testified before KY interim H&W committee in 2013

# Glaucoma & Cannabis



- ▶ American Glaucoma Society stated: “It has been **definitely demonstrated**, & widely appreciated, that **smoking marijuana lowers Intra Ocular Pressure (IOP)** both in normal individuals & in those with glaucoma & therefore might be a treatment for glaucoma.”

[http://www.americanglaucomasociety.net/patients/position\\_statements/marijuana\\_glaucoma](http://www.americanglaucomasociety.net/patients/position_statements/marijuana_glaucoma)

- ▶ KY citizen/patient Eric Crawford was told by **Dr. Kaplan**, Director & chairman Department Ophthalmology & Visual Sciences @ UofL, that **he would go blind** due to his glaucoma if he does not resume consuming cannabis.



# Neuropathic Pain & Cannabis

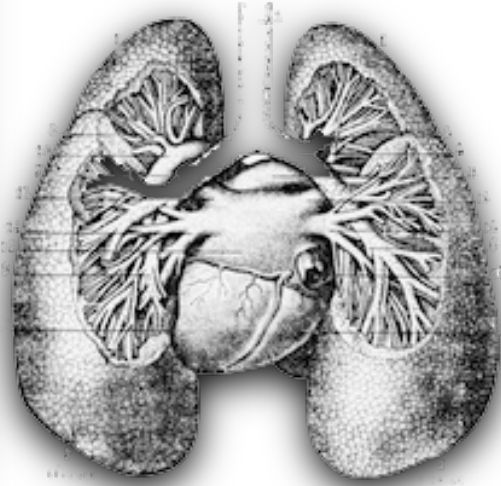


- ▶ FDA, DEA, NIDA, NIH approved **clinical trial**
- ▶ Found **smoked/vaporized whole cannabis** to be an **analgesic** useful in treatment of neuropathy due to **spinal cord injury, HIV, & Multiple Sclerosis**
- ▶ “We now have reasonable evidence that **cannabis is a promising treatment** in selected pain syndromes caused by injury or diseases of the nervous system, & possibly for painful spasticity due to multiple sclerosis.”

<http://www.cmcrc.ucsd.edu/>



# Cannabis Smoke Cause Lung Damage?



## Donald P. Tashkin

American pulmonologist

- ▶ **30+** year FDA/DEA/NIDA/NIH cannabis lung study with over **5000 patients**

<http://www.atsjournals.org/doi/abs/10.1513/AnnalsATS.201212-127FR#.VMamWkfF-Sp>  
<http://www.washingtonpost.com/wp-dyn/content/article/2006/05/25/AR2006052501729.html>

- ▶ Initially **set out to prove harmful** to lungs
- ▶ **Proved was protective**
- ▶ Even very heavy marijuana smokers showed **no increased** incidence of the 3 cancers studied
- ▶ Found **protective effect** against cancers possibly due to **thc killing** aging cancerous cells
- ▶ **No** clear link to COPD
- ▶ Cannabis use **leads to an increase** in ability to **inhale** while tobacco use leads to decreased ability to inhale

# Many ways to use cannabis



Edibles



Cannabis Tincture



Vaporized



Cannabis Oil aka Rick Simpson Oil (RSO)



Transdermal Patch



Smoked



Salves



Suppository



Raw Juicing

# FDA Approved Cannabinoids



- **Dronabinol (Marinol)** is synthetic **thc**, approved by fda in **1985** used to treat AIDS wasting syndrome and nausea/vomiting caused by cancer chemotherapy.

<http://www.marinol.com/>

- **Nabilone (Cesamet)** is synthetic **thc** approved by fda in **1985** for treatment of chemotherapy induced nausea and vomiting.
- Also used to treat neuropathic pain

<https://www.nlm.nih.gov/medlineplus/druginfo/meds/a607048.html>



**Both are highly cost restrictive**



# Experimental Cannabis Medications



- **Epidiolex (cannabidiol)** - 98% CBD extract from cannabis for use in severe epilepsy; granted Orphan drug status by FDA; Approx. 420 IND patients & 225 through state programs; est. **95% are 1-17 y/o**

<http://www.gwpharm.com/Epidiolex.aspx>

- **NKY pediatric epilepsy patient** out of pharmaceutical options travels to Chicago to acquire Epidiolex monthly.
- **Maxed out on epidiolex** & still having seizures
- In need of other varieties/concentrations of cannabis oil.



# Experimental Cannabis Medications



**Sativex (nabiximols)**- is a **whole plant cannabis extract** with an equal 1:1 ratio of THC to CBD. Approved in U.K. for M.S. related spasticity & pain. Granted fast track designation by US fda for cancer related pain. <http://www.gwpharm.com/Sativex.aspx>

- **KY cancer patient** Rob Burgin, was approved for Sativex study & then denied due to being in **too much pain** following chemotherapy.
- Shortly before his passing in 2014 his wife testified before our legislators regarding the immediate need for legal medical cannabis in KY.



# National Cancer Institute (NCI)

NCI reports suggest cannabis may **protect against the *development of certain types of tumors.***

Antitumor effects include:

- ▶ Induction cell death
- ▶ Inhibition of cell growth
- ▶ Inhibition of tumor angiogenesis invasion
- ▶ Metastasis
- ▶ Apoptosis

The logo of the National Cancer Institute, featuring the words "NATIONAL", "CANCER", and "INSTITUTE" stacked vertically in a red, serif font.

- "Cannabis and cannabinoids may have benefits in **treating the symptoms of cancer or the side effects** of cancer therapies."

Cannabinoids appear to **kill tumor cells** while protecting healthy cells from death



# National Institute on Drug Abuse (NIDA)

- ▶ **THC** increases appetite & reduces nausea
- ▶ May also decrease pain, inflammation & muscle control problems



- ▶ **CBD** may be useful in reducing pain & inflammation, controlling epileptic seizures, & possibly even treating mental illness & addictions

- ▶ Extracts of THC and CBD, when used with radiation, **increased the cancer-killing effects** of the radiation

- ▶ Marijuana extracts **kill** certain **cancer** cells & reduce size of others
- ▶ Extracts of whole-plant marijuana **can slow the growth of cancer** cells from one of the most serious types of **brain tumors**

# Can Cannabis Treat PTSD?

- ▶ **Dr. Sue Sisley** received a **\$2 million** federal grant to **study cannabis** in the treatment of **combat Veterans with PTSD**
- ▶ Subjects will **smoke/vaporize federally** grown cannabis
- ▶ Testified before the **2014 KY General Assembly** about her upcoming study



**Decorated KY Vietnam Combat Veteran** Danny “**Greasy**” Belcher, says it helps him cope with unimaginable **horrific thoughts of war.**

## 22 Veterans commit suicide a day

# Cannabis Safety Compared to Similar FDA Approved Drugs

F. TOTALS of A-E	Primary Suspect	Secondary Suspect (Contributing to death)	Total Deaths Reported 1/1/97 - 6/30/05
• TOTAL DEATHS FROM MARIJUANA	0	279	279
• TOTAL DEATHS FROM 17 FDA-APPROVED DRUGS	10,008	1,679	11,687

➤ **FDA** data confirmed **0 deaths** attributed to cannabis

<http://medicalmarijuana.procon.org/view.resource.php?resourceID=000145>

On average **1 person** dies from pharmaceuticals **every 19 minutes**

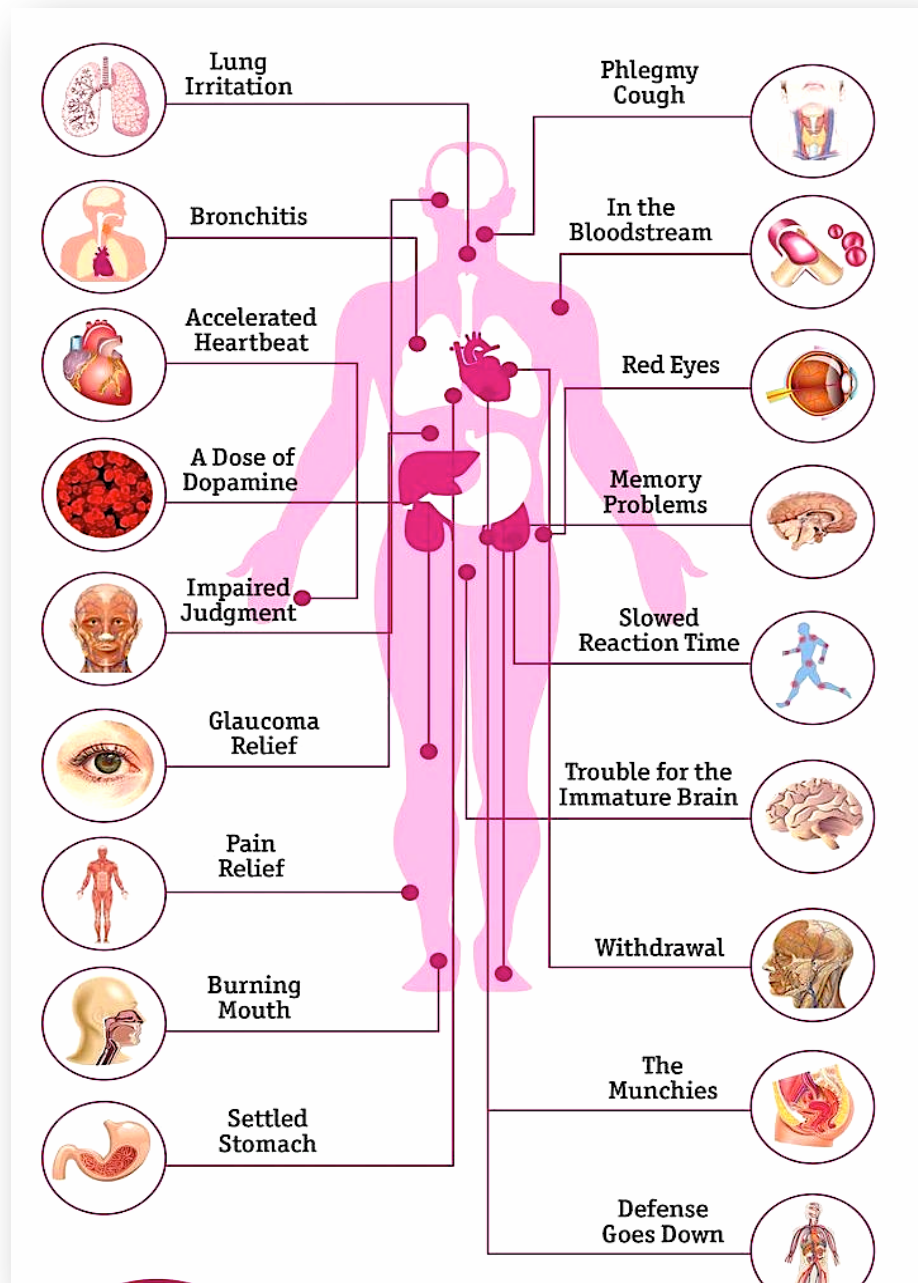
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>

➤ **24.8%** reduction in opioid **overdoses** in states with **medical marijuana** legislation which strengthened over time.

<http://archinte.jamanetwork.com/article.aspx?articleid=1898878>

# JAMA<sup>®</sup>

The Journal of the American Medical Association

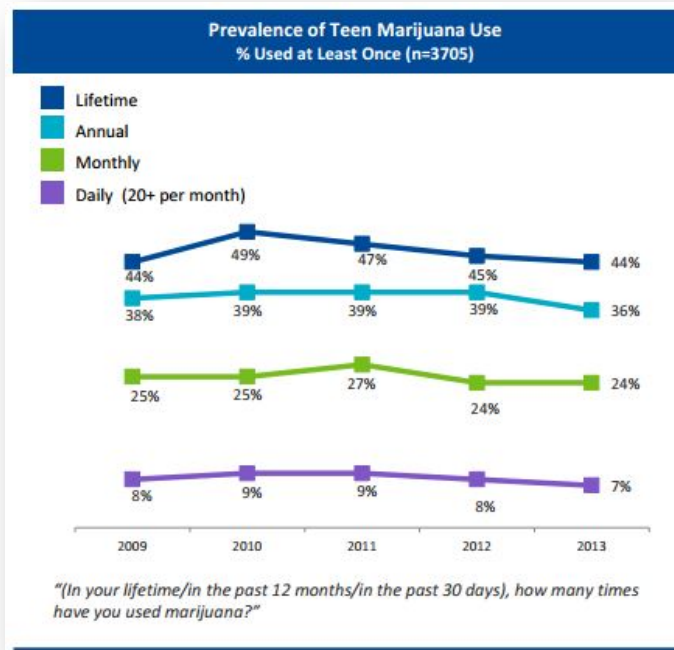


# Cannabis Side Effects

<http://www.healthline.com/health/addiction/marijuana/effects-on-body>

- There's no safe drug, but there is a safer choice.

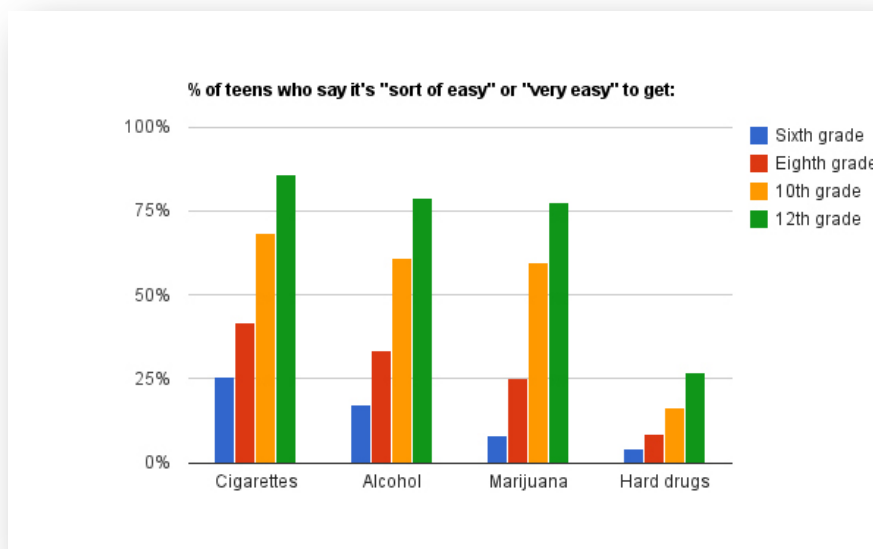
# Current KY Teenage Use



## KY Office Drug Control Policy

- ▶ **44%** Teens have tried cannabis
- ▶ **24%** Use Monthly
- ▶ **41%** Users claim started before 15 y/o

<http://www.hhs.gov/ash/oah/adolescent-health-topics/substance-abuse/states/ky.html>



- ▶ Teens claim cannabis is **easier** to find than cigarettes & alcohol.

Prohibition **DOES NOT WORK.** We need regulation & accountability



# Federal Guidelines

<http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>

**“Federal law & preemption:** state laws are not preempted unless they compel citizens to break federal law. The federal government has not argued that any state laws regulating marijuana violate this principle...”



- ▶ Preventing distribution to **minors**
- ▶ Preventing revenue of cannabis sales from criminal enterprises, gangs, & **cartels**
- ▶ Preventing **diversion** to other states
- ▶ Preventing authorized cannabis activity from being used as a cover for trafficking other illegal drugs or illegal activity
- ▶ Preventing violence & use of firearms in cultivation & distribution of cannabis
- ▶ Preventing **drugged driving**
- ▶ Preventing growing of cannabis on public lands
- ▶ Preventing cannabis possession or use on federal property



**“The Laboratories of Democracy:** federal marijuana policy gives state legislatures and voters the opportunity to implement laws that make the most sense for their own citizens.”



# Federal Licenses & Medical Cannabis

- ▶ To date no physician has been prosecuted federally for abiding by a state measure allowing them to provide a patient with a medical cannabis **“recommendation”**
- ▶ Being that a physician’s license is registered federally and cannabis is a schedule 1 drug they **may not “prescribe”** cannabis no matter the states laws. They **may only “recommend”**
  - ▶ **Conant vs. McCaffrey** [https://en.wikipedia.org/wiki/Conant\\_v.\\_McCaffrey](https://en.wikipedia.org/wiki/Conant_v._McCaffrey)
- ▶ **Pharmacies** are also federally registered and regulated therefore **may not** handle or distribute cannabis

# Cannabis Compassion Act Qualifying Conditions (DSM 5)

- ▶ Peripheral neuropathy
- ▶ **Cancer**
- ▶ Glaucoma
- ▶ Acquired Immune Deficiency Syndrome (AIDS)
- ▶ Amyotrophic Lateral Sclerosis (ALS)
- ▶ **Alzheimer's** disease
- ▶ Muscular Dystrophy
- ▶ **Seizures**
- ▶ Severe nausea
- ▶ Mood Disorder
- ▶ Lupus
- ▶ Diabetes
- ▶ Sleep Disorder
- ▶ **Parkinson's**
- ▶ Fibromyalgia
- ▶ **Autism**
- ▶ Tourette syndrome
- ▶ Crohn's disease
- ▶ **Substance use disorder**
- ▶ Terminal Illness
- ▶ Anorexia
- ▶ Post-traumatic stress disorder (**PTSD**)
- ▶ Hepatitis C
- ▶ Ulcerative colitis
- ▶ **Multiple sclerosis**
- ▶ Severe debilitating pain
- ▶ Arthritis
- ▶ Traumatic brain injury
- ▶ Anxiety disorder
- ▶ **ADD/ADHD**

# Who requires a license?

- ▶ **Patients** - KY citizen with qualifying condition
- ▶ **Caregivers** - responsible provider for qualifying patient
- ▶ **Compassion center & agents** - provides safe environment where patients obtain cannabis
- ▶ **Cultivation facility & agents** - cultivates cannabis for compassion centers
- ▶ **Safety compliance facility & agents** - checks for cannabis product quality

# Licenses Provided by KY Cannabis Enforcement Department (CED)



- ▶ Department grades all applicants
  - Based on **security, prevention of diversion, facility location**
  - Plan for: **packaging/labeling /safety**
  - Awards best proposals with a registration certificate/license
- ▶ Non refundable application **fee**
- ▶ Yearly licensing **fee**
  - ▶ KY Department of Health estimated program would cost **\$2 million funded by license fees**
  - Suggest adding **Agricultural Department** to lighten the load on the CED

# Patient Registration Example

- ▶ **Patient** acquires written recommendation signed by their **KY practitioner**, as defined by KRS 218.010, stating that they may benefit from the use of medical cannabis.
- ▶ Patient then applies for license through **KY Cannabis Enforcement Department**
- ▶ Yearly application fee applied



# Enforcement Questions

- ▶ **All** participants **must register** through the state
- ▶ Must be registered to enter any cannabis facility
- ▶ Law enforcement has **24 hour registry** access
- ▶ **NO** bill board, radio, or TV **advertisements** 
- ▶ Program fees pay for **drug prevention & education**
- ▶ Practitioners **may not refer** compassion centers or vice versa
- ▶ Any cannabis facility must be **1000ft from** property line of **schools**
- ▶ Cultivated cannabis must be in a **"Enclosed, locked facility"**
- ▶ **NO** public smoking 
- ▶ **Employers** need not cater to registered patients
- ▶ Use while driving is prohibited
- ▶ Cardholders **risk loosing license**



# Implications

- ▶ Better **quality of life** for an est. **100,000+ KY patients**
- ▶ Puts regulation in place making it **more difficult for our children** to find while allowing those who need it to use it without fear of imprisonment
- ▶ Judicial & Penal **savings**
- ▶ **Revenue** from licenses, fees, & taxes
- ▶ **Economic growth** - brand new cannabis industry that until now is **black market**
  - ▶ 15 compassion centers & 15 cultivation facilities (**one per Area Development District**) 1 year after implementation
  - ▶ After 2 years should begin applying for 1 license per 100,000 citizens throughout KY with enough cultivation facilities to provide sufficient supply.
  - ▶ Minimum 3 safety compliance facilities one East, Central, & West

Interesting side note; Every **10 Colorado patients = 1 job**

# Medical Cannabis Supporters





**Contact your legislators**  
**(800) 372-7181**



Hopkinsville KY Hemp Field 2014



COMPASSIONATE MEDICINE

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