The New Mexico Department of Health Medical Cannabis Program

The Medical Provider's Role

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History of Medical Cannabis

- Cannabis plant and its uses date to as early as 4000 BC
- Long recorded history in medical writing
- Rendered illegal in 1937
- Dropped from the US Pharmacopeia in 1941
- 1970 - Controlled Substances Act Classifies Marijuana as a Drug with "No Accepted Medical Use“
- Nov. 24, 1976 - Federal Court Rules Robert Randall's Use of Marijuana a "Medical Necessity“
- There are currently 23 states and the District of Columbia that have a medical cannabis program

History of Medical Cannabis in NM

- Passage of the Controlled Substances Therapeutic Research Act in 1978 (renamed in honor of Lynn Pierson in 1979) allowed UNMH to obtain cannabis for research & treatment of cancer patients.
- New Mexico became the 12th state to allow medical cannabis with the Lynn and Erin Compassionate Use Act in 2007 (through legislative action)
- In 2010 the Departments Rules and Regulations were revised, the number of qualifying patients exceeded 3,000.
- The Medical Cannabis Fund was signed into law in 2012, enabling the Department to apply license fees to Program operations.
- Over 900 New Mexico licensed practitioners have certified the eligibility of applicants for enrollment in the Program. There are approximately 14,000 qualified patients enrolled.

Purpose of the Program

The Lynn and Erin Compassionate Use Act (CUA):

"The purpose of the act is to allow the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments (CUA, 2007)."

* The objective of the department is to ensure the safe use and possession of cannabis for individuals living with debilitating medical conditions.

Definitions

- **Practitioner** means a person licensed in New Mexico to prescribe and administer drugs that are subject to the Controlled Substances Act, Sections 30-31-1 *et seq.*, NMSA (1978).
- **Medical Director** means a medical practioner designated by the department to determine whether the medical condition of an applicant qualifies as a debilitating medical condition eligible for enrollment in the program.

Qualifying Conditions

- **Amyotrophic Lateral Sclerosis**
- **Cancer**
- **Crohn's Disease**
- **Epilepsy**
- **Glaucoma**
- **Hepatitis C infection** *(proof of current anti-viral treatment required)*
- **HIV/AIDS**
- **Huntington's Disease**
- **Hospice Care**
- **Inclusion Body Myositis**
- **Inflammatory Autoimmune-mediated arthritis**
- **Intractable Nausea/vomiting**
- **Multiple Sclerosis**
- **Damage to the nervous tissue of the spinal cord** *(with proof of objective neurological indication of intractable spasticity)*
- **Painful Peripheral Neuropathy**
- **Parkinson's Disease**
- **Post-Traumatic Stress Disorder**
- **Severe Chronic Pain**
- **Severe Anorexia/Cachexia**
- **Spasmodic Torticollis (Cervical Dystonia)**
- **Ulcerative Colitis**

The Provider's Role

- A patient applying on the basis of having any qualifying condition must submit written certification (in the form of the patient application) from the patient's practitioner which must attest:

  (1) to the diagnosis of the medical condition;

  (2) that the condition is debilitating;

  (3) that potential risks and benefits of the use of medical cannabis for the condition have been discussed with the patient (NMAC 7.34.3.9).

- The department may verify information on each application and accompanying documentation.

Patient Statistics

Active Patients as of 5/28/2015 14,623

- New Patients approved in May 2015-749
- Re-enrolling patients approved in May 2015-755

Condition Count Status of Active Patients			
ALS	7	Ulcerative Colitis	20
Cancer	**1333**	Inflammatory autoimmune –mediated arthritis	162
Chronic Pain	**3824**	Intractable nausea/vomiting	322
Crohn's Disease	93	Multiple Sclerosis	267
Epilepsy	288	Painful Peripheral Neuropathy	650
Glaucoma	157	Parkinson's Disease	65
Hepatitis C (Under Treatment)	40	**Post Traumatic Stress Disorder**	**6682**
HIV/AIDS	341	Severe Anorexia/Cachexia	150
Hospice Care	44	Cervical Dystonia	16
Huntington's Disease	3	Spinal Cord Damage	158

Confidentiality

- *Names and contact information regarding a certifying provider shall be confidential and shall not be subject to disclosure, except:*

  - *to applicable licensing bodies, for the purpose of verifying the practitioner's licensure status, or in the event that the medical cannabis program manager or designee has reason to believe that a practitioner may have violated licensing requirements or an applicable law;*

  - *to employees of New Mexico state or local law enforcement agencies, in the event that the medical cannabis program manager or designee has reason to believe that a certifying provider may have violated an applicable law;*

  - *as provided in the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996 and applicable state and federal regulations.*

Protection

- A practitioner shall not be subject to arrest or prosecution, penalized in any manner or denied any right or privilege by the state of New Mexico, or political subdivision thereof, for recommending the medical use of cannabis or providing written certification for the medical use of cannabis pursuant to the Lynn and Erin Compassionate Use Act"

- A person shall not be subject to arrest or prosecution for a cannabis-related offense for simply being in the presence of the medical use of cannabis as permitted under the provisions of the Lynn and Erin Compassionate Use Act.

Will the federal government come after me?

U.S. Dept of Justice Memorandum Oct. 19, 2009

Subject: Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana

"As a general matter, pursuit of there 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 individual with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable state law, or those caregivers in clear and unambiguous compliance with existing state law who provide such individuals with marijuana, is unlikely to be an efficient use of limited federal resources."

Review Process

- *Within 30 days:*
  - **Program staff will verify** that all required documents are present (NM ID, Consent to release, enrollment information and certification). If documents are missing, staff will either send a letter or contact the applicant.

  - **Medical Director reviews/approves application**
    - Verifies provider's authority to certify
    - If needed, calls certifying provider for verification of the patient's medical condition, history, time in care, etc.
    - Confirms that the certifying medical provider believes that the benefits of medical cannabis usage outweigh the risks for the applicant.

  - **If denied, a formal notice is mailed to the patient.**

  - **If approved, the patient will receive;**
    - Patients registry I.D. Card
    - Contact information for licensed non-profit producers.
    - Basic Do's and Do Not's of the Program (including instructions regarding annual renewal.
    - Patients have the option of applying for a Personal Production License or buying from an LNPP.

What Enrollment Provides

- **Under Lynn and Erin Patients receive:**
  - Legal protection to possess an adequate supply which is defined in regulation as a supply of about 8 ounces (calculated in units) over a three month period.
  - The right to purchase from Licensed Non-Profit Producers.
  - The option of applying for a personal production liscense
  - The right to be is possession of any paraphernalia used in connection with their use of medical cannabis.

  A patient or primary caregiver shall be granted full legal protection if they are in possession of their medical cannabis card. If they are not in possession of their card they shall be given time to produce the card before any arrest or criminal charges (Lynn and Erin Compassionate Use Act Section 4 (D))

Patient Limitation

The statute states:

Participation in a medical use of cannabis program by a qualified patient or primary caregiver **does not** relieve the qualified patient or primary caregiver from:

(1) criminal prosecution or civil penalties for activities not authorized in the Lynn and Erin Compassionate Use Act;

(2) liability for damages or criminal prosecution arising out of the operation of a vehicle while under the influence of cannabis; or

(3) criminal prosecution or civil penalty for possession or use of cannabis:

(a) in a school bus or public vehicle;

(b) on school grounds or property;

(c) in the workplace of the qualified patient's or primary caregiver's employment; or

(d) at a public park, recreation center, youth center or other public place.

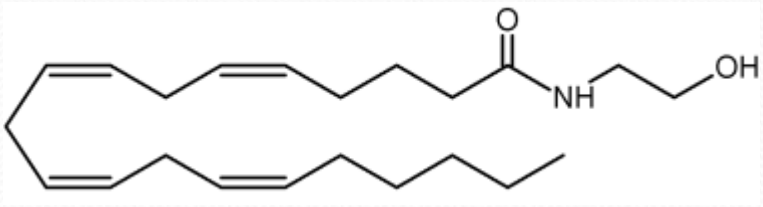
**This does not offer protection from housing, employment, patient sales, ect.*

Notice

- The following information is based upon review of published studies.
- The information such as sample size is limited and the studies are not recognized legally as cannabis is still illegal at a federal level.
- The following are not recommendations by the Department of Health, rather information as to how cannabis MAY effect a person.

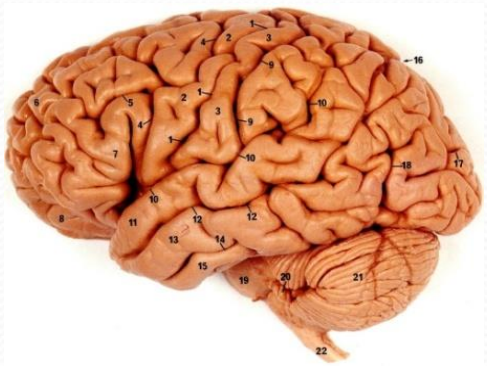
Endocannabinoids

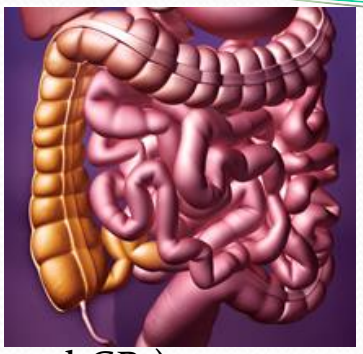
- Natural substances produced by the body
- Bind to receptors throughout the body
- No receptors in brainstem
- Exogenous cannabis plant has > 60 cannabinoids



CB1 Receptors

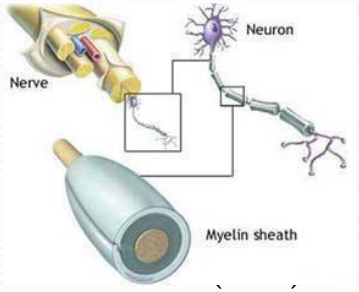
CB2 Receptors

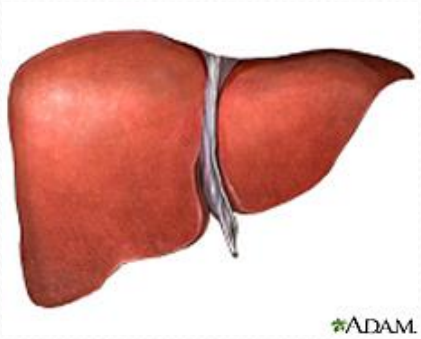




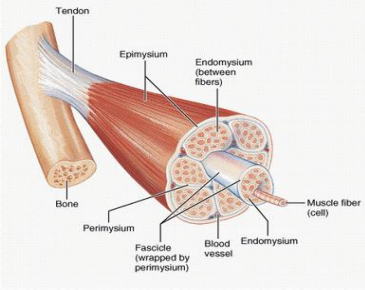
and CB1)

Endocannabinoid System





Liver
(CB1 and CB2)



Skeletal Muscle

Immune System (CB2)

Endocannabinoids

- Anandamide and 2AG

1. Synaptic moderators – move both ways at synapse unlike Dopamine
2. May be involved in Runners High

Components of Cannabis

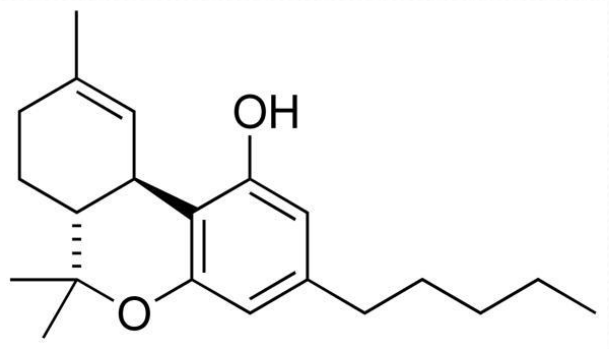
- Cannabis sativa (high psychoactive properties) and Cannabis Indica (generally higher ratio of CBD:THC) are composed of up to 400 components

- *Non-psychoactive components-*
  - *120 terpenoids: aromatic compounds*
  - *21 flavonoids: antioxidants*
  - *11 plant sterols (seed)*
  - *22 Fatty acids*

- *CBD and THC are two main studied chemical components of cannabis out of 60-100 active cannabinoids.*

- *CBD with THC has a mitigation on THC induced side effects*

THC (delta-9-tetra hydrocannabinol)



- euphoric
- stimulant
- muscle-relaxing
- analgesic
- anti-emetic
- appetite stimulating
- lowers intra-ocular pressure

- A High THC is 15-25%

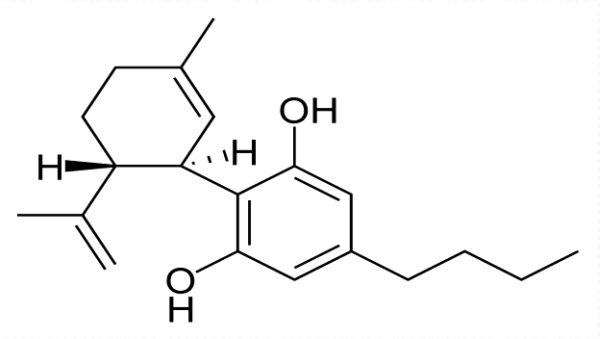
Oral THC Pharmacology

- Low (6-20%) and variable bioavailability
- Peak plasma within 1-6 and may remain elevated for several hours
- Initially oxidized in liver to 11-OH-THC, a potent psychoactive metabolite
- Further oxidation of 11-OH-THC leads to elimination products (urine and feces)
- Terminal half life 20-30 hrs.

Smoked THC Pharmacology

- Rapidly absorbed into bloodstream and redistributed
- Considerable amount of dose lost in pyrolysis
- Peak blood levels achieved at end of smoking, decline rapidly over 30 minutes
- Smoking achieves higher peak concentration but shorter duration of effect
- Smaller amounts of 11 OH-THC formed

CBD (Cannabidiol)



Researched Attributes

Anxiolytic
Anti-psychotic
Anticonvulsant
Anti-oxidant
Anti-inflammatory

Anti-ischemic
Anti-emetic
Anti-tumor
Neuroprotection

*CBD mitigates the psychoactive side effect of THC A high CBD is 5-15%

Potential Benefits

Researched Benefits of Cannabis Use:

- ✓ Appetite stimulation
- ✓ Antiemetic
- ✓ Antispasmodics
- ✓ Analgesic
- ✓ Lowering of intraocular pressure
- ✓ Anticonvulsant
- ✓ Neuroprotective and antioxidant
- ✓ No lethal dose of THC
- ✓ Enhance the analgesic activity of co-administered opiates

Potential Risks

Researched Long-term Risks of Cannabis Use:

- Risks of smoking product (low COPD risk)
- Cardiovascular issues
- Neuropsychiatric
  - Largest concern in adolescent and younger population with questions regarding cognitive development, memory and psychiatric illness.
- Dependence in 9-10% of population
- Is marijuana a “gateway” drug? No conclusive evidence

Adverse Effects

- CNS side effects primarily anxiety and paranoia
  - Strains with lower THC content less psychoactive
- General physical effects
  - changes in appetite, thirst, nausea, headache, decreased coordination, reduced muscle strength, dry mouth, and sensitivities including redness and dryness of the eyes.
- Toxicity
  - No lethal overdoses reported with non derivative products
  - Less toxicity/ lethality ratio than alcohol, opiates, barbiturates, and some common meds

Acute Drug Interactions

- Acute medical risk of THC are rather low
- Fatal overdose with cannabis alone has not been reported
- Additive effects of cannabis, anticholinergics and CNS depressants
  - (e.g., sedation, dry mouth, dizziness, and confusion)
- Smoking itself (cannabis or tobacco) induces CYP 1A2
  - May increase clearance of anti-psychotics and anti-depressants

  Metabolized by P450, little evidence supporting drug-drug interaction
- Chronic opiate users have seen a potential reduction of doses when in conjunction with medical cannabis

Cannabis in Painful HIV-associated sensory neuropathy, A randomized placebo controlled study, Abrams et al Neurology 2007

- 50 patients concluded trial (N=25 in each group)
- NIDA provided pre-rolled cannabis cigarettes either 0% or 3.5% delta-9-THC. Patients continued pre-study pain medications
- Smoked cannabis reduced daily pain by 34% ($p<0.03$)
- >30% reduction in pain reported by 52% of cannabis group vs 24% of placebo ($p=0.04$)
- The magnitude of pain reduction from smoked cannabis is comparable to that reported in trials of gabapentin for HIV-related neuropathy.

Cannabinoid-Opioid Interaction in Chronic Pain Abrams et al Clinical Pharmacology & Therapeutics 2011

- Objectives
- Evaluate effect of vaporized cannabis on Blood levels of prescribed opiates (SR morphine and SR Oxycodone)
- Determine the short-term side effects of co-administration of cannabis and opioids
- Assess effect of vaporized cannabis on level of Chronic pain
- N = 21
- Funded in part by NIDA and NIH CRC grants

Abrams Cannabis : Opioid Conclusions

- Co-administration of vaporized cannabis with oral sustained release opiates is safe
- Co-administration of vaporized cannabis in subjects on stable doses of morphine or oxycodone appears to enhance analgesia
- Co-administration of vaporized cannabis trends towards lowering serum concentration of the opioids
- The PK effects would be expected to reduce the analgesic effects of opioids.
  - The effects of vaporized cannabis to enhance opioid analgesia occurs by a pharma-dynamic , not a pharmacokinetic effect

Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in The United States 1999-2010 Bachhuber et al JAMA 2014

- Time series analysis of medical cannabis laws and state-level death certificate data in the US from 1999 to 2010; all 50 states included
- States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate (95%CI, -37%to -9%, P = 0.003)
- Examination of the association between medical cannabis laws and opioid analgesic overdose mortality in each year of implementation of the law showed a lower rate of OD mortality over time that generally strengthened over time

Synthetics

•Dronabinol (Marinol), is Δ^9-tetrahydrocannabinol (THC), used as an appetite stimulant, anti-emetic, and analgesic. Approved in 1986 for N&V from Chemotherapy; AIDS anorexia in 1992

•Nabilone (Cesamet), a synthetic cannabinoid and an analog of Marinol. It is Schedule II unlike Marinol, which is Schedule III

•Sativex, a cannabinoid extract oral spray containing THC, CBD, and other cannabinoids used for neuropathic pain and spasticity in 22 countries including England, Canada and Spain. Sativex develops whole-plant cannabinoid medicines

•Rimonabant(Acomplia), a selective cannabinoid (CB_1) receptor inverse agonist once used as an anti-obesity drug. It was also used for smoking cessation

Why Isn't Marinol Enough?

- Marinol is synthetic THC
  - Only one of many cannabinoids in the cannabis plant
  - The psychoactive component
  - Dosing maybe difficult for patients to control due to delayed onset and long duration of THC side effects
- Many other cannabinoids in plant have important effects
- Anti-inflammatory, anti-nausea, neuroprotection
- Strains of cannabis differ in THC/CBD content resulting in variable efficacy and adverse effects

Safety of Pharmaceutical Cannabinoids

- Low abuse potential of prescription cannabinoids
  - Dronabinol (Calhoun 1998)
  - Nabilone (Ware 2010)
  - Nabiximols (Robson 2011)

No evidence of tolerance (Rog 2007, Serpell, 2013)

Questions and Answers

For More Information

- Website: nmhealth.org (About-MCP)
- Phone: (505) 827-2321
- Email: medical.cannabis@state.nm.us
- 24 Hour Law Enforcement Number 505-231-6740