Objectives

1. To understand the evolution of marijuana from recreational to medical use
2. To list the scientific evidence of the clinical use of medical marijuana
3. To list the common adverse effects of marijuana
4. To learn how to incorporate medical marijuana in the clinical practice of medicine
The earliest dated reference to marijuana was made in Chinese literature. Emperor Fu Shi in 2900 referred to the Chinese hemp as "Ma" and in 2737 BC, Emperor Shen Nung was said to have discovered its healing properties to treat rheumatism, gout and malaria.

**Terminology 101**

- **Cannabis**: a genus of flowering plant that includes three species: sativa, indica and ruderalis.
- **Marijuana (Marihuana)**: means all parts of the plant Cannabis sativa L., whether erroneously or not, the seeds thereof, the resin-extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin-extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (21 USC 801(16)).
- **Hemp**: an industrial variety of cannabis sativa that is valued for its fibrous stalk. According to the CSA Hemp, a term that is not found in federal law, it is a product that does not cause THC to enter the human body, and therefore it is a non-controlled substance that may lawfully be used in the United States.

**Terminology 102**

- **Cannabinoids**: make up at least 85% of the natural compounds in cannabis. While some cannabinoids are psychoactive (THC) others (CBD) are not.
- **Tetrahydrocannabinol (THC)**: a compound, C_{21}H_{30}O, obtained from cannabis or made synthetically, that is the primary psychoactive in marijuana.
- **Cannabidiol (CBD)**: a major phytocannabinoid, accounting for up to 8% of the plant’s extract. CBD is considered to have a wide range of potential medical applications despite its lack of psychoactive properties.
- **Bud/Harvest**: refers to the actual flower of the marijuana plant. These are the fuzzy, hairy, crystal-covered parts that are harvested and used for recreational or medicinal purposes as they contain the highest concentrations of active cannabinoids. When they are allowed to be fertilized by male plants, these flowers will produce cannabis seeds.
- **Teas**: is the excess stems and leaves that are trimmed off the buds.

**Table 2. Common Cannabis Preparations**

<table>
<thead>
<tr>
<th>Preparations</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marijuana*</td>
<td>Dried plant product consisting of leaves, stems, and flowers; typically smoked or vaporized</td>
</tr>
<tr>
<td>Hashish</td>
<td>Concentrated resin cake that can be ingested or smoked</td>
</tr>
<tr>
<td>Tincture*</td>
<td>Cannabidiol liquid extracted from plant, consumed sublingually</td>
</tr>
<tr>
<td>Hashish oil</td>
<td>Oil obtained from cannabis plant by solvent extraction, usually smoked or inhaled, butane hash oil (sometimes referred to as “wax”), for example</td>
</tr>
<tr>
<td>Infusion*</td>
<td>Plant material mixed with non-alcoholic solvents such as butter or cooking oil and ingested</td>
</tr>
</tbody>
</table>

* These preparations are available from state-approved medical marijuana dispensaries.

**Terminology 103**

- **Extraction**: cannabinoids are not water soluble, so to extract them properly the cannabinoids must be dissolved in a solvent. Butane, hexane, isopropyl alcohol and ethanol are all solvents that are commonly used in cannabis concentrate extraction.
- **Cannabis Concentrates**: include cannabis oil, butter, wax and shatter.
- **Edibles**: any food which has marijuana as an ingredient.

The earliest dated reference to marijuana was made in Chinese literature. Emperor Fu Shi in 2900 referred to the Chinese hemp as “Ma” and in 2737 BC, Emperor Shen Nung was said to have discovered its healing properties to treat rheumatism, gout and malaria.
The History

1500 AD. The discovery of the Ebers Papyrus in Ancient Egypt provided the oldest complete medical textbook and this has mentioned cannabis as treatment for gonorrhea, inflammation of the mucous membranes, pain, etc.

The History

1000 BC. Bhang was a popular drink in India, by combining milk and cannabis. It was used for many ailments but mostly for its anesthetic properties. In 600 BC, it was used to cure leprosy.

The History

Cannabis was used in Ancient Greece. In 30 AD, it was also alleged that Jesus Christ used an anointing oil made from olive oil, spices, herbs that was called kaneh-bosm, which was actually cannabis.

The History

The Jamestown settlers from England brought cannabis to the USA in 1611 AD, and was used to treat from depression to gout. George Washington in 1790 AD, grew hemp for 30 years at his Mt. Vernon plantation. He was intrigued by the plant’s medicinal properties so he concentrated his efforts on the production of plants with high THC content.

The History

In 1890, Sir John Russell Reynolds, neurologist and personal physician of Queen Victoria prescribed a cannabis tincture for the relief of the symptoms of migraine. A cannabis product was introduced commercially, cannabis was one of the most valuable medicines ever produced.

Reynolds was then the president of the British Medical Association and in 1890 published in Lancet his 30 years experience with cannabis using it for migraines, neuralgia and dysmenorrhea. By 1928, it was added to England’s most dangerous drug list.
1876: Hash Reaches America

World Fairs and International Expositions featured Turkish Hashing Smoking Exhibit which became popular with the Americans.

The History

Massachusetts First State To Outlaw Cannabis – 1911AD, NY followed in 1914.

The prohibition era began in the USA in earnest in 1910 and as well as banning alcohol, cannabis began to be outlawed in many states. Massachusetts was the first to set the example in 1911 and various other states followed shortly after. The move was made in order to prevent future use and misuse of the drug rather than because of existing widespread use. Further states followed the same pattern into the 1920s.

Marijuana vs Hemp

• Marijuana and Hemp
  – Same genus – Cannabis
  – Same species – Sativa

• THC content
  – Hemp - 0.3%
  – Marijuana - 6-20%

Appointed Director of Federal Narcotics Bureau
1930-1962: Harry J. Anslinger

Reefer makes dandies think they’re as good as white men

There are 100,000 total marijuana smokers in the US, biological and drug use, Italians, Filipinos and entertainers. Their skeptical, mean, and stingy would fear marijuana usage. This marijuana serves white women to have brutal relations with negroes, entertainers and any others.

— Harry J. Anslinger —

Reefer Madness

Film: Tell Your Children - financed by a church - "tells the story of how refer addiction ruins the life of its young protagonist and gets a lot of people killed, sexually compromised and committed to lunatic asylums."

The tax was imposed on physicians prescribing cannabis, retail pharmacist selling cannabis and medical cannabis cultivations/manufacturing.

This law was repealed by the Controlled Substances Act of 1970.

Outlaw and Regulation of Marijuana

- 1931 – 29 states outlawed marijuana
- All 48 states enacted laws to regulate marijuana
- Mr. Samuel L. Caldwell – 4 years of hard labor

Controlled Substance Act 1970

- Congress passes the CSA
- Marijuana – “No Accepted Medical Use”
  - Classified as Schedule 1
  - Further studies completed
  - Schafer Commission

The History

Two US Food and Drug Administration (FDA)-approved cannabinoids: Drorabinol (Marinol) and Nabilone (Cesamet)

Marinol

In 1985, FDA approved Marinol for nausea and vomiting associated with cancer chemotherapy, for:

- Full Form

Marinol

California - First State to Legalize Cannabis for Medicinal Use – 1996

Scientists discovered the cannabinoid receptors in the brain in 1990 and in 1996 California legalized the medicinal use of marijuana. Oregon followed suit two years later in 1998 along with Alaska and Washington.
The History

2003 - Canada became the first country in the world to offer medical marijuana for pain.

• According to a NIH-sponsored survey in 2013, marijuana is the most abused drug in children under 12 years old. 29.8% of students in 10th grade reported using it during the past year. Synthetic marijuana came in second at 7.4%.

Rising support for legalization follows a massive political spending campaign.

Money also may explain the success of marijuana initiatives in Alaska, Oregon, and DC in 2014.

This tide of money has resulted in legalization across a large portion of the United States.

• In California alone, up to $25 million is expected to be spent promoting the 2016 "recreational" marijuana initiative.
**Legalization has birthed a marijuana industry, fueled by private equity and Wall Street**

- NYC-based private equity firm focused on cannabis
- $16 million round of funding closed July 2015
- Partnership with Willie Nelson to develop a marijuana brand

**“Big Marijuana”: a $10 billion/year dream for the tobacco industry since the 1970s**

- “The use of marijuana... has important implications for the tobacco industry in terms of an alternative product line. [We] have the land to grow it, the machines to roll it and package it, the distribution to market it. In fact, some firms have registered trademarks, which are taken directly from marijuana street jargon. These trade names are used currently on little-known legal products, but could be switched if and when marijuana is legalized.
- Estimates indicate that the market in legalized marijuana might be as high as $10 billion annually.
- ’70s report commissioned by cigarette manufacturer Brown and Williamson (now merged with R.J. Reynolds)"

**Maya & Whoopi**

Cannabis-businesswoman Maya Elizabeth teams up with Whoopi Goldberg launching a medical-marijuana company

- The company Maya & Whoopi will offer cannabis edibles, tinctures, topical rubs and a THC-infused bath soap-designed to provide relief for menstrual cramps.

**Marijuana edible displays**

**Edibles: a clear and present danger to Colorado’s children**

- Doctors at the UCH and Children’s Hospital Colorado emergency departments identified edible marijuana as the culprit behind the most troubling cases there, including severe burns and cycling vomiting syndrome.
ASAM recommends that jurisdictions that have already legalized marijuana or that may act to legalize it in the future implement the following public health and safety measures to minimize potential harms to vulnerable populations.

ASAM encourages addiction medicine physicians to champion the implementation of these safeguards in all jurisdictions where marijuana has been legalized or may be legalized in the future.

1. Prohibit the legal sale of marijuana products to anyone younger than 25 years of age.
2. Prohibit marketing and advertising to youth, akin to the current restrictions on tobacco product advertising.
3. Require that products made available for retail sale be tested for potency and clearly labeled with THC content.
4. Require rotating warning labels to be placed on all marijuana and marijuana products not approved by the U.S. Food and Drug Administration (FDA) which are offered for sale in retail outlets, stating, "Marijuana use increases the risk of serious problems with mental and physical health, including addiction," or "Marijuana should not be used by pregnant women or persons under age 25," or "Marijuana should not be used by persons prior to operating motor vehicles and heavy machinery."
5. Require that marijuana products (such as edibles and beverages) be sold only in child-proof packaging and be accompanied by the mandatory distribution of educational flyers regarding the risks of overdose and poisoning in cases of accidental ingestion by children or household pets.
6. Earmark taxes placed on marijuana and marijuana product sales, wholesale or retail, such that a majority of tax revenues are required to be devoted to public education about addiction, prevention of addiction, health effects of cannabis and synthetic cannabinoid use, prevention of initiation of cannabis and cannabinoid use by youth, addiction treatment, or research on the health risks and potential benefits of marijuana, "natural" cannabinoids, and synthetic cannabinoids.
7. Limit marijuana and marijuana product sales to state-operated outlets, akin to Alcohol Beverage Control regulations existing in several states and Canadian provinces, which preserve both public access and the potential for governmental revenues linked to sales, while limiting the broad commercialization of public sale of potentially harmful but brain-rewarding products.
8. Implement public awareness campaigns which highlight the risks of marijuana use to discourage vulnerable populations, including youth (i.e., adolescents and young adults), individuals with mental illness, and those with a history of addiction involving alcohol or other drugs, from using marijuana products.

The Pharmacology of Marijuana

- Comprises more than 60 pharmacologically active cannabinoids
- They act on cannabinoid receptors located on the brain and spinal cord
- Activation of CB1 and CB2 receptors exert multiple actions by directly inhibiting the release of multiple neurotransmitters i.e. acetylcholine, dopamine, and glutamate while indirectly affecting gaba-aminobutyric acid, N-methyl-D-aspartate, opioid, and serotonin receptors.

Primary cannabinoids in marijuana: delta-9-tetrahydrocannabinol (THC) and cannabidiol.

THC can produces euphoria and psychosis. Cannabidiol has anti-anxiety and anti-psychotic effects.

Therapeutic effects depend on concentration of the THC and the ratio of THC to cannabidiol.

Three Species of Cannabis Have Different THC/CBD Levels

- **Cannabis sativa**
  - THC > CBD
- **Cannabis indica**
  - CBD > THC
- **Cannabis ruderalis**
  - CBD >> THC
The Evidence

Literature search from 1948 to January 2016 using MEDLINE

Searched terms: cannabis, cannabinoids, tetrahydrocannabinol, with limits used: administration, dosage, therapeutic trial or clinical trial

562 articles

40 clinical trials of marijuana and cannabinoids published - strongest evidence so far for its use for chronic pain, neuropathic pain and spasticity associated with multiple sclerosis.

MS patients claim at least 20% reduction in symptoms - data from studies done in 11 countries.

The American Academy of Neurology (AAN) published evidence-based guidelines that recommended an oral cannabis extract containing both THC and cannabidiol for the highest level of empirical support as treatment for spasticity and pain associated with MS.


CANNABINOIDS ARE EFFECTIVE IN ALL NEUROPATHIC PAIN MODELS

- Nerve Injury
- Scleral nerve ligation (SNL and PSN)
- Diabetic neuropathy
- Strep totoxin
- Chemotherapy
- Paclitaxel, Capain
- HIV neuropathy

(Pain, Pharmacology and Therapeutics, 2006)

GW PHARMACEUTICALS PHASE 3 TRIALS OF NABIXIMOLS (SATIVEX) SHOW BENEFIT FOR CANCER PAIN

- Randomized 300 subjects to placebo or one of three experimental groups
- Best results with 4 sprays per day (10mg THC / 10g CBD)
- Higher doses were not well-tolerated
  - more adverse events
  - higher drop-out rates

(System of Neurology, 2012)

PATIENTS WITH CHRONIC PAIN SUCCESSFULLY SUBSTITUTE MEDICAL CANNABIS FOR OPIOIDS

- Linne survey or use medical cannabis patients was chronic pain to examine whether medical cannabis changed individual patterns of opioid use
- 1814 analysts
- Found that cannabis was associated with
  - Decrease in opioid use (40%)
  - Improved quality of life (45%)

(System of Neurology, 2016)

SYSTEMATIC REVIEW OF RANDOMIZED TRIALS

- “Effective therapeutic options for patients living with chronic pain are limited”
- A systematic review of 18 randomized controlled trials (RCTs) with a total of 766 participants with chronic non-cancer pain found that 15/18 trials showed a significant analgesic effect of cannabinoids, compared to placebo.
- Conditions studied included neuropathic pain, “chronic pain”, rheumatoid arthritis, fibromyalgia, and central pain in multiple sclerosis.
- No serious adverse events were reported.

(Bosch and Campbell, Br J Clin Pharmacol, 2011)

CANNABIS IS A BENEFICIAL ADJUVANT ON ALL STEPS OF ANALGESIC LADDER

- Synergistic actions between cannabinoids and opioids can lower dose of opioids needed to control pain
- Cannabis-based medicine containing both THC and CBD appears to be more effective and better tolerated than synthetic THC (dronabinol)
- Modified WHO analgesic ladder includes cannabis as adjuvant medications that may be considered at all steps of treatment of cancer or other chronic pain

((Vargas-Schaffer, Can Fam Phys, 2010)

NATIONAL ACADEMY OF SCIENCES

- In adults with chronic pain, patients who were treated with cannabis or cannabinoids are more likely to experience a clinically significant reduction in pain symptoms
- In adults with multiple sclerosis (MS) relaxed spasticity, short term use of oral cannabinoids improves patient-reported spasticity symptoms.

(National Academies of Sciences, Engineering, and Medicine 2017)
MORE CANNABIS, FEWER OPIOIDS

- Data compiled by RAND Corp 2015
- Patients far less likely to become addicted to opiate pain relievers in jurisdictions that permit medical marijuana
- Opioid-related overdose deaths fell 20% in first year following implementation of legalization
- Declined by as much as 33% by the 6th year
  - (JAMA 2014)

MORE CANNABIS, FEWER OPIOID DEATHS

A time-series analysis was conducted of medical cannabis laws and state-level death certificate data in the United States from 1999 to 2010, all 50 states were included. Reported age-adjusted opioid analgesic overdose death rate per 100,000 population in each state.

Regression models were developed including state and year fixed effects, the presence of three different policies regarding opioid analgesics, and the state-specific unemployment rate.

Results showed states with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate (95% CI −37.5% to −9.5%; P<.001) compared with states without medical cannabis laws.

The association between medical cannabis laws and opioid analgesic overdose mortality in each year after implementation of the law strengthened over time.

Concluded that medical cannabis laws are associated with significantly lower state-level opioid overdose mortality rates.

(Buchalter 2014)

MORE CANNABIS, FEWER OPIOID DEATHS

![Graph showing the relationship between cannabis use and opioid overdose deaths](image)

- Mean Age-Adjusted Opioid Analgesic Overdose Death Rate. States with medical cannabis laws compared with states without such laws in the United States, 1999-2010.

MEDICAL CANNABIS SAFETY

“Medical cannabis used for chronic pain over one year appears to have a reasonable safety profile (199 Patients; no difference in risk of serious adverse events).”


“0% of patients surveyed after one year reported a ‘Great deal of Negative Mental Side Effects’ (241 Patients, 12 months)”


REDUCED PRESCRIPTION DRUG SPENDING

- Patient use of all varieties of prescription drugs is reduced when medical cannabis is an option
- Relationship assessed between medical marijuana legalization laws and physicians’ prescribing patterns in 17 states from 2010-2013
- Patients consumption of and spending on prescription drugs approved under Medicare Part D for nine domains/conditions
- Pharmaceutical drug use fell significantly in 7/9 domains resulting in annual savings of $165.2 million

CANNABIS USE DISORDER

- Dependence Rates
  - National Institute on Drug Abuse
  - Tobacco: 32%
  - Heroin: 23%
  - Cocaine: 17%
  - Alcohol: 15%
  - Caffeine: 9%
  - Cannabis: 9%
AAN also published a systematic review of medical marijuana as a treatment for neurological disorders and suggested Nabiximols, a oromucosal spray containing both THC and cannabidol, as effective in treating spasticity, central pain and urinary dysfunction associated with MS.

Dronabinol - is also an effective treatment for spasticity and central pain associated with MS.


The Evidence

Medical cannabis proposed for pediatric developmental and behavioral disorders i.e. autistic disorder but best current evidence is limited to case series or single studies.


Cancer treatment - studies reported that medical synthetic cannabis inhibit cancer growth and spread of cancer.


Treatment of epilepsy - 2 double blinded study, conflicting results. Current evidence base data is lacking.


Treatment of cluster headache - lack of randomized controlled trials.


The Evidence

Treatment of neuropathy - still with limited studies about its clinical safety or comparing its efficacy with conventional treatments.


The Evidence

Treatment of Amyotrophic Lateral Sclerosis (ALS) - Not enough data but has been postulated that it can help in the regulation of the immune system through its action on the CB 2 receptors.

Treatment of digestive problems, including inflammatory bowel disease (IBD). Can help reduce inflammation but lack objective evidence as there is no monitoring of IBD activity.


Two Anecdotal Cases

Michael is 62 years old WM, dx in 2012 with Stage IV Glioblastoma. Had chemo and chemoradiation with low dose Temodar. He has been smoking marijuana to help his occasional headaches and done very well. No recurrence of the tumor.

Stacie is 53 years old with IBD with chronic abdominal pain from adhesions, irritable bowel syndrome, GERD, etc. and she stopped going to GI since none of the medications helped. She found something better which worked - smoking marijuana.
Look at the evidence with caution!

Most studies are case reports or cross-sectional studies. Not enough comparison studies with conventional medications to prove superiority of medical cannabis.

We do not have enough randomized clinical trials.

Medical Cannabis has approximately 5 times higher affinity for the CB 1 receptors and 10 times higher affinity to the CB 2 receptors. This will predispose individuals to more psychotic experiences.

Psychiatric Adverse Effects

Meta-analysis of 31 studies involving 112,000 individuals has found a positive association between anxiety disorder and cannabis usage. A study by K.K.Kedzior and L.T. Laeber. A positive association between anxiety disorders and cannabis use or cannabis use disorders in the general population—a meta-analysis of 31 studies. BMC Psychiatry, Vol 14, No 1, article 136, 2014.

Multiple studies show modest increment in the risk of developing depression. It might also increase the severity and duration of maniac symptoms with bipolar disorder.

Cannabis usage is associated with a twofold increment in the risk of acquiring schizophrenia and corresponding fourfold increase in the risk of psychosis. Studies show global, positive and disorganized schizotypal personality traits and elevated risk of suicide in those with or without psychosis.

Psychiatric Adverse Effects

Other Medical Adverse Effects

Cannabis Induced Arteritis


Cannabis Induced Posterior Circulation Stroke


Chronic Cough, bullous emphysema, and chronic obstructive lung disorder


Cannabis Hyperemesis Syndrome


Adipose tissue insulin resistance, pancreatitis


Adverse Effects of Marijuana

- Impaired short term memory
- Impaired motor coordination
- Poor judgement
- High risk for motor vehicle crash
- Paranoid ideations, psychotic symptoms
- Hugh Addiction - causes problems in work, school or relationships in about 9% of adults and 17% of adolescent users
- Associated with anxiety, depression and psychiatric illness, poor school performance, lower income, usuallly with increased likelihood of requiring socioeconomic assistance, unemployment, criminal behavior and decreased satisfaction with life
- Regular use also prone to respiratory infections and chronic bronchitis
- May cause myocardial infarctions, stroke, and peripheral vascular disease

Most of the plantations and the largest producers of Marijuana is in Paraguay. Mexico is only #2.

The Colorado Experience

- 155,170 patients as of August 31, 2014 with 271,325 pending applications.
- Demographics: 66% male, 44 is average age and 60% reside in the Denver Metro area.
- Another 32% reside in the 64-85 age group.
- Medical Conditions reported:
  - Severe Pain
  - Muscle Spasms
  - Severe nausea
  - Cancer
  - Seizures
  - Glaucoma
  - HIV/AIDS
  - What is disturbing - 50% of these prescriptions are only coming from an elite 15% of certified physicians.

Patient is allowed to self medicate with inhaled cannabis with THC content varying from 10% to more than 25%, several times a day. They can also ingest a variety of edible products, candies, sodas, etc all with variable THC content. Heroin is not允许.

<table>
<thead>
<tr>
<th>The Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the condition? Is there good evidence and/or approved condition for this particular state?</td>
</tr>
<tr>
<td>2. Is it unclear for a 2nd line evidence based treatment?</td>
</tr>
<tr>
<td>3. Comprehensive assessment should be done a primary care physician (PCP) who knows the patient well and with a full understanding of patient’s debilitating condition.</td>
</tr>
<tr>
<td>4. If the certifying physician is not the PCP, the certifying physician should report the evaluation to the PCP.</td>
</tr>
<tr>
<td>5. Patient’s history should be focused on previous treatments, possible contraindication to medical marijuana, unstable mental illness and substance use disorder or current viral URI.</td>
</tr>
<tr>
<td>6. Discuss adverse effects and side-benefits of medical marijuana.</td>
</tr>
<tr>
<td>7. Have a signed provider-patient contract.</td>
</tr>
</tbody>
</table>

The Colorado Experience

- Decline in traffic fatalities by 15% between 2007 and 2012 but traffic fatalities in operators testing positive for cannabis increased by more than 100% (7.04% and 16.53% respectively)
- Adolescents use (age 12-17 years old) was 39% higher than the national average; increased diversion to younger individuals
- June 2014 survey of state schools reported increase in marijuana violations and noted that 23% were getting their marijuana from their parents.
- Between 2011 and 2013, a 57% increase in ER visits related to marijuana; 62% increase in hospitalization related to marijuana from 2008 to 2012.
- Accidental ingestion (<12 years old) - there was 2 in 2009 and now 12 in 2014.
- Poison control saw a significant rise (268%) in marijuana-related exposures in the 0 to 5 year old age group during the 2006 to 2009 and 2010 to 2013. There was also a 100% increase in children aged 13 to 17.

Figure: Rate (per 1 million population) of unintentional pediatric marijuana exposure poison center calls by marijuana legalization status, 2005–2010.
Conflicts & Controversies

1. Federal vs. State Laws
The Department of Justice (DOJ) is responsible for enforcing the Controlled Substances Act of 1970 which banned and criminalized marijuana. In 2014, Congress passed the Continuing Resolution Omnibus Spending Bill that prevents the DOJ, including the FBI, from interfering with state medical marijuana laws.

2. Banking Laws
Federally regulated banks are prohibited by law to open accounts for state licensed marijuana companies. Some companies just open bank accounts with state chartered institutions.

3. Tax Laws
An illegal business is subject to tax on its income in the same manner as any legal business would be and is entitled to the same business deductions as are available to a legal business. However, ordinary and business deductions under Section 280E are disallowed. The business owner will be taxed on its gross income and may not deduct what are clearly business expenses, such as rent and employee salaries.

Definition of Serious Condition
Patients with one of the following severe debilitating or life-threatening conditions:

- Cancer
- HIV positive status or AIDS
- Amyotrophic Lateral Sclerosis (ALS)
- Parkinson’s Disease
- Multiple Sclerosis
- Spinal cord damage with objective indication of intractable spasticity
- Epilepsy
- Inflammatory Bowel Disease
- Neuropathies
- Huntington’s Disease

AND
**Definition of Serious Condition**

- The condition is clinically associated with cachexia, severe or chronic pain, severe nausea, seizures or severe or persistent muscle spasms.

- The Commissioner of Health may add other serious conditions.

**Registered Organizations - Dispensing**

- Dispensing facilities are required to have a pharmacist with an active NYS pharmacist license on the premises and directly supervising the activity within the facility.
- 30-day supply limitation (unless the certified patient has exhausted all but a seven day supply provided pursuant to a previously issued certification).
- Pharmacist must consult the PMP Registry prior to dispensing to verify the 30 day supply is not exceeded.

**Registered Organizations - Manufacturing**

- Dosage forms permitted:
  - liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube;
  - metered liquid or oil preparations for vaporization;
  - and capsules for oral administration.
- Maximum of 10mg total THC per single dose
- Smoking of marijuana is expressly prohibited by the Compassionate Care Act. Edibles prohibited in 10 NYCRR § 1004.11 (g)(5).

**Laboratory Testing**

Registered organizations are required to submit final medical marijuana products to an independent laboratory certified by the department’s Environmental Laboratory Approval Program for testing of the following:

- Cannabinoid profile specified in §1004.11(c)(2);
- Contaminants specified in §1004.14(g);
- Pesticide Screen

**Practitioner Registration**

- Practitioners must be qualified to treat patients with one or more of the serious conditions in the Compassionate Care Act;
- Be licensed, in good standing as a physician and practicing medicine, as defined in article one hundred thirty one of the Education Law, in New York State; and
- Have completed a department-approved course on the medical use of marijuana.

**Medical Use of Marijuana Course**

- The four-hour NYSDOH approved medical use of marijuana course is available online.
- The course is provided by TheAnswerPage, an established online medical education site.
- The cost to take the course is $249. Successful completion of the course will provide 4.5 hours of CME credits.
- Pharmacists working in the dispensing facilities are required to take the same course.
Patient Certification

The expiration date cannot be more than one year from the date issued, unless the patient is terminally ill. If the patient is terminally ill and a resident of New York State, as indicated by selecting "Y" for the "Terminally Ill" field and "N" for the "Temporary Resident" field, the certification will not have an expiration date.

Terminally Ill, in Public Health Law 3360(13) (a), means an individual has a medical prognosis that the individual’s life expectancy is approximately one year or less if the illness runs its normal course.

Patient Certification – Attestation

Table 1: Patient certification by age and gender, recorded from December 23, 2017 to May 21, 2018

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24</td>
<td>100</td>
<td>150</td>
<td>250</td>
</tr>
<tr>
<td>25-34</td>
<td>200</td>
<td>300</td>
<td>500</td>
</tr>
<tr>
<td>35-44</td>
<td>300</td>
<td>450</td>
<td>750</td>
</tr>
<tr>
<td>45-54</td>
<td>400</td>
<td>600</td>
<td>1000</td>
</tr>
<tr>
<td>55-64</td>
<td>500</td>
<td>800</td>
<td>1300</td>
</tr>
<tr>
<td>65+</td>
<td>600</td>
<td>1000</td>
<td>1600</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24</td>
<td>100</td>
<td>150</td>
<td>250</td>
</tr>
<tr>
<td>25-34</td>
<td>200</td>
<td>300</td>
<td>500</td>
</tr>
<tr>
<td>35-44</td>
<td>300</td>
<td>450</td>
<td>750</td>
</tr>
<tr>
<td>45-54</td>
<td>400</td>
<td>600</td>
<td>1000</td>
</tr>
<tr>
<td>55-64</td>
<td>500</td>
<td>800</td>
<td>1300</td>
</tr>
<tr>
<td>65+</td>
<td>600</td>
<td>1000</td>
<td>1600</td>
</tr>
</tbody>
</table>

Sample ID Card

The sample ID card shows a photograph, name, and ID number for an individual.
**Practitioner Reporting Requirements**

- Death or change in status of a certified patient’s serious condition if such change may affect the patient’s continued eligibility for certification (not more than 5 business days after becoming aware of such facts).

- Patient adverse events (not more than 5 business days after becoming aware, except that serious adverse events shall be reported not more than 1 business day after becoming aware).

**Protections: PHL §3369(1)**

Certified patients, designated caregivers, practitioners, registered organizations and the employees of registered organizations shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marijuana, or for any other action or conduct in accordance with this title.

**PATIENT CASE #1**

KK is a 36 year old white male diagnosed with severe Ulcerative Colitis. He suffers from frequent nausea, vomiting, severe cramping, and diarrhea which causes problems both at work and home. He has exhausted his medication options with his GI doctor and was very interested to try medical marijuana.

**Current Medication**

- Lialda 1.2gm QID
- Librax 2 tabs QID
- Amitriptyline HCl 75-100mg QHS
- Omeprazole DR 20mg Daily
- Hydrocodone/APAP 5/325mg 1-2 tabs PRN

**Results to date**

- Significant reductions in painful cramping and morning nausea or vomiting
- Complete resolution of symptoms at mealtime
- No longer late or missing work
PATIENT CASE #2

CR is an 9 year old white male. He is developmentally delayed and diagnosed with Lennox-Gastaut Syndrome. He has 8-10 seizures every day, averaging around 300 monthly, of varying types and severities.

Current Medications

- Onfi 5mg BID and 10mg QD
- Keppra 100mg/mL 5mL BID and 6 mL Qday
- Gabapentin 250mg/mL 1.5 mL BID
- Pulmicort QD
- Clonazepam 0.25 mg BID
- Trileptal 300mg/5mL 4 mL BID
- Baclofen 5mg/mL 1mL BID
- Diastat 10 mg Supp

CR first visited the dispensary with his parents in July 2016
• Started therapy on a Low THC:High CBD (1:20) tincture
• Started at 25 mg daily with an increase to 50 mg after 2 weeks
• Current dose is 60 mg CBD Qq hs with plans to increase to 75 mg (5mg/kg) q hs

Results to date:
• Seizure frequency reduced to 1-2 seizures per month from 300 per month
• His parents state that he is much happier and more interactive
• Parents will discuss about reducing some of his other medications

PATIENT CASE #3

NS is a 27 year old white male who is paralyzed from the waist down due to a birth deformity at thoracic spine 10-11. He suffers from severe spasms in his legs and neuropathy in the lower portion of his body.

Current medications

- Gabapentin 300mg TID
- Oxybutynin 5mg BID-TID
PATIENT CASE #3

• NS first visited the dispensary at the end of June
• Started therapy on a combination of tincture and capsule in the Equal THC:CBD products
• Uses capsules for maintenance and tincture for breakthrough symptoms
• Current dose is 1 capsule TID and 3-5 drops of tincture PRN for breakthrough

PATIENT CASE #3

• Results to date
• Significant reduction in neuropathy symptoms
• Complete resolution in muscle spasms
• Noticeable reduction in muscle tension and rigidity

SUMMARY

• Marijuana does not kill patients (no case of overdose has ever been reported)
• Medical Marijuana has been shown to be effective for chronic pain. Neuropathy has the highest quality evidence.
• Medical Marijuana has well-tolerated side effect profile
• Medical Marijuana works synergistically with opioids.
• Look at the evidence with caution. We still lack comparison studies and randomized control trials to consistently prove its superiority.
• If at all possible, avoid prescribing medical marijuana for patients under 25 years old.
• We, the medical community should be the pillar of education and we should continue to be well-versed and a good resource for alternative therapies available for patients including support for medical marijuana if the benefits outweigh the risks for prescribing this medication.

Q&A

Let your voice be heard!
Evaluate workshops on the NC app

Stay Connected

www.facebook.com/fmignetwork
@aafp_fmg
Use #AAFPNC