

Disclosures

Joseph Friedman, RPh, MBA is Chief Operations Officer, PDI Medical. The conflict of interest was resolved by peer review of the slide content.

Bradley Carlson, PharmD is Principal Consultant, CannaRPH, LLC. The conflict of interest was resolved by peer review of the slide content.

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Learning Objectives

- Describe the unique challenges and opportunities for pharmacists in the medical marijuana industry.
- Discuss the health benefits and possible side effects for patients using medical marijuana for health-related conditions.
- Evaluate the business dynamics and opportunities of the medical cannabis industry, and the growth curve of medical cannabis.

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In Loving Memory



Jerrold Gorsky RPh

February 6, 1946 – September 8, 2017

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Hey, Wadda ya think about an Informal Survey?

Should we have Pharmacist involvement in our nations medical cannabis industry?

YES



NO

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JOE & BRAD AT YOUR SERVICE!

- History of Marijuana Prohibition
- Federal Government
- State Government
- The Medical Cannabis Business Environment
- PDI Medical – A Day In The Life
- Pharmacist Involvement
- Medical Cannabis Educational Opportunities
- Chicago Based - Aclara Research
- CBD Opportunities for Drug Stores
- CannaRPh – A New and Unique Consulting and Educational Organization

Joseph Friedman, R.Ph.
*History, Politics, Legal, Business,
 Research, & Drug Store Opportunities*

Bradley Carlson, Pharm D.
*Cannabis Science, Pharmacology,
 Pharmacokinetics, & Dosing*

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Good Afternoon



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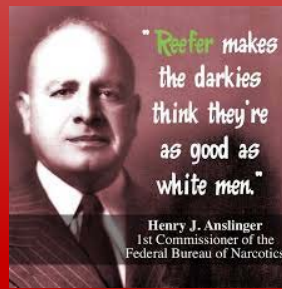


• Marijuana Prohibition

• The Crimes of Reefer Madness



Its first effect is sudden, violent, uncontrollable laughter; then come dangerous hallucinations — space expands—time slows down,



What were they thinking?



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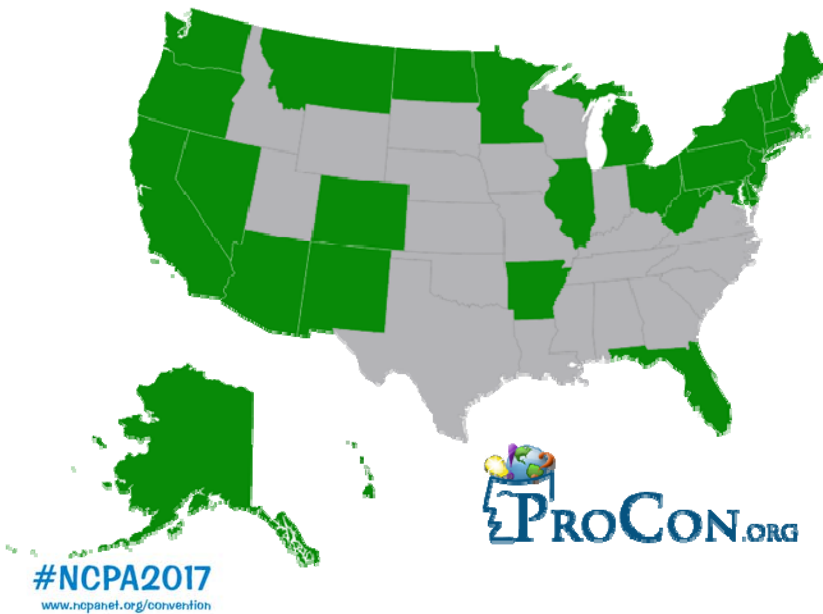
FEDERAL GOVERNMENT Marijuana Prohibition 2017



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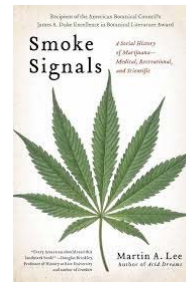
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29 LEGAL MEDICAL MARIJUANA STATES AND DC



Sanjay Gupta, MD, Chief Medical Correspondent for CNN
Aug 8, 2013.

"We have been terribly and systematically misled for nearly 70 years in the United States, and I apologize for my own role in that."



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MEDICAL CANNABIS STATES

- ARIZONA
- **ARKANSAS**
- CALIFORNIA
- **CONNECTICUT**
- DELAWARE
- FLORIDA
- HAWAII
- ILLINOIS
- LOUISIANA
- MARYLAND
- MICHIGAN
- **MINNESOTA**
- MONTANA
- NEW HAMPSHIRE
- NEW JERSEY
- NEW MEXICO
- **NEW YORK**
- NORTH DAKOTA
- OHIO
- **PENNSYLVANIA**
- RHODE ISLAND
- VERMONT
- WEST VIRGINIA

LEGAL CANNABIS STATES

- ALASKA
- COLORADO
- D.C.
- MAINE
- MASSACHUSETTS
- NEVADA
- OREGON
- WASHINGTON

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Do Cannabis Dispensary Staff Receive Sufficient Training?

- Mean Age 31.9 years (22 – 63)
- Caucasian 86%
- Female 55%, Male 45%
- Full Time 84%
- Average Salary \$15/hr (\$8 - \$25)
- Medical or scientific training 20%
- Giving advice to patients 94%
- Formal training 55%

“Some of the cannabis recommendations made by dispensary staff have not been shown to be effective and could even cause a patient’s condition to worsen.”

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Training and Practices of Cannabis Dispensary Staff, 2016 - Nancy A. Haug, Dustin Kieschnick, James E. Scottile, Kimberly A. Babson, Ryan Vandrey, and Marcel O. Bonn-Miller

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Pharmacists should play ‘front-line’ role in dispensing cannabis

- APHA: American Pharmacists Association
- Canadian Pharmacists Association
- Pharmacist Mandate
 - Connecticut
 - New York
 - Minnesota
 - Arkansas
 - Pennsylvania

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Pharmacists and Medical Cannabis The Risks and Benefits of Cannabis Therapy

- Real drug with real side effects
- Pharmacists are the drug experts
 - Basic skills
 - Necessary training and education
 - Practical Experience
 - Patient-focused mindset
 - Pharmacists are healthcare professionals
 - The public trusts us

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Pharmacists and Medical Cannabis The Risks and Benefits of Cannabis Therapy

- Gallop Poll – Honesty/Ethics in Professions
 - Nurses 29%
 - Pharmacists 15%
 - Car Salesman 1%
 - Members of Congress 1%

Pharmacist Gallop Poll History
 Nov 1999 – 18%
 Nov 2004 – 19%
 Nov 2007 – 16%
 Nov 2012 – 19%
 Dec 2016 – 15%

SO WHAT ARE THE ISSUES?

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Pharmacists and Medical Cannabis

The Risks and Benefits of Cannabis Therapy

- Pharmacists are the best positioned professional to head up this industry
- Historical Gallop Poll
 - **Pharmacist damage – Must rebuild – Can possibly do it now with medical cannabis involvement**
 - *High cost of generics*
 - *Chicago Tribune, December 2016*
 - Investigation of deadly drug interactions – failure to warn patients
 - Clarithromycin and Ergotamine
 - Simvastatin and Clarithromycin
 - Colchicine and Verapamil
 - Tizanidine and Ciprofloxacin
 - Norgestimate/ethinyl estradiol and Grisesofulvin

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Pharmacists and Medical Cannabis

The Risks and Benefits of Cannabis Therapy

Chicago Tribune Results – Failure Rates

| | |
|-------------------------------|------------|
| Independent pharmacies | 72% |
| CVS | 63% |
| Target | 62% |
| Kmart | 60% |
| All Chains Combined | 49% |
| Wal-Mart | 43% |
| Jewel-Osco | 43% |
| Mariano's | 37% |
| Walgreens | 30% |

The test was recorded as a fail if the store did not warn about the drug interaction and did not try to discuss it with the prescribing physician

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Pharmacists and Medical Cannabis The Risks and Benefits of Cannabis Therapy

- State Medical Cannabis Programs with Pharmacist Mandate

Connecticut

New York

Minnesota

Pennsylvania

Arkansas

MORE COMING....



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Marijuana
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Daily®

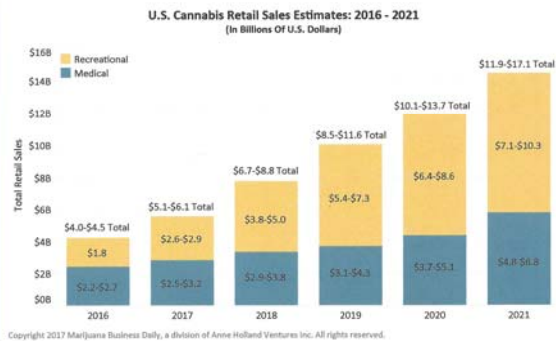
Exclusive Financial Data
For Cannabusiness &
Major Investors

**Marijuana
Business
Factbook
2017**

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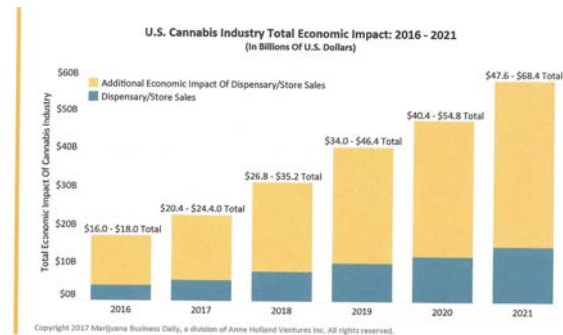


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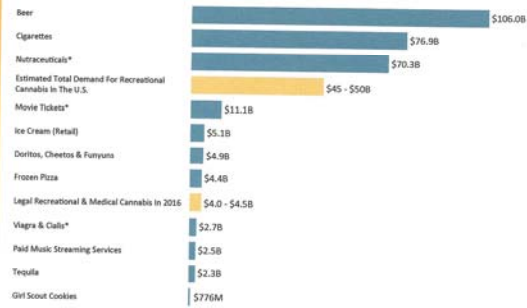


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Marijuana Business Daily®

Annual U.S. Cannabis Sales Vs. Other Industries & Goods



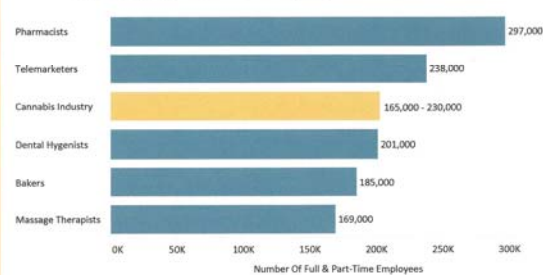
*Includes U.S. and Canada
 Source: Brewers Association, IRI, Monitor Intelligence, MPA, Statista, EB Lilly and Company, Pibar, RIAA, U.S. Distilled Spirits Council
 Note: All data is for 2015 or 2016, most recent figures are reported in the chart.
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Number Of Employees: Cannabis Industry Compared To Mainstream Professions



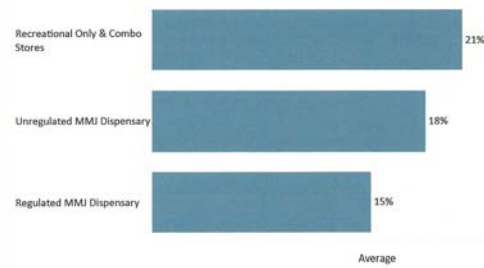
Source: U.S. Bureau Of Labor Statistics Employment Projections: 2014-2024
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Average Profit Margin For Dispensaries & Rec Stores By Store Type

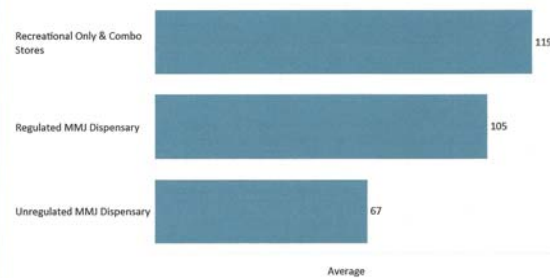


Note: Profits are calculated on an after-tax basis.
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Average Number Of Daily Customers For Dispensaries & Rec Stores

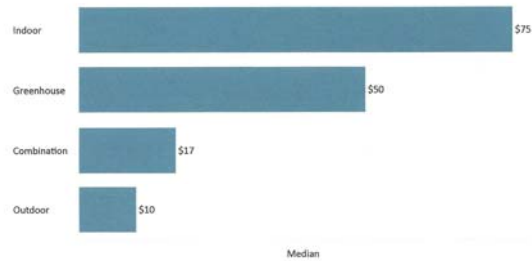


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Wholesale Cultivator Typical Startup Costs Per Square Foot By Cultivation Type

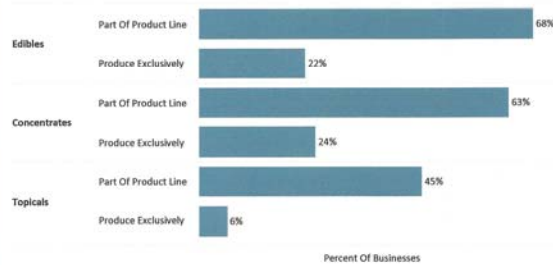


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Which Products Do Infused Manufacturers Typically Make?



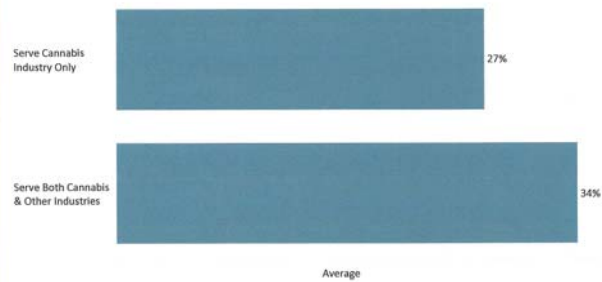
Note: Multiple-choice question; respondent total may be greater than 100%.
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Profitable Ancillary Services Firms: Average Profit Margin

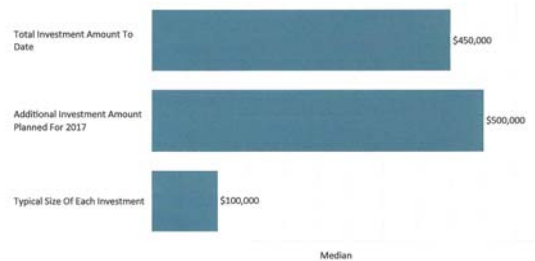


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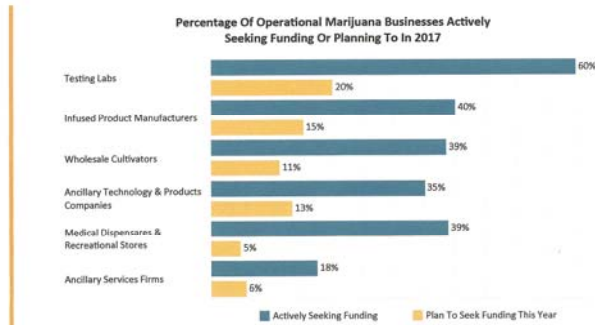
Cannabis Industry Investors: Typical Investment Amount To Date, Additional Investment Amount Planned For 2017 & Size Of Each Investment



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PDI MEDICAL – A DAY AT THE DISPENSARY

- Patient Cases
- Patient Testimonials
- Pharmacy Students
- Standards of Care and Practice at PDI Medical

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PDI Medical – A Day In The Dispensary

Patient Cases



Lisa K

Angela H

Daniel W

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PDI Medical – A Day In The Dispensary

Lisa K

Celiac Disease
GERD
Sjogren's Syndrome
Polyarthralgias
Joint Hypermobility
Myofascial Pain Syndrome
Neuritis/Neuropathy, Trigeminal Neuralgia from Arachnoid cyst
Raynauds Syndrome
Eczema
Asthma
Restless Leg Syndrome
Cognitive Impairment
Fibromyalgia
Myalgias, Myositis
Ocular Migraines
Gastroparesis
IBS
Tendonitis both knees, Baker's cyst behind right knee



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PDI Medical – A Day In The Dispensary

Lisa K



Coconut Oil 1.3:1.0 (1ml) RSO

- **Harlequin – Sativa Dominant Hybrid**
- **Bruce Banner – Indica**
- **Canna – Tsu – Hybrid**



THC 2.06%, CBD 3.4%

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PDI Medical – A Day In The Dispensary

Angela H

Complex Regional Pain Syndrome



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An Incredible Patient Letter

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August 28, 2017

Dear Carl,

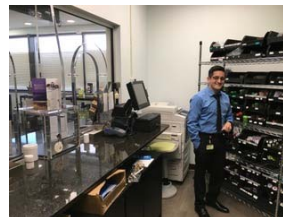
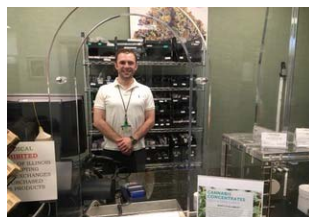
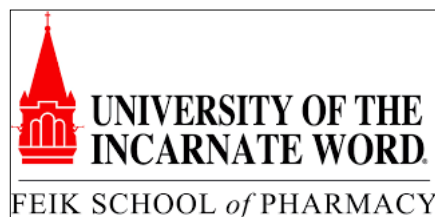
I have a deep love for PDI Medical. Every time I walk in the door, I feel like I am coming home. I want to help spread the word about PDI's unique pharmacist-driven approach to medical cannabis patient care. I feel strongly about helping PDI fulfill its mission as an innovative leader in the dispensary business.

PDI Medical has changed my life. PDI gave me my first completely pain-free day after nearly a decade of chronic, intractable pain. I never thought relief was something that I could experience. I never thought that my quality of life would be better than 95% bedrest. The knowledgeable and caring professionals at PDI have taught me that life can get better, even from the darkest depths of pain and suffering.

I want everyone else to know what I know about PDI: how accessible and welcoming the staff are, how much compassion and knowledge exist inside your four walls, and how you are improving quality of life for your many patients above and beyond what a "normal" dispensary service offers.

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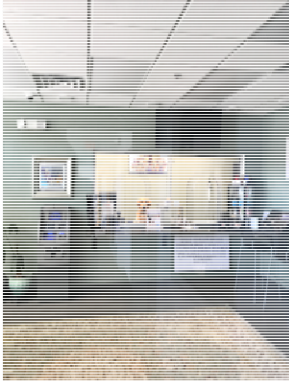
PDI Medical – PHARMACY STUDENT CLINICAL ROTATIONS



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PDI Medical – A Day In The Dispensary



Jaxson Bear



Sarah C., RN

Nick S., RPh



PDI Medical Staff Holiday Party 2016

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PDI Medical – A Day In The Dispensary



PDI CARES

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DISPENSARY ACCREDITATION



NMMAO accreditation indicates a dispensary's achievement of a high level of organizational proficiency

- May Lower Insurance Premiums
- May reduce serious complaints
- Enhances reputation to peers, law enforcement, regulators, prescribers, community and patients
- Improves work culture, staff morale and relations

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Jean Milford CEO, NMMAO
816-617-0658
Jean.Milford.MMConsulting@gmail.com



MEDICAL CANNABIS EDUCATION AND TRAINING

HOLISTIC CANNABIS NETWORK (HCN) + HOLISTIC CANNABIS ACADEMY (HCA)

- * HCN is the only cannabis education program produced by holistic nutrition practitioners
- * HCN/HCA is the only cannabis education program that teaches how to integrate cannabis into "alternative" modalities
- * HCA provides patient education materials for immediate use with clients
- * HCA delivers tools + resources directly to your door
- * HCA is a turnkey solution for busy professionals to integrate cannabis into their practices

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MEDICAL CANNABIS EDUCATION AND TRAINING
 HOLISTIC CANNABIS NETWORK (HCN) + HOLISTIC CANNABIS ACADEMY
 (HCA)

Holistic Cannabis Practitioner

31 modules in 4 tracks

Exam leading to a certificate

Collateral materials to download

Hot off the presses resources delivered directly to you

Online access to 2016 Holistic Cannabis Summit

Private FaceBook page for networking

Google hangouts with HCA team

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Credentialed professionals only



MEDICAL CANNABIS EDUCATION AND TRAINING
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 (HCA)

Curated Cannabis Packages

MMJ Primer (5 modules)

Herbal + Nutrition Toolbox (6 modules)

The Wellness Package (6 modules + bonus)

The Holistic Healer (4 modules)

Caregivers, patients, *canna curious* individuals

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AclaraResearch

Impact of Medical Cannabis on Prescription Drug Usage

Illinois Medical Cannabis Patients
Online Questionnaire
401 Respondents
September 2017

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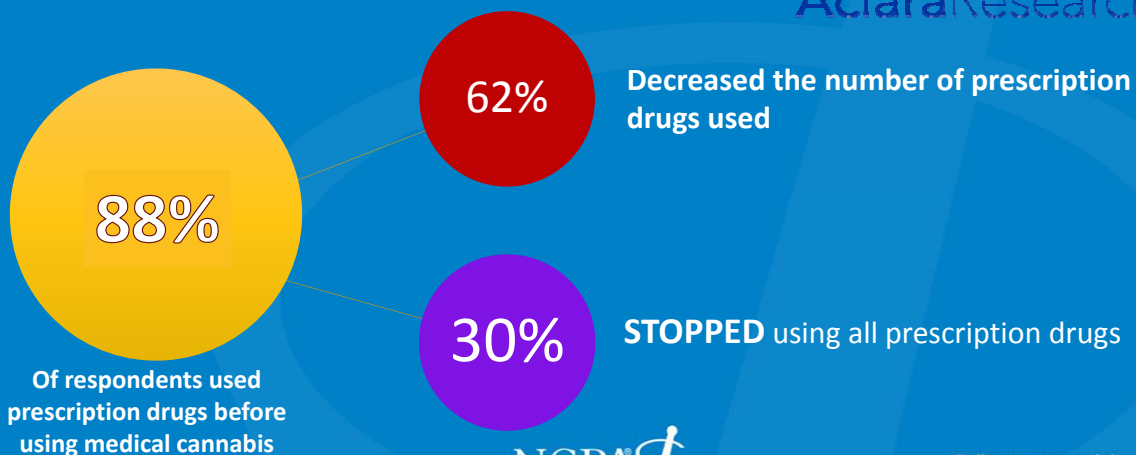


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30% of respondents stopped using ALL
prescription drugs after using medical cannabis

AclaraResearch



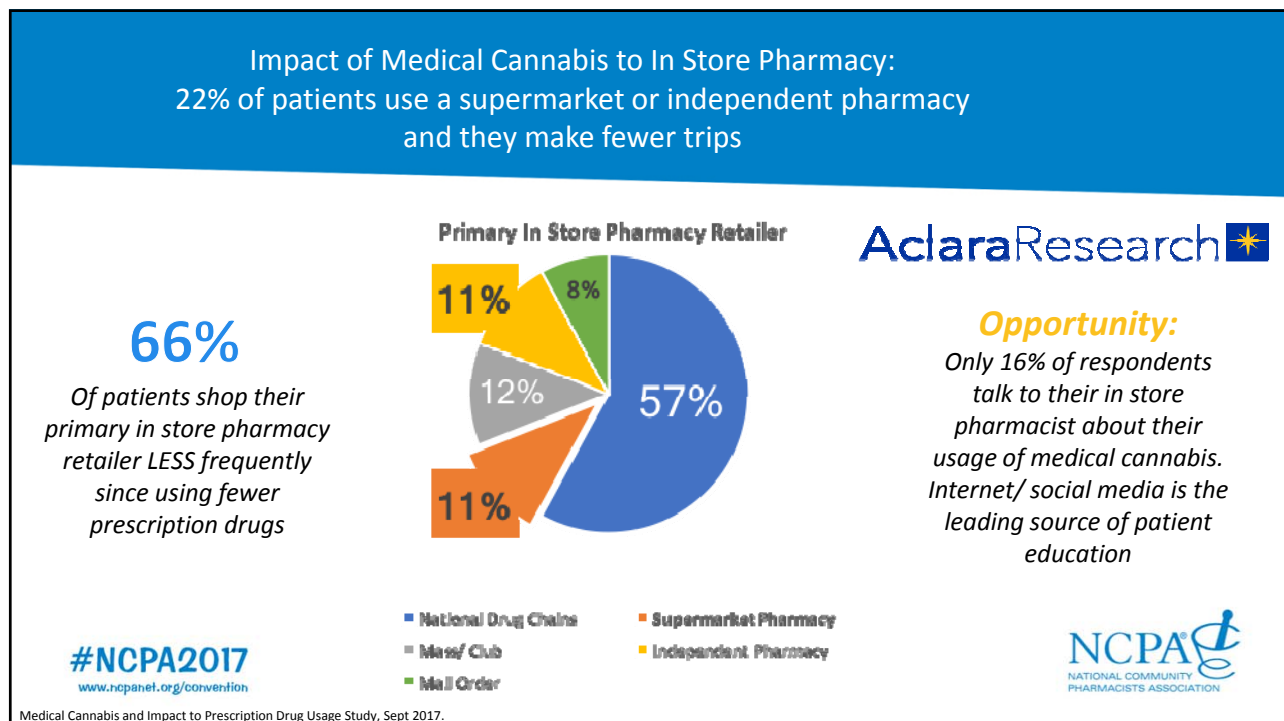
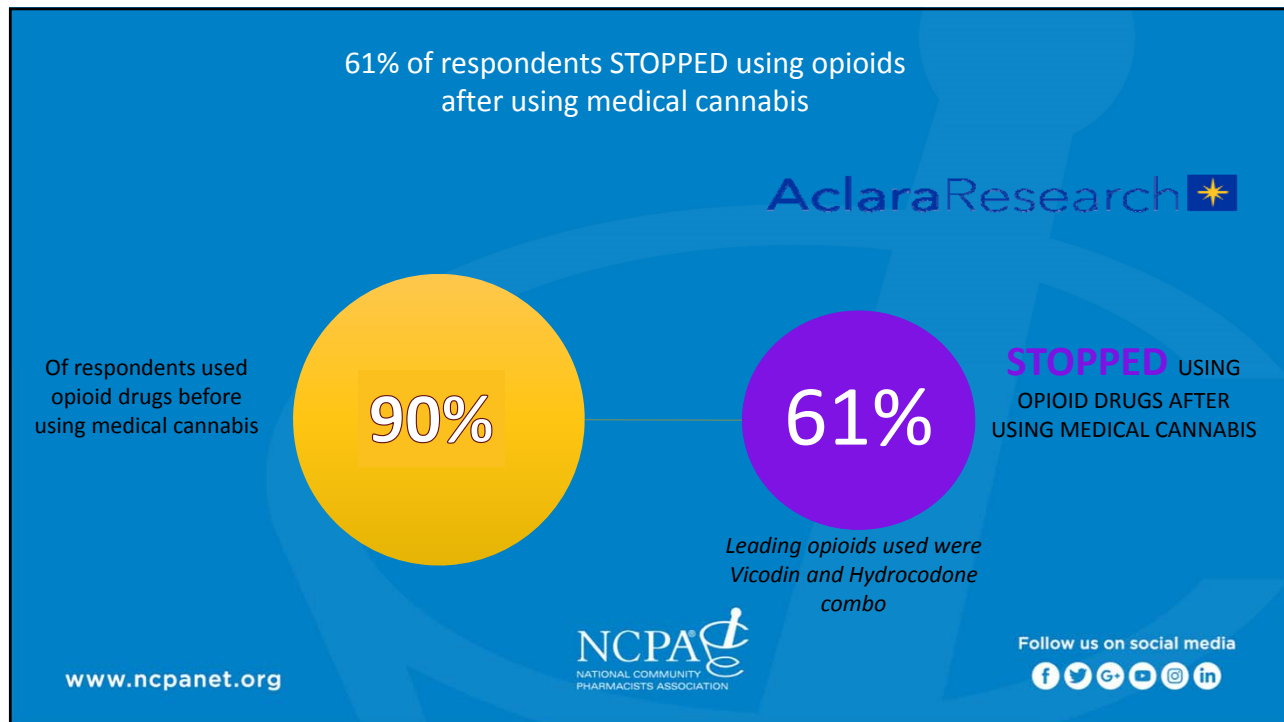
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Medical Cannabis and Impact to Prescription Drug Usage Study, Sept 2017.



Medical Cannabis and Impact to Prescription Drug Usage Study, Sept 2017.

Cannabidiol or CBD – DEA vs. Mankind

Establishment of a New Drug Code for Marijuana Extract – Highlights

New drug code established for marijuana extracts – An extract containing one or more cannabinoids that has been derived from any plant of the genus *Cannabis*, other than the separated resin (whether crude or purified) obtained from the plant. Extracts of marijuana will continue to be treated as Schedule 1 controlled substances.

For practical purposes, all extracts that contain CBD will also contain at least small amounts of other cannabinoids.[1] However, if it were possible to produce from the cannabis plant an extract that contained only CBD and no other cannabinoids, such an extract would fall within the new drug code 7350. In view of this comment, the regulatory text accompanying new drug code 7350 has been modified slightly to make clear that it includes cannabis extracts that contain only one cannabinoid.

DEA FOOTNOTE

Although it might be theoretically possible to produce a CBD extract that contains absolutely no amounts of other cannabinoids, the DEA is not aware of any industrially-utilized methods that have achieved this result.

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Cannabidiol or CBD – DEA vs. Mankind

DEA classification is a drug code, not a law

The senate makes laws, not the DEA.

Even if that were the law, the DEA recognized that Section 7606 protects hemp products out of approved industrial hemp research programs.

The DEA tacitly acknowledged that CBD sourced from industrial hemp cultivated lawfully pursuant to a State's industrial hemp laws enacted under the 2014 US Farm Bill is legal. This is because "industrial hemp" is itself specifically excluded from the CSA's definition of marijuana in Section 7606 of the Farm Bill.

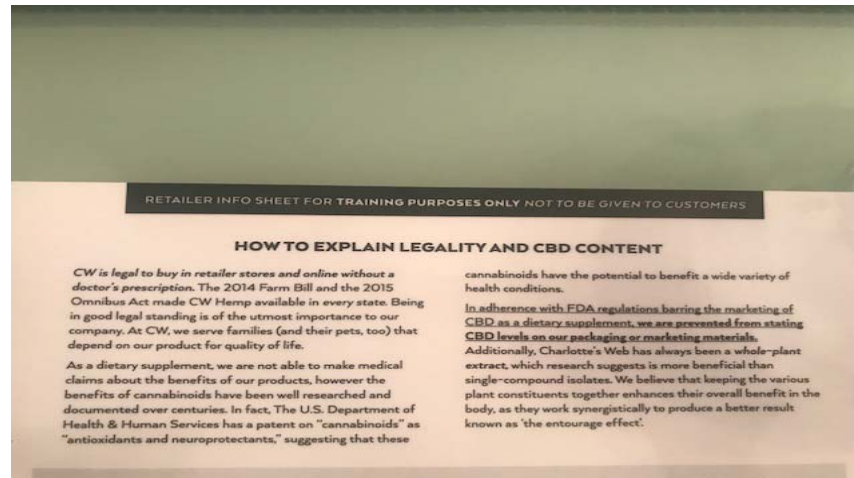
Since industrial hemp is excluded from the definition of the CSA, and a "product consist[ing] solely of parts of the cannabis plant excluded from the CSA definition of marijuana" is not included in the new drug code, then such product (CBD) is also excluded from the definition of marijuana under the CSA and is thus legal, at least at the Federal level."

Although Federally legal, states have the ability to pass laws prohibiting CBD sales from Agricultural Programs. So far, Denver is the only governing body has done so.

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Cannabidiol or CBD – DEA vs. Mankind



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Cannabidiol or CBD – DEA vs. Mankind

SACRED BODY



1844-OurSacredCbd
sacredbodycbd.com

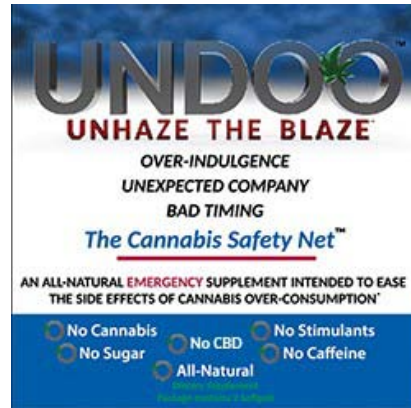


Hemp For Fitness
Natural Happiness®

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UNDOO



THE CANNABIS SAFETY NET

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CannaRPh
Medical Cannabis Advancement & Innovation

www.cannarph.com

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THE CHOICE



Reefer Madness

VS



Rph-er Sanity

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"Ten years from now, when we look back on this period, the most significant cultural shift in America will have been that of the transformation of the view of marijuana in the political-legal establishment from being a scourge to a blessing."

B. Valentine
Noted Futurist



Thank You!

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**Carpe' Diem
"seize the day"**
**Latin aphorism from Book 1 of the
Roman poet Horace's work Odes (23 BC)**

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Hitting the High Points of Medical Cannabis Part 2

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(Professional Dispensaries of Illinois)
Co-Founder, Principal
CannaRPh, LLC

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Change in Paradigm:
Cannabis IS Medicine



"It should **NOT** be a
crime for people to heal
themselves through a
medicine as **SAFE** and
EFFECTIVE as
Cannabis!"

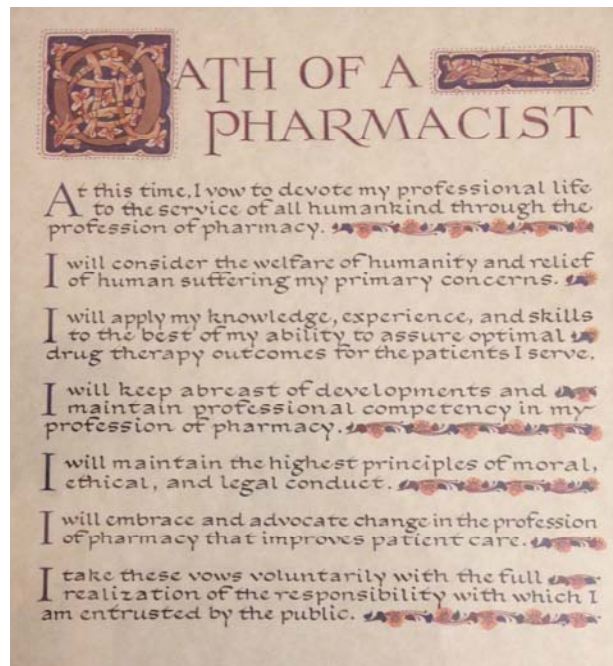


Seek...Discover...and above all,
Think for Yourself!

HempTherapy.net

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photo by B. Carlson, 2016

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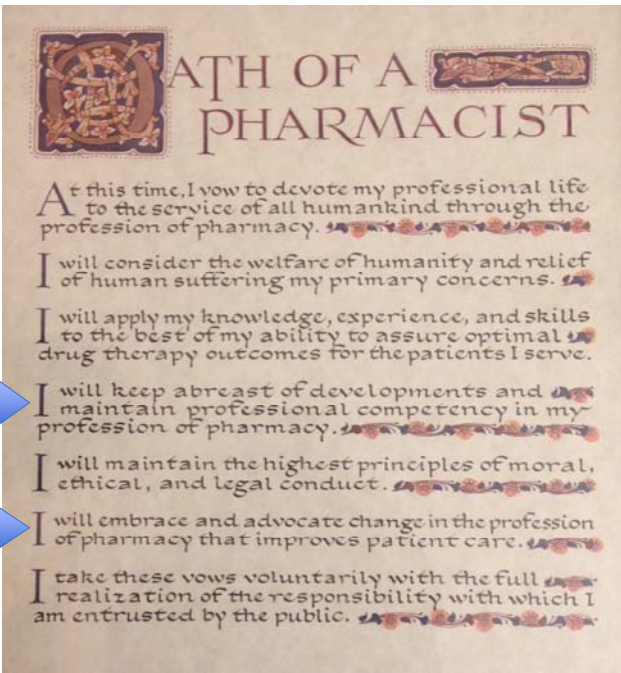
precipice

noun *prec-i-pice* \ˈpre-s(ə-)pəs\
: a very steep side of a mountain or cliff
: a point where danger, trouble, or difficulty begins

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photo by B. Carlson, 2014

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OATH OF A PHARMACIST

At this time, I vow to devote my professional life to the service of all humankind through the profession of pharmacy.

I will consider the welfare of humanity and relief of human suffering my primary concerns.

I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug therapy outcomes for the patients I serve.

I will keep abreast of developments and maintain professional competency in my profession of pharmacy.

I will maintain the highest principles of moral, ethical, and legal conduct.

I will embrace and advocate change in the profession of pharmacy that improves patient care.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

THIS
is why
WE are
HERE!

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photo by B. Carlson, 2016

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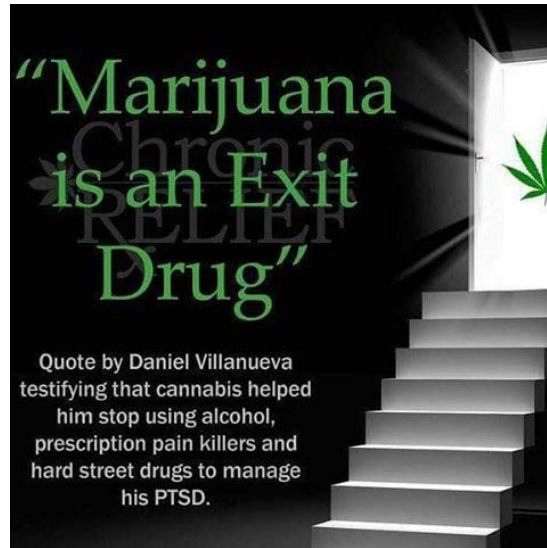
“What is half of 8?”

- Four (or 4)
- E or 3
- 0

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Change in Paradigm: Cannabis IS Medicine



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Session Objectives

At the end of this discussion, pharmacists will be familiar with:

- A Brief History of Cannabis as Medicine
- Overview of Endocannabinoid System, Cannabinoids, and targets for cannabis-based medications
- Summary of the role of synthetic cannabinoids, and compare to whole plant-based medication
- Compare and contrast common cannabis formulations and routes of administration, including pharmacokinetics and pharmacodynamics
- Clinical evidence for use of cannabis as medicine
- Use of cannabinoids for state-approved medical conditions.

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QUICK POLL QUESTION!!!

**How long has cannabis been utilized
and valued by humans?**

1. Approximately 400 years
2. Approximately 1000 years
3. Approximately 2000 years
4. Greater than 2000 years



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BRIEF Cannabis History

- Plant has been valued for millennia!
- Used as medicine, textile, food
- Complex history of use and control of use
- Medical use and recreational use becoming more widely accepted in US (although being used medicinally in other countries for years)

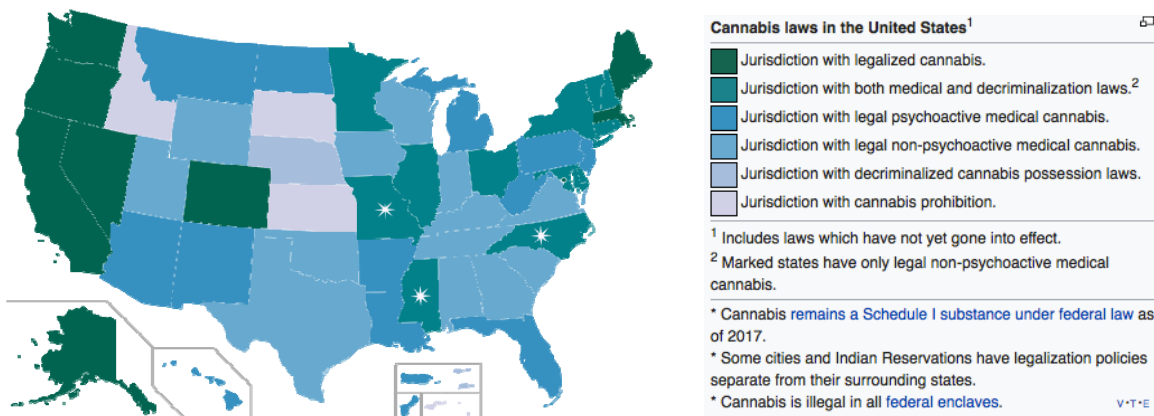


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The National Landscape



***** States + the District of Columbia have
State-Based Medical Cannabis Programs**

California was 1st State in 1996; up to 29 states as of 11/2016
 8 States Permit Recreational Use

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Image by Lokal_Profil, CC BY-SA 2.5,
<https://commons.wikimedia.org/w/index.php?curid=2370050>

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Medical Cannabis vs. Recreational Marijuana

- How do we “RECOGNIZE” Cannabis as medicine???
- Recreational use titrates to a “high”
 - “Risk-Risk” utilization
- Medical use titrates to symptom relief
 - “Benefit - Risk” utilization
 - PHARMACIST’S ROLE!!!!
- Some states allow different products / different quantities of product for medical vs. recreational
- PK / PD essentially the same; varies between patients and products

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QUICK POLL QUESTION!!!

Chemicals found within Cannabis effect which areas of the body?

1. Brain and Central Nervous System
2. Gastrointestinal System
3. Musculoskeletal System
4. Immune System
5. Reproductive System



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Targets for Cannabis Therapy:

The Human Endocannabinoid System

THC and CBN are known to "fit" like lock and key into network of existing receptors. The Endocannabinoid System exists to receive cannabinoids produced inside the body called "Anandamide" and "2-Arachidonylglycerol". Stimulating the ECS with plant-based cannabinoids restores balance and helps maintain symptoms.

CB1 receptors are concentrated in the brain and central nervous system but also sparsely populates other parts of the human body.

Receptors are found on cell surfaces



www.the-human-solution.org

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www.thsintl.org

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The Human Endocannabinoid System

- ✦ Endocannabinoids and their receptors found throughout body: brain, organs, connective tissues, glands, and immune cells.
- ✦ In each tissue, the cannabinoid system performs different tasks; goal is always homeostasis
- ✦ When cannabinoid receptors are stimulated, a variety of physiologic processes occur
 - ✦ CB1 receptors: nervous system, connective tissues, gonads, glands, organs
 - ✦ CB2 receptors: immune system and associated structures
- ✦ Endocannabinoids are substances our bodies make naturally to stimulate CB1 and CB2
 - ✦ Anandamide
 - ✦ 2-arachidonoylglycerol (2-AG)

<http://norml.org/library/item/introduction-to-the-endocannabinoid-system> Accessed June 9, 2015
Neuro Endocrinol Lett. 2008 Apr;29(2):192-200.
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Endocannabinoid Pharmacology

- Anandamide
 - partial agonist at CB receptors
 - slightly higher affinity for CB1
- 2-arachidonoyl glycerol
 - full agonist at CB1 receptor
- Stimulation of CB receptors has an effect to suppress neurotransmission at both excitatory and inhibitory synapses
- Ultimate action of CB stimulation is preservation of homeostasis - varies greatly depending on organ/tissue
 - pain modulation, lipid metabolism, mood, motor function, appetite stimulation, GI function, CV function, etc.

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Cannabis-Derived Pharmaceuticals

- ✦ Single molecule pharmaceuticals
 - ✦ Dronabinol (Schedule III)
 - ✦ Nabilone (Schedule II)
- ✦ Liquid extract: nabiximols (Sativex®)
 - ✦ Approved in 27 countries; U.S. - Phase III trials
- ✦ Liquid extract: cannabidiol (Epidiolex®)
 - ✦ FDA: orphan drug status for Dravet and Lennox-Gastaut syndromes
 - ✦ Expanded access INDs to several independent investigators
- ✦ ~~Phytocannabinoid-dense botanicals~~
 - ✦ *Cannabis sativa* – medicinal plant
 - ✦ (Schedule I)



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Single Molecule Pharmaceuticals

- Dronabinol (Marinol®) - synthetic THC
 - nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond to conventional antiemetics
 - anorexia associated with weight loss in patients with AIDS
- Nabilone (Cesamet®) - synthetic THC similar
 - nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond to conventional antiemetics
- Both agents have been utilized off-label for other indications



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Plant Extract Pharmaceuticals

Nabiximols (Sativex®)

*Spasticity (muscle stiffness/spasm) due to Multiple Sclerosis

*Neuropathic pain in MS

***Adjunctive analgesic treatment in patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain

Cannabidiol (Epidiolex®)

*Pediatric epilepsy

-Lennox-Gastaut Syndrome

-Dravet Syndrome

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8
2

Synthetics: A Thing of the Past?

- Whole Plant Extracts = Entourage Effect?



Jon Lane 2014

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Whole-Plant Extracts

- Cannabinoids
- Terpenes
- Lipids
- Flavonoids
- Sterols
- ENTOURAGE EFFECT!



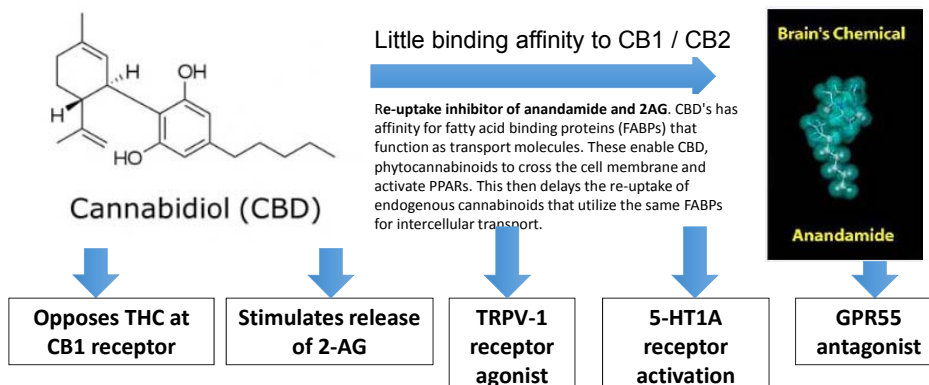
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The “New Kid” on the Block...

The cannabinoid that has sparked the most interest is a non-psychoactive component called Cannabidiol (CBD).



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Epilepsia 2014;55(6):791–802.
Slide adapted from Borgelt with permission. Anandamide image from drugabuse.gov

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QUICK POLL QUESTION!!!

Which of the following forms of Cannabis has the fastest onset of action?

1. Intravenous
2. Inhaled
3. Enteral
4. Sublingual



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Medical Cannabis: Formulations



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3 Most Common Routes of Administration



LUNGS

Vaporized or
Smoked

Organic material,
hash, waxes &
extracted oils



ENTERAL

Oral Ingestion

Lipophilic, alcoholic,
supercritical &
subcritical oil extracts
of plant material



TOPICAL

Application

Creams, buccal
tinctures, and
patches made from
plant extracts

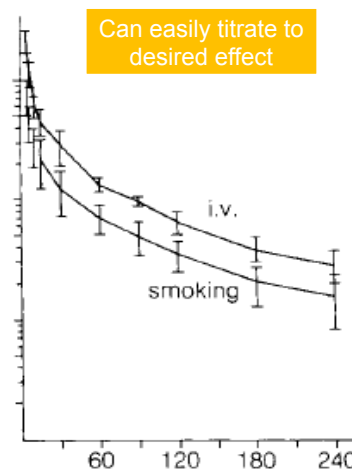
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Inhalation Delivery of Cannabis

- ✦ Similar to IV bolus
- ✦ Passive diffusion into alveolar capillaries
- ✦ Bioavailability: 2-56%
- ✦ Fraction absorbed: 10-20%
- ✦ Rapid onset (sec-min)
- ✦ Maximal onset 30 minutes and lasting 2-3 hours
- ✦ Metabolism in liver, lung, and brain
- ✦ Elimination $t_{1/2}$ = 20 hrs (2-13 days)
- ✦ Elimination primarily via feces (65%) and urine (20%)



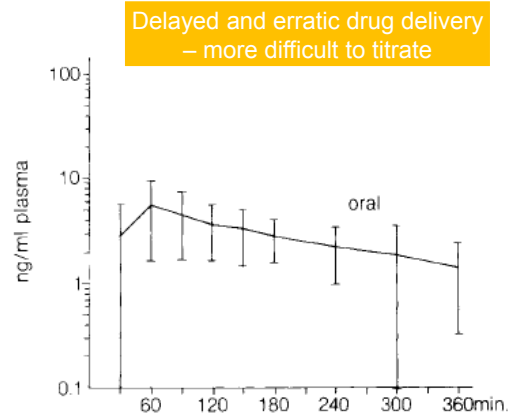
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Clin J Pain 2013;29:162-71. Brit J Clin Pharm 2009;67(1):5-21. Iran J Psychiatry. 2012;7(4):149-156. Clin Pharmacol Ther 2007;82:572-8. Pharmacol Rev 1986 Mar;38(1):21-43. Chem Biodivers. 2007;4(8):1770-804. Clin Pharmacol Ther 1980 Sep;28(3):409-16. Slide used from Borgelt with permission.

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Enteral Delivery of Cannabis

- ✦ Variable absorption
- ✦ Bioavailability ranges 4-20%
- ✦ Onset: 30 minutes-2 hours
- ✦ Duration: 5-8 hours
- ✦ Metabolized primarily in the liver
 - ✦ 11-hydroxy-THC
- ✦ Elimination $t_{1/2}$ = 20-30 hrs
- ✦ High inter- and intra-patient variability



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Pharmacotherapy 2013;33:195-209
Brit J Clin Pharm 2009;67(1):5-21
Clin Pharmacol Ther 1980 Sep;28(3):409-16
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Cannabis Through the Oral Mucosa

- ✦ Onset: 15-40 minutes
- ✦ Duration: 45 minutes-3 hours
- ✦ May have inter- and intra-patient variability
- ✦ Plasma levels of THC and other cannabinoids are lower compared with the levels achieved following inhalation of cannabinoids at a similar dose (nabiximols)
- ✦ Metabolized in the liver
- ✦ Elimination via feces (65%) and urine (35%)

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Ther Adv Neurol Disorders. 2012;5(5):255-66.
http://www.medicines.org.uk/emc/medicine/23262#PHARMACOKINETIC_PROPS
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Metabolism and Elimination

- Primary Hepatic via various CYP P450 Enzymes
 - THC = CYP2C9, CYP3A4
 - CBD = CYP2C19, CYP3A4
- Uridine diphosphate glucuronosyltransferases also play a role in metabolism
- *In vitro* Microsome studies suggesting many other elements involved in metabolism
- Other prescription medications influencing metabolism of Cannabis (and vice versa)

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Cannabis - Adverse Effects

- Serious Adverse Effects
 - psychosis
 - hypertension, increased pain, hyperemesis
 - birth defects
- Mild adverse effects
 - anxiety
 - disorientation, dizziness
 - difficulty concentrating
 - headache
 - dry eyes
 - burning sensation in throat
 - numbness
 - Psychoactive effects (such as feeling “high”)



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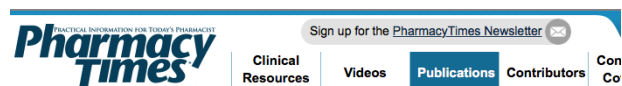
Cannabis - Safety Profile

- Therapeutic Index
- LD 50
- Deaths from use?

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Drug - Drug Interactions



• Back to issue

Drug Interactions with Marijuana

DECEMBER 09, 2014

John R. Horn, PharmD, FCCP, and Philip D. Hansten, PharmD

Marijuana has been approved for recreational use in 2 states and for medicinal use in about 20 states. Of course, the unapproved use of marijuana is fairly common. In addition to its recreational use, marijuana has been used (1) to control chemotherapy-induced nausea and vomiting and (2) as an analgesic, antispasmodic, appetite-stimulating agent, sedative, antiepileptic, and euphoric. Side effects associated with tetrahydrocannabinol (THC) include sedation, euphoria, dizziness, ataxia, tachycardia, hypotension, dry mouth, anxiety, and paranoia. THC is the primary psychoactive constituent of marijuana, but the plant contains more than 50 cannabinoids.

In addition to THC, cannabidiol (CBD) is found in high concentrations in marijuana. CBD does not produce any of the psychoactive responses and appears to block some of the effects of THC by acting as an antagonist at the cannabinoid receptors. Cannabinol is weakly psychoactive and appears to be primarily formed from the metabolism of THC. Another metabolite of THC is thought to contribute to the tachycardia and appetite-stimulating effects of cannabis.^{1,2}

The common natural sources of THC are *Cannabis sativa* and *Cannabis indica*. These differ in that *C sativa* is known to produce more of a "high" and lively feeling than *C indica*, which tends to produce a more relaxed feeling. This difference in response may be due to the THC:CBD ratios in the 2 plants. C

<http://www.pharmacytimes.com/publications/issue/2014/december2014/drug-interactions-with-marijuana>

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Drug-Drug Interactions

- Opioids
- Benzodiazepines, “z-drugs”
- Anticoagulation
- Anti-epileptic drugs
- Antibiotics
- Anticholinergics
- Sympathomimetics

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Key Point



Given the wide variety of formulations available, it is important to consider various pharmacokinetic and pharmacodynamic parameters.

A patient-determined, self-titrated dosing model should be used. The most effective and tolerable formulation and dose will vary based on body type, weight, and condition.

Providers need to step into a shared decision making model with patients.

Complex therapies NEED pharmacist Involvement!!

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Cannabis - Efficacy in Practice

- Few clinical trials exist
- Common phrase from practitioners:
 - “The jury is out” on efficacy
- Most evidence anecdotal
 - from personal experience, very positive!
- Many clinical trials used products that are not whole plant extracts
- Dronabinol and Nabiximols commonly utilized in clinical evaluations

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Clinical Trials: Medical Cannabis

SHOW ME THE MONEY!!!

A Review of Medical Cannabis Studies
relating to Chemical Compositions and
Dosages for Qualifying Medical Conditions

JULY 2017

<http://www.health.state.mn.us/topics/cannabis/practitioners/dosagesandcompositions2017.pdf>



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Minnesota Statistics

| Qualifying Condition | Patients Certified: N (%) |
|---|---------------------------|
| Glaucoma | 53 (1%) |
| HIV/AIDS | 63 (1%) |
| Tourette Syndrome | 51 (1%) |
| ALS | 18 (<1%) |
| Seizures | 379 (6%) |
| Muscle Spasms | 1055 (17%) |
| Inflammatory Bowel Disease, Including Crohn's Disease | 238 (4%) |
| Cancer | 742 (12%) |
| Terminal Illness | 98 (2%) |
| Intractable Pain | 4265 (69%) |
| Total | 6184 |

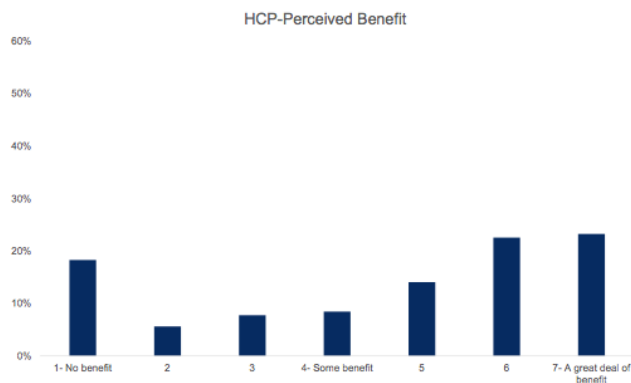
*Patients certified total more than 100% because 11.9% of the 6184 patients have had more than one qualifying condition certified; in this table each certified condition is counted.

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Clinician Perception of Benefit

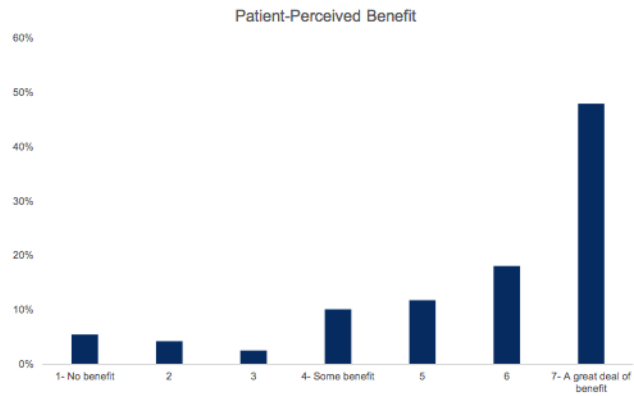


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Patient Perception of Benefit



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Cannabis as Medicine??

- In my personal experience:

• **IT WORKS!!!**



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Cannabis Research

- New dosage forms
 - Rectal, topical, transdermal, inhalation variations
- New indications
- Standardization of dosing
- Continued expansion of state programs
- Clinical trials?

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Key Point



Pharmacist Involvement

IS ESSENTIAL

for progression
of medical cannabis
and acceptance as
legitimate drug
therapy!!!

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Conclusions

- Cannabis has been used and valued by humans for millennia
- Cannabis-derived medication works by regulating and supplementing the body's endocannabinoid system
- Synthetic cannabinoids have helped paved the way for medical use of cannabis; whole-plant extracts are the focus of many current medication producers
- Cannabis can be successfully utilized in a variety of different dosage forms, most commonly inhalation, oral and topical
- Cannabis is being used successfully by patients with many disease states with many symptoms; more research needs to be done to expand and standardize these practices
- Pharmacists will have a key role to play as dosage forms and indications expand

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Special Thanks!!!

- Joseph Friedman
- Stuart Gimbel
- Dr. Laura Borgelt
- Dr. Angela Birnbaum
- Minnesota Department of Health
- Martin Lee
- Jon Lane

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?QUESTIONS?

Thank you for your time and attention!

Joseph Friedman & Bradley Carlson



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