(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD RETREAT

April 16, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:05 am

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury
Cynthia Warriner

MEMBER ABSENT:
James L. Jenkins, Jr.
Ryan Logan

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

GUEST SPEAKERS:
Carmen Catizone, MS, RPh, DPh, Executive Director/Secretary, National Association of Boards of Pharmacy
Peter Vlasses, PharmD, DSc(Hon), FCCP, Executive Director, Accreditation Council for Pharmacy Education
Aron Lichtman, PhD, Professor and Associate Dean of Research and Graduate Studies, VCU School of Pharmacy
Al Domeika, Pharmacist-in-Charge, Prime Wellness of Connecticut

QUORUM: With eight members present, a quorum was established.

APPROVAL OF AGENDA: The agenda was unanimously approved as presented.

PURPOSE OF MEETING:	Learning session for the Board of Pharmacy members to provide education on topics of Standards of Care, Pharmacy Technician Education Standards, Endocannaboid System and Cannaboid Research, and Medical Marijuana Dispensary Operations. Board members asked questions of the presenters following each presentation.
PRESENTATIONS:	
STANDARDS OF CARE REGULATORY APPROACH (ATTACHMENT 1)	Carmen Catizone, MS, RPh, DPh, Executive Director/Secretary, National Association of Boards of Pharmacy provided a presentation on the topic of Standard of Care Regulatory Approach.
PHARMACY TECHNICIAN EDUCATION STANDARDS (ATTACHMENT 2)	Peter Vlasses, PharmD, DSc(Hon), FCCP, Executive Director, Accreditation Council for Pharmacy Education, provided a presentation on the topic of Pharmacy Technician Education Standards.
ENDOCANNABINOID SYSTEM AND CANNABIS RESEARCH (ATTACHMENT 3)	Aron Lichtman, PhD, Professor and Associate Dean of Research and Graduate Studies, VCU School of Pharmacy, provided a presentation discussing the topic Endocannabinoid System and Cannabis Research.
MEDICAL MARIJUANA DISPENSARY OPERATIONS (ATTACHMENT 4)	Al Domeika. Pharmacist-in-Charge provided a presentation on the topic of Medical Marijuana Dispensary Operations.
UPDATE ON IMPLEMENTATION OF PHARMACEUTICAL PROCESSOR PROGRAM	Ms. Juran, Mr. Johnson, and Melody Morton provided a brief presentation to update the board on the status of the pharmaceutical processor program.
ADJOURN:	With all business concluded, the meeting adjourned at 3:15 pm.

Rafael Saenz, Chairman

6-5-19
DATE:

Caroline D. Juran, Executive Director

6/5/19
DATE:

Standard of Care Regulatory Approach

Virginia Board of Pharmacy Retreat

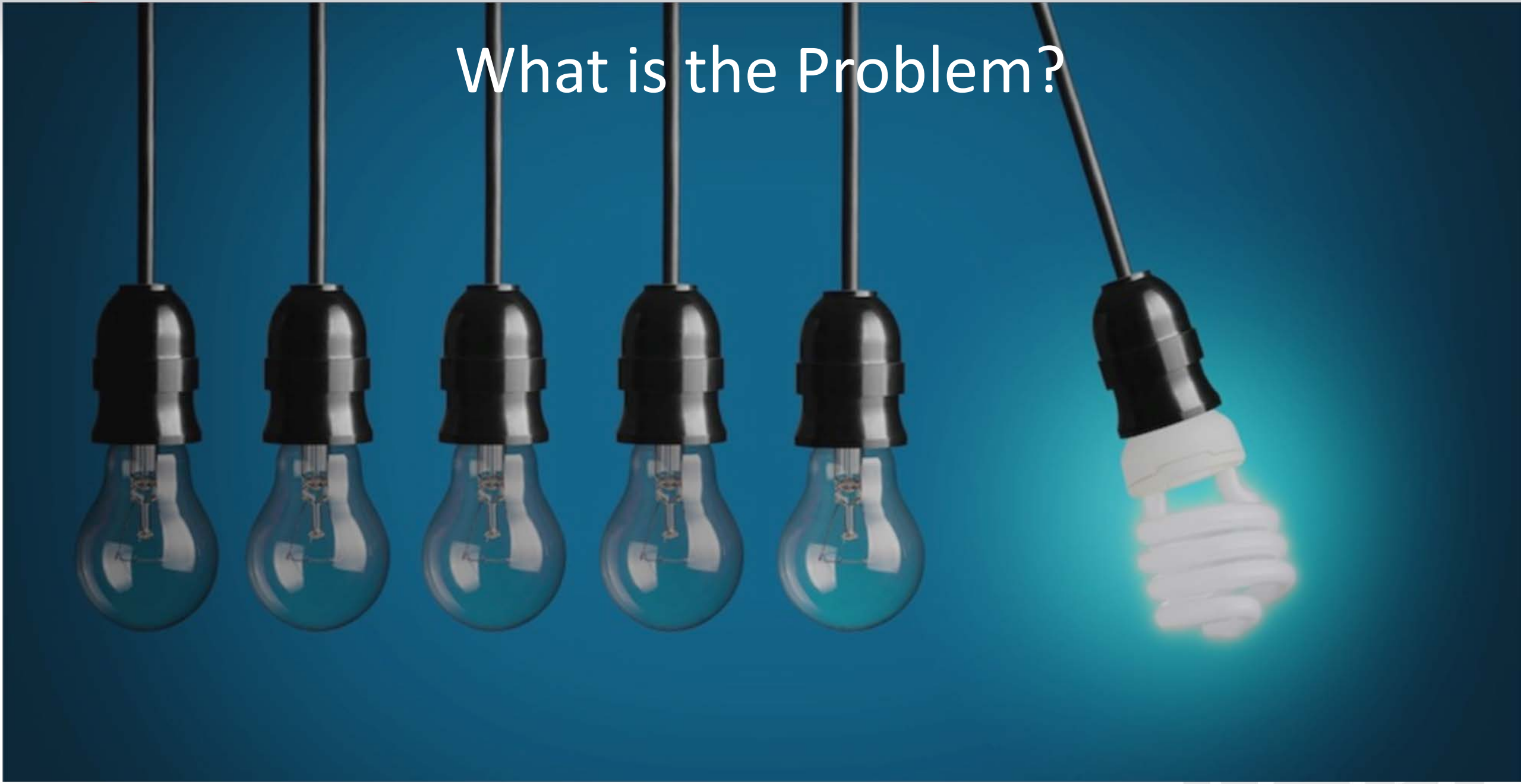
2019

Report of the Task Force to Develop Regulations Based on Standards of Care

The Task Force met on October 9-10, 2018, at NABP Headquarters.

Established in response to Resolution 114-4-18, Task Force to Develop Regulations Based on Standards of Care

What is the Problem?



Board of Pharmacy

- Regulate the practice of pharmacy to ensure protection of the public
  - License pharmacists, pharmacies, technicians (individuals cannot practice pharmacy or sell prescription medication without being licensed by the state board)
  - Develop, adopt and enforce pharmacy practice statutes and regulations
  - Perform regular onsite practice compliance reviews and inspections
  - Discipline

Relevant?
Effective?
Dynamic?
Clear?

NABP Task Force

Recommendation 1:

NABP Should Encourage State Boards of Pharmacy to Review Their Practice Acts and Regulations, Consistent With Public Safety, to Determine What Regulations Are No Longer Applicable or May Need to Be Revised or Eliminated While Recognizing Evolving Pharmacy Practice.

NABP Task Force

Recommendation 2: NABP Should Encourage State Boards of Pharmacy to Consider Regulatory Alternatives for Clinical Care Services That Require Pharmacy Professionals to Meet the Standard of Care.

New Regulatory Philosophies

Standard of Care

Right Touch

Responsive Regulation

“Permissionless innovation refers to the notion that experimentation with new technologies and business models should generally be permitted by default. Unless a compelling case can be made that a new invention will bring serious harm to society, innovation should be allowed to continue unabated and problems, if any develop, can be addressed later.”

Standard of Care

Defined

Origins in medical malpractice

Standard of Care ≅ Breach of Duty

Defined as Custom

Defining court cases

- **TJ Hooper 1932 - reasonable prudence**
- **Helling vs Carey 1974 - custom not key factor**

Legal profession and jury not the medical profession

Standard of Care

Medical malpractice is a legal fault by the physician or surgeon. It arises from the failure of a physician to provide the quality of care required by law. When a physician undertakes to treat a patient, he takes an obligation enforceable by law to use minimally sound medical judgement and render minimally competent care in the course of services he provides.

Minimally competent care …

> **“does not even have to be average … otherwise 50% of all medical care would be malpractice by definition.”**

The mere fact that the plaintiff’s expert may use a different approach is not considered a deviation from the recognized standard of medical care. Nor is the standard violated because the expert disagrees with a defendant …

Standard of Care - Nursing

1975 nurses identified as professionals – other medical professionals

Legal Definition

- **Broad statement**
- **Unlikely to be state statutes, public health codes, or practice acts**
- **Established by ordinary, reasonable nurse – similar circumstances**
- **Guidelines do not define standard of care**

Standard of Care

- **Duty to the patient**
- **Nurse breached the duty**
- **Patient injury occurred**
- **Casual relationship between the breach of duty and patient injury**

Right Touch Regulation

- **Proportionate**
- **Consistent**
- **Targeted**
- **Transparent**
- **Accountable**

Right Touch Regulation

- **Right Touch Regulation**
  - **“Minimum regulatory force required to achieve the desired result.”**
  - **Agility in regulation – “… looking forward to anticipate change rather than looking back to prevent the last crisis from happening again.”**
- **No Zero Risks**
- **More than one way to solve a problem**
- **Regulation not always the best answer (example addiction)**
- **Public protection vs responsiveness to practitioners**

Right Touch Regulation

- "Minimum regulatory force required to achieve the desired result."
- Agility in regulation – "… looking forward to anticipate change rather than looking back to prevent the last crisis from happening again."
- No Zero Risks
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Standard of Care

Recommendation 3:

NABP Should Collaborate With States That May Adopt Standards of Care-Based Regulations to Identify, Monitor, and Disseminate Outcomes.

Recommendation 5:

NABP Should Monitor the Adoption of the Standards of Care-Based Regulation Model by the States and, if and When Appropriate, Consolidate and Share Information and Tools Obtained From Professional Regulatory Groups and Relevant Stakeholders for Regulating Standards of Care-Based Practice.

Pharmacy – Standards of Care

Regulatory standards vs practice standards

- Check the PMP vs drug, dosage, quantity

Clinical training, experience, and knowledge vital to SOC investigative processes

Changes in SOC - complaint filed, investigation, and ultimately hearing

Finding expert witness for certain SOC – beyond state's border

Next A Pharmacist

ET KIM KARDASHIAN WEST IS STUDYING TO BECOME A LAWYER

NOW -1° AFT 3° NITE 2°

EB 401 HWY 25 ▸ 427 HEAVY 51 min

E BAN ON ABORTION IS UNCONSTITUTIONAL AND MUST BE LIFTED BY END OF 2020

8:15 AM

New ASHP/ACPE Accreditation Standards for Educational Preparation of Pharmacy Technicians

Peter H. Vlasses, PharmD, DSc(Hon), FCCP, ACPE

Virginia Board of Pharmacy Retreat

Perimeter Center, Henrico, VA

April 16, 2019

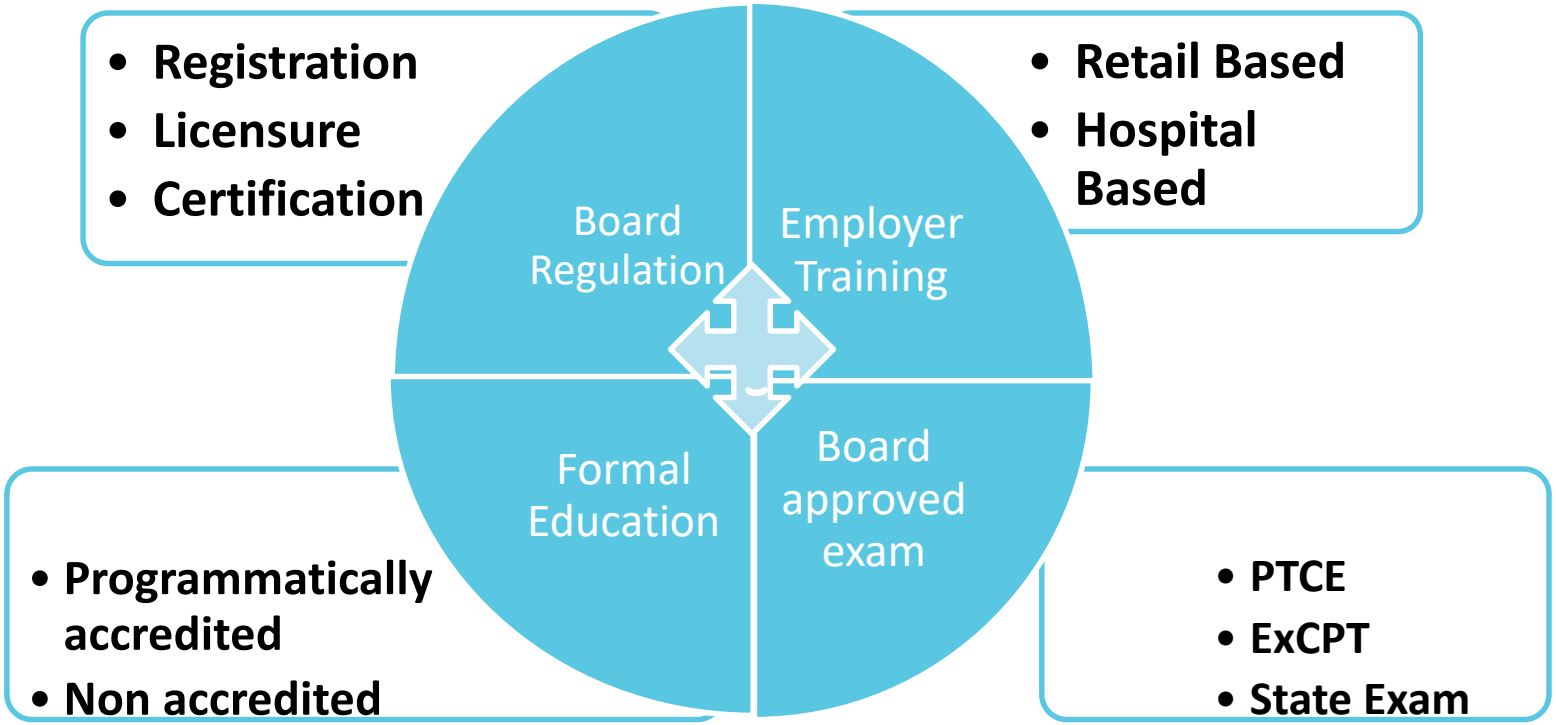
ashp pharmacists advancing healthcare®

ACPE®

LEARNING OBJECTIVES

- Discuss the variation in pharmacy technician education and accreditation requirements across U.S. states
- Describe the purpose of the 2017 *Pharmacy Technician Stakeholder Consensus Conference* and the consensus reached regarding pharmacy technician education
- Describe the new *ASHP/ACPE Accreditation Standards for Pharmacy Technician Education and Training Programs* developed in response to the findings of the 2017 *Pharmacy Technician Stakeholder Consensus Conference*
- Discuss growing support for national education standards for entry level pharmacy technicians

VARIOUS POINTS OF ENTRY FOR PHARMACY TECHNICIANS



TYPES OF PHARMACY TECHNICIAN EDUCATION/TRAINING PROGRAMS

- Certificate and degree programs in community colleges or technical schools
- College of Pharmacy associated programs
- Employer sponsored programs
- High school programs
- Military training programs
- Certification review courses
- Distance education programs

PHARMACY TECHNICIAN ACCREDITATION COMMISSION (PTAC)

- ASHP has been accrediting technician programs in the 1970's on a voluntary basis
- In 2012, NABP requests for ACPE to participate in pharmacy technician education and training accreditation
- PTAC formed through ASHP/ACPE collaboration in 2013
- ACPE Board approved ASHP standards, guidelines, and procedures for PTAC
- PTAC recommendations require approval of both ASHP and ACPE Boards
- First PTAC recommendations to ASHP and ACPE boards for accreditation actions occurred at their June 2015 meetings and were approved
- There are 265 ASHP/ACPE accredited pharmacy technician education and training programs and an estimated greater number of unaccredited programs

PTAC MEMBERS

- Donna S. Wall, BCPS, FASHP *Chair*
- Barbara Lacher, BS, RPHTECH, CPHT *Vice Chair*
- John J. Smith, ED *Past Chair*
- Charles E. Daniels, PhD
- Michael Diamond, MSc
- Denise Frank, RPh
- Barbara Giacomelli, PharmD, MBA
- Janet Kozakiewicz, MS, PharmD, FASHP
- Jeannie Pappas, RPT, CPhT
- Matthew A. Rewald, CPhT
- Lisa S. Lifshin, BS Pharm, ASHP *Secretary*

LIAISON TO ACPE BOARD OF DIRECTORS

- Michael A. Moné, RPH, JD, FAPHA

LIAISON TO ASHP BOARD OF DIRECTORS

- Kathleen S. Pawlicki, BS Pharm, MS, RPh, FASHP

PHARMACY TECHNICIAN

Stakeholder Consensus Conference

http://www.ajhp.org/content/ajhp/early/2017/06/07/ajhp170283.full.pdf?sso-checked=true

WHY NOW?

- **Technician roles are evolving and scope of practice is expanding**
  - Technicians play integral roles in supporting pharmacists in all practice settings
  - Provider status for pharmacists doesn't work without technicians
  - Complexity + Complications = Collaborative Healthcare
- **Greater expectations for technician**
  - Not just technical but patient focus
- **Regulations governing technician entry & practice vary widely**
- **Consider standards necessary within the profession to meet demands of growing healthcare system**

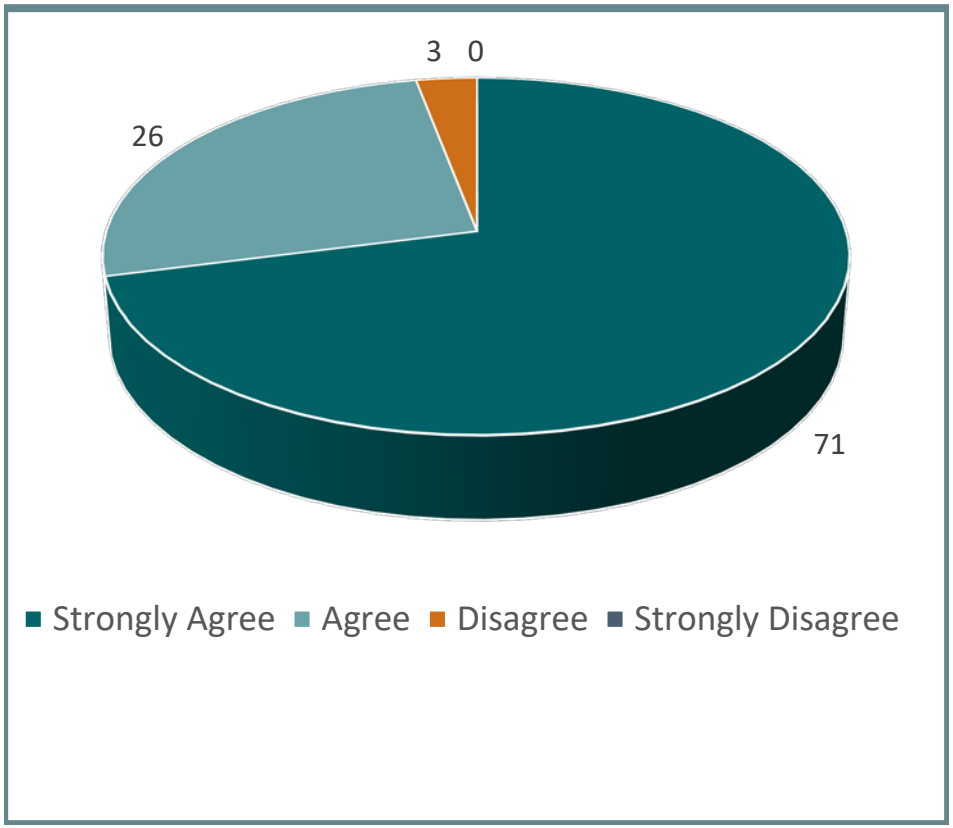
ABOUT THE CONFERENCE

- Planned by PTCB, ASHP, ACPE with the help of a multi-stakeholder advisory group
- Sponsored by the Pharmacy Technician Certification Board
- Held February 14 – 16, 2017 in Irving, Texas
- 89 invited participants
- 350 individuals participated remotely in the plenary sessions
- Attendees included the pharmacists and technicians from various types of practice and education settings and public members

Recommendations from Stakeholder Consensus Conference

- Defining Pharmacy Technicians
- Pharmacy Technician Education
- Required Knowledge, Skills, and Abilities of Entry--Level Pharmacy Technicians
- Certification of Pharmacy Technicians
- State Laws and Regulations on Pharmacy Technicians
- Advanced Pharmacy Technician Practice
- Moving Forward on Pharmacy Technician Issues

EDUCATION OF PHARMACY TECHNICIANS



Most conferees **agreed that national standards** should guide technician education, and that technician education **programs should be accredited**.

Standard Writing Subcommittee*

- **Tim Koch, RPh, PD,CHC**
  Sr Director, Pharmacy Practice Compliance
  Walmart Corporate Office
- **Kenneth Mark Ey, RPh**
  Vice President of Operations
  CARE Pharmacies Cooperative Inc.
- **Rafael Saenz, PharmD, MS, FASHP**
  Administrator, Pharmacy Services, University of Virginia Health System
  Assistant Dean, VCU School of Pharmacy - UVA Division
- **John J. Smith, Ed.D**
  Deputy Superintendent
  East San Gabriel Valley Regional Occupational Program & Technical Center
  West Covina, CA
  PTAC Chair
- **Barbara Lacher, BS, RPHTECH, CPHT**
  Assistant Program Director & Associate Professor of Pharmacy Technician Program
  North Dakota State College of Science
  PTAC Member
- **Peter H. Vlasses, PharmD, DSc(Hon), FCCP**
  Executive Director
  Accreditation Council for Pharmacy Education
- **Janet A. Silvester, PharmD, MBA, FASHP**
  Vice President, Accreditation Services
  Accreditation Services Office, ASHP
- **Lisa S. Lifshin, RPh, BCNSP**
  Director of Pharmacy Technician Accreditation and Residency Services.
  Secretary to PTAC
  Accreditation Services Office, ASHP
- **Sheri Roumell, BS, CPhT, RPT**
  Pharmacy Technology Program Director
  Casper College
  Casper, WY
  ASHP/ACPE Lead Surveyor
- **Donna S. Wall, BCPS, FASHP**
  Clinical Pharmacist
  Indiana University Hospital
  Indianapolis, IN
  PTAC Vice Chair
- **Supported by Angela Cassano, PharmD, BCPS, FASHP**
  President
  Pharmfusion Consulting, LLC
  PTAC Member

*Appointed July 2017

Standard Revision Process

- Review of the PTSCC recommendations
- PTCE job analysis review
- ExCPT blue print review
- Compared job analyses to the existing standard
- Any PTSCC recommended entry-level competencies missing were added
- Separated entry-level competencies from advanced-level competencies

Standard Revision Process (cont.)

- Identified additional advanced-level competencies
- Identified Key Elements for achieving a standard at each level
- Minimum hour requirements have been edited to reflect education and training needs for entry-level and advanced-level competencies and were established by an independent review of the standard by a group of educators

MOVING FORWARD ON PHARMACY TECHNICIAN ISSUES

- Unanimous agreement that the conference planners should establish a coalition of stakeholders to pursue the consensus recommendations from the conference
- Most conferees agreed that participants in this stakeholder event have a responsibility to work toward achieving the consensus recommendations

The Stakeholder Advisory Group Members*

- Ann Barnes, PTEC
- Cynthia Boyle, Univ. Md Eastern Shore
- Malcolm Broussard, LABOP +
- Liz Cardello, APhA
- Al Carter, CVS (now Walgreens) +
- Mark Ey, Care Pharmacies+
- Diane Halvorson, Nd BOP +
- Tim Koch, Walmart +
- Scott Meyers, IL CHP +
- Michael Moné, Cardinal Health
- Matt Osterhaus, Osterhaus Pharmacy +
- Sara Roszak, NACDS
- Jon Roth, Ca PhA +
- Rafael Saenz, Univ. VA +
- Ed Sperry, Id BOP
- Ed Webb (now Kathy Pham), ACCP
- Lisa Schwartz, NCPA

*Met October 31, 2017
+ On PTSCC planning team

Supported by ASHP, ACPE and PTCB staff and facilitated by William Zellmer

Standard Revision Process

- The draft standards were reviewed by the Stakeholder Advisory Group and PTAC in October
- Changes were incorporated
- The new draft was sent to members of the Stakeholder Advisory Group again for additional comment prior to the public comment period
- Went out for stakeholder comment the end of January 2018 for two months
- The writing group reviewed the feedback and submitted their edits to PTAC for their May 2018 meeting for review
- Final draft went from PTAC to the ASHP and ACPE Boards in for approval
- ASHP and ACPE boards approved the new standards in June 2018; posted on both web sites

Implementation Timeline

- The new standards became effective for first time applicant programs as of January 1, 2019.
- Existing accredited pharmacy technician programs will have until January 1, 2020 to incorporate the new standards into their programs and will be surveyed against these revised standards after that date.

Revised ASHP/ACPE Accreditation Standards for Pharmacy Technician Education and Training Programs

Purpose:

- protect the public by ensuring the availability of a competent workforce;
- describe pharmacy technician education and training program development at the Entry-level and Advanced-level;
- provide criteria for the evaluation of new and established education and training programs; and
- promote continuous improvement of established education and training programs

SECTION I: COMPETENCY EXPECTATIONS

Entry-Level

- **The program prepares students for practice as Entry-level pharmacy technicians in a variety of contemporary settings (e.g., community, hospital, home care, long-term care) and has students acquire knowledge, skills, behaviors, and abilities needed for such practice.**

Advanced-Level

- **The program prepares students for practice as Advanced-level pharmacy technicians, in a broad range of advanced roles in a variety of contemporary settings (e.g., community, hospital, home care, long-term care) and has students acquire additional knowledge, skills, behaviors, and abilities beyond those of the Entry-level pharmacy technician, needed for such advanced practice.**

Three Sections of the ASHP/ACPE Standards

- **SECTION I: COMPETENCY EXPECTATIONS**
  - Standards # 1 to 5
- **SECTION II: STRUCTURE AND PROCESS TO PROMOTE ACHIEVEMENT OF COMPETENCY EXPECTATIONS**
  - Standards # 6 to 13
- **SECTION III: ASSESSMENTS OF STANDARDS AND KEY ELEMENTS**
  - Standards # 14 to 15

SECTION I: COMPETENCY EXPECTATIONS

- **Standard 1: Personal/Interpersonal Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 4 Key Elements
- **Standard 2: Foundational Professional Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 3 Key Elements
- **Standard 3: Processing and Handling of Medications and Medication Orders**
  - Entry-level: 22 Key Elements
  - Advanced-level: 9 Key Elements
- **Standard 4: Patient Care, Quality and Safety Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 5 Key Elements
- **Standard 5: Regulatory and Compliance Knowledge and Skills**
  - Entry-level: 8 Key Elements
  - Advanced-level: 2 Key Elements

SECTION II: STRUCTURE AND PROCESS TO PROMOTE ACHIEVEMENT OF EDUCATIONAL OUTCOMES

- **Standard 6: Authority and Responsibility provided to Program Director**
  - 9 Key Elements
- **Standard 7: Strategic Plan**
  - 2 Key Elements
- **Standard 8: Advisory Committee**
  - 5 Key Elements
- **Standard 9: Curricular Length**
  - Entry-level: 4 Key Elements
  - Advanced-level: 2 Key Elements

SECTION II: STRUCTURE AND PROCESS TO PROMOTE ACHIEVEMENT OF EDUCATIONAL OUTCOMES

Standard 9: Curricular Length

- **Entry-level: 400 hours, ≥ 8 weeks**
  - 300 hours divided as:
    - Didactic – 120 hours
    - Simulation – 50 hours
    - Experiential – 130 hours
  - 100 hours allocated as program director and faculty see fit
- **Advanced-level: 600 hours, ≥ 15 weeks (includes Entry-level hrs)**
  - 460 hours divided as:
    - Didactic – 160 hours (40 more hours beyond Entry-level)
    - Simulation – 100 hours (50 more beyond Entry-level)
    - Experiential – 200 hours (70 more hours beyond Entry-level)
  - 140 hours allocated as program director and faculty see fit

SECTION II: STRUCTURE AND PROCESS TO PROMOTE ACHIEVEMENT OF EDUCATIONAL OUTCOMES (cont.)

- **Standard 10: Curricular Composition and Delivery (includes distance learning expectations)**
  - 8 Key Elements; Distance Learning – 4 Key Elements
  - Entry-level: Students complete at least **one experiential rotation** in a dispensing pharmacy setting where the student will utilize skills learned during their entry-level curriculum
  - Advanced-level: Students complete at least **one additional experiential rotation**, in addition to any completed during an entry-level program. This advanced experiential rotation takes place in a facility where the student will utilize skills learned during the advanced-level curriculum.
- **Standard 11: Student Recruitment, Acceptance, Enrollment, and Representation -** 8 Key Elements
- **Standard 12: Faculty/Instructors -** 4 Key Elements
- **Standard 13: Documentation -** 8 Key Elements

SECTION III: ASSESSMENTS OF STANDARDS AND KEY ELEMENTS

- **Standard 14: Assessment of Competency Expectations**
  - 14.1 Student Learning Assessments – 6 Key Elements
  - 14.2 Program assessments – 5 Key Elements

    (a) program completion;

    (b) performance on national certification examinations or; performance on a psychometrically valid evaluation;

    (c) program satisfaction, including student, graduate, and employer satisfaction;

    (d) job placement; and

    (e) assessment data used in the continuous quality improvement process is actively maintained.
- **Standard 15: Assessments of Structure and Process**
  - 3 Key Elements

Pharmacy in relation to other Allied Health Professions standards for support staff education

Allied Health Position	Training
Clinical Lab Technician	2-4 years
Dental Hygienist	2-6 years
Dental Assistant	1-2 years
Dietetic Technician	3-4 years
Medical Assistant	1-2 years
Occupational Therapy Assistant	2 years
Pharmacy Technician	**Entry Level - 400 hours >= 8 weeks Advanced Level -600 hours >= 15 weeks**
Physical Therapy Assistant	2 years
Surgical Technologist	1-2 years
EMT	2 years
Veterinary tech	2 years
2017 Liaison International	

Presentations re: New Pharmacy Technician Education Accreditation Standards

2018

- Joint Commission of Pharmacy Practitioners
- VSHP Spring Commonwealth Leadership Forum
- All five NABP/AACP District meetings
- Maryland Technician Consensus Conference
- ASHP Midyear meeting
- Vizient Pharmacy Leadership meeting
- Illinois Collaborative Pharmaceutical Task Force

2019

- APhA Annual Meeting
- Virginia Board of Pharmacy
- Pharmacy Technician Educators Council

RECENT JCPP PRESS RELEASE

National pharmacy organization members of the Joint Commission of Pharmacy Practitioners (JCPP) have agreed to support "the adoption of national standards to ensure that pharmacy technician education consistently achieves quality outcomes." Their statement of support adds, "In applying developed standards, accrediting bodies should allow for innovation and flexibility in program delivery." The following organizations worked to draft the statement, and their boards have voted to support the adoption of national standards:

- Academy of Managed Care Pharmacy
- Accreditation Council for Pharmacy Education
- American Association of Colleges of Pharmacy
- American College of Apothecaries
- American College of Clinical Pharmacy
- American Pharmacists Association
- American Society of Consultant Pharmacists
- American Society of Health-System Pharmacists
- College of Psychiatric and Neurologic Pharmacists
- Hematology/Oncology Pharmacy Association
- National Alliance of State Pharmacy Associations
- National Association of Boards of Pharmacy

LEARNING OBJECTIVES

- Discuss the variation in pharmacy technician education and accreditation requirements across U.S. states
- Describe the purpose of the 2017 *Pharmacy Technician Stakeholder Consensus Conference* and the consensus reached regarding pharmacy technician education
- Describe the new *ASHP/ACPE Accreditation Standards for Pharmacy Technician Education and Training Programs* developed in response to the findings of the 2017 *Pharmacy Technician Stakeholder Consensus Conference*
- Discuss growing support for national education standards for entry level pharmacy technicians

QUESTIONS?

Endocannabinoid System and Cannabis Research

Aron H. Lichtman
Department of Pharmacology and Toxicology
Department of Medicinal Chemsitry

Disclosures

Scientific Advisory Board member

- Abide Therapeutics
- Sea Pharmaceuticals

Consulting

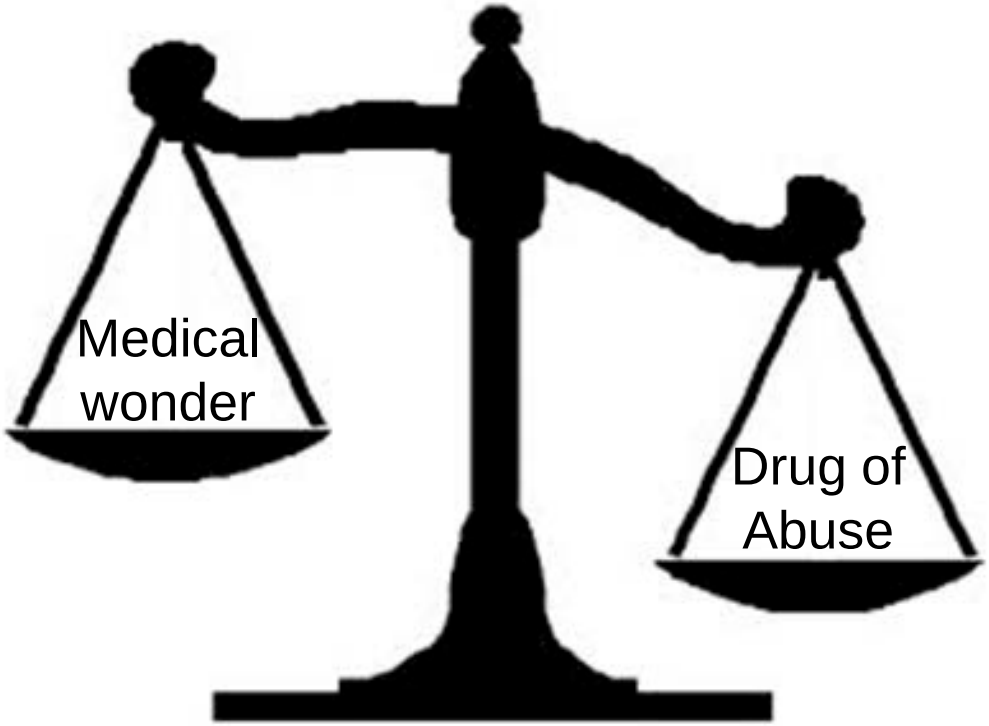
- F. Hoffmann-La Roche Ltd
- Corbus Pharmaceutics

Learning Objectives

a. REVIEW the primary constituents of cannabis and their mechanisms of action.
b. Identify key components and physiologic effects of the endogenous cannabinoid system
c. REVIEW the physical properties and effects of synthetic cannabinoid drugs

The Paradox of “Medical” Cannabis

Although most states in the USA have legalized cannabis and/or its primary constituents for medical use, it remains illegal under the federal law



Many originally plant-derived medications work upon endogenous systems

Cannabis
Cannabis sativa

Willow Tree
Salix

Opium
Lachryma papaveris

Foxglove
Digitalis purpurea

What are Cannabinoids?

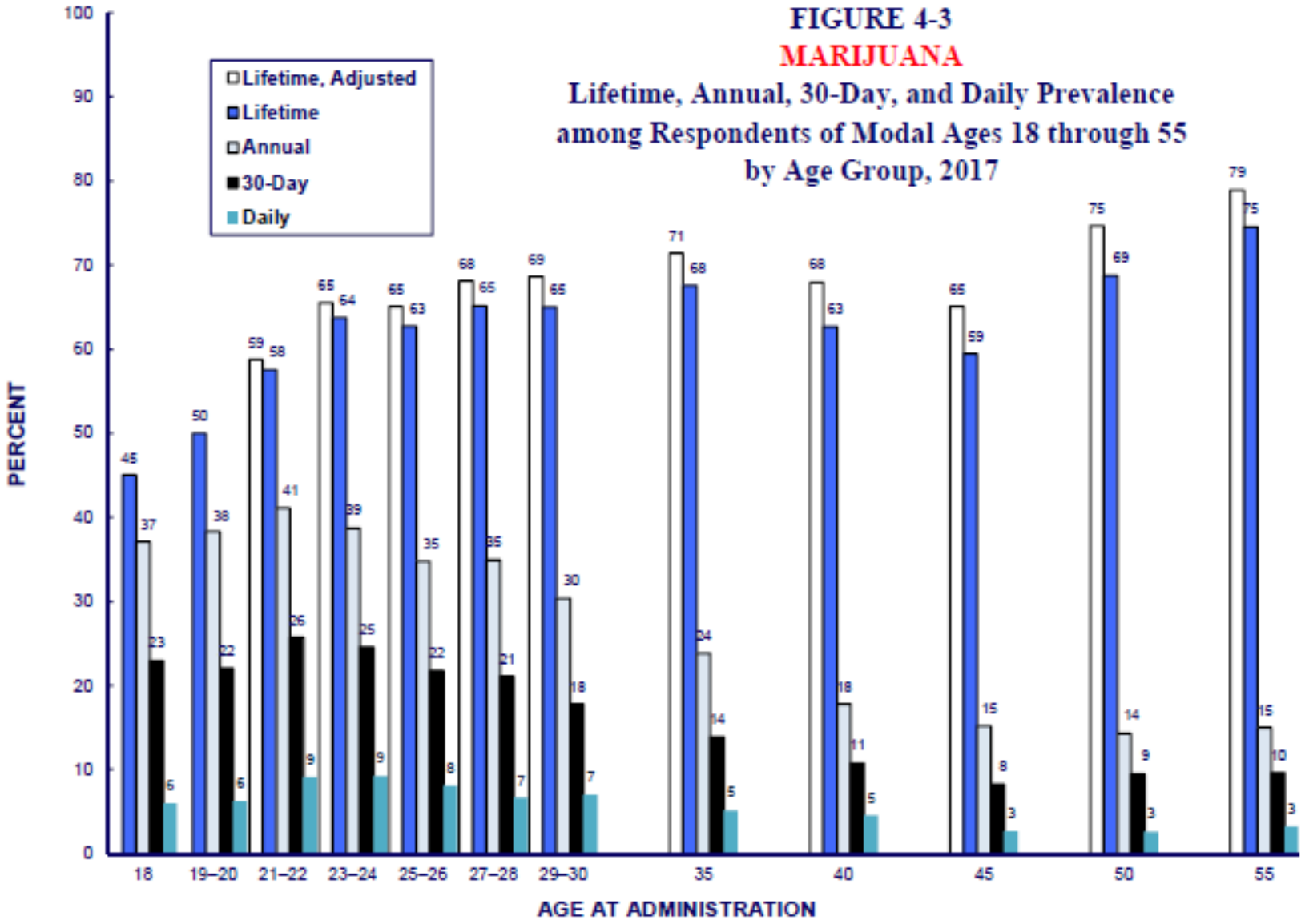
Diverse drug class of differing chemical structures

Originally discovered in marijuana

Present in the brains and bodies of humans and other animals

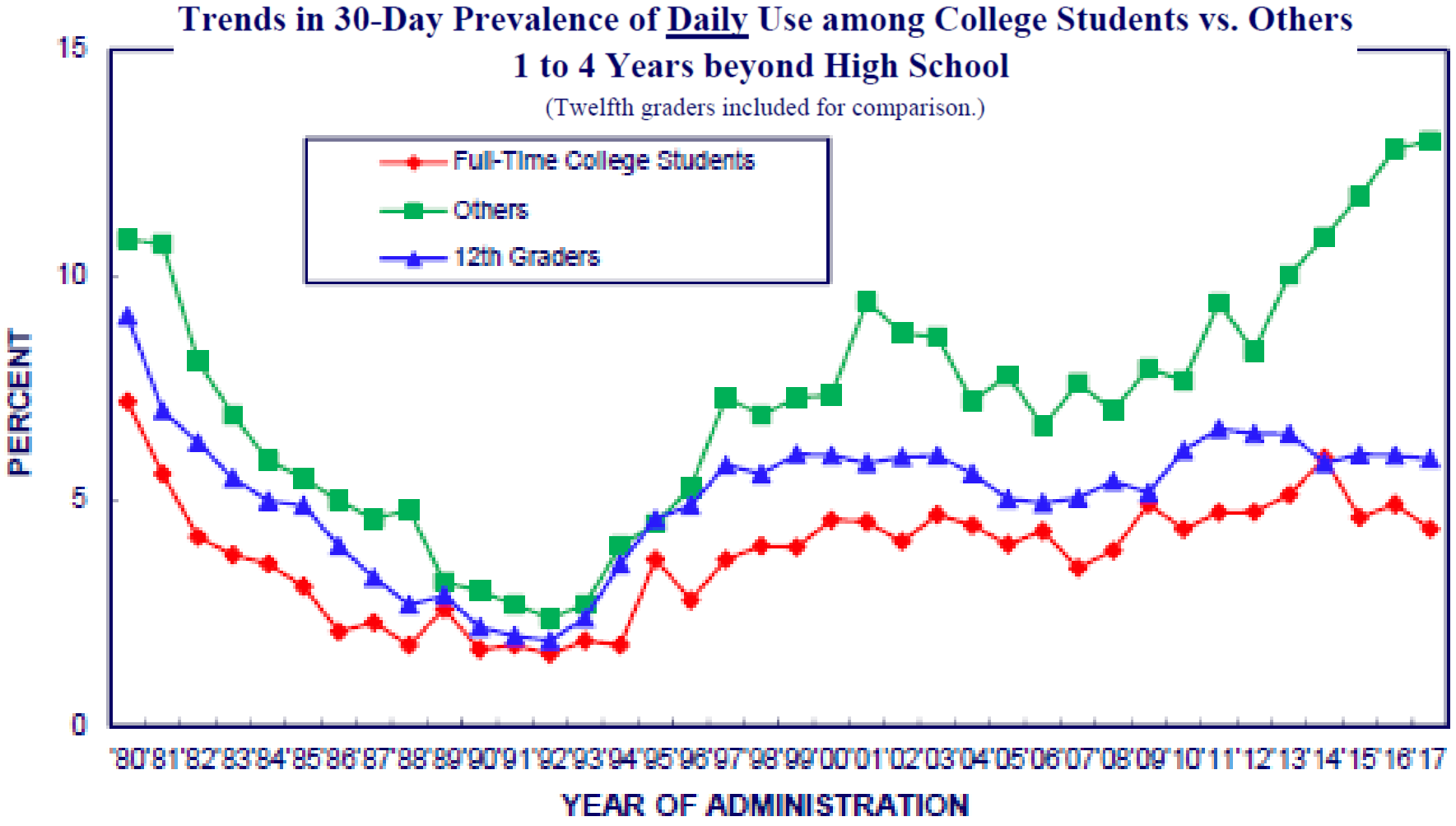
Synthesized by chemists

Most Adults Have Smoked Marijuana



http://www.monitoringthefuture.org/

Cannabis Use in Young Adults: Daily



http://www.monitoringthefuture.org/

Cannabis Intoxication in Humans

Intoxicating effects

- “High”
- Mild euphoria and relaxation
- Perceptual alterations
- Time distortion
- Ordinary sensory experiences intensified
- Increased sociability

Pharmacological Properties in Humans

- Heart rate increased (common effect)
- Blood pressure generally unchanged
- Orthostatic hypotension (high doses)
- Diuretic effects
- Conjunctival reddening

✓ Appetite/food intake increased

✓ Anti-emesis/anti-nausea

- Reduction in intraocular pressure
- Bronchodilation

Given that so many people smoke cannabis or ingest cannabis edibles, is it a safe drug?

Concerns

- High THC content
- Adulterants and lack of accurate labeling
- Abuse potential
- Physical dependence (anxiety & irritability, impaired sleep, decreased appetite, cannabis craving, etc.)
- Impaired driving (e.g., increased automobile accidents)
- Panic reactions (emergency room visits)
- Associated with schizophrenia
- Impaired short-term memory
- Legal/socioeconomic hindrance

Pharmacological Effects of Cannabinoids in Laboratory Animals

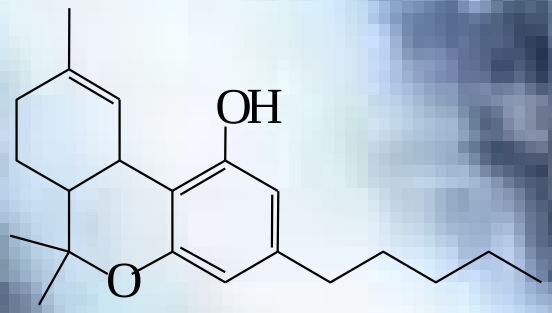
Increased heart rate
Ataxia
Tetrad
- Decreased locomotion
- Analgesia
- Catalepsy
- Hypothermia

Increased appetite
Diminished muscle tone
Discriminative cue
Self-administration
Memory disruption

Chemical constituents of cannabis

Chemical classes

Cannabinoids (100+)
Nitrogenous cmpds (27)
Amino acids(18)
Proteins/ enzymes (11)
Sugars (34)
Hydrocarbons (50)
Simple alcohols (7)
Simple aldehydes (12)
Simple ketones (13)
Simple acids (21)
Fatty acids (22)
Simple esters/lactones (13)
Steroids (11)
Terpenes (20)
Non-cannabinoid phenols (25)
Flavoroids (21)
Vitamins (1)
Pigments (2)
Elements (9)
Total known compounds (483)



THC

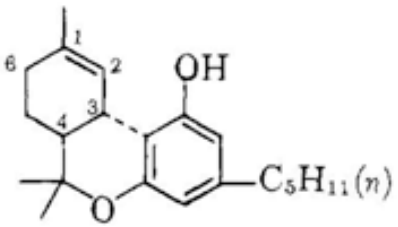
Gaoni and Mechoulam (1964)* Elucidated the Structure of THC

Isolation, Structure, and Partial Synthesis of an Active Constituent of Hashish[1]

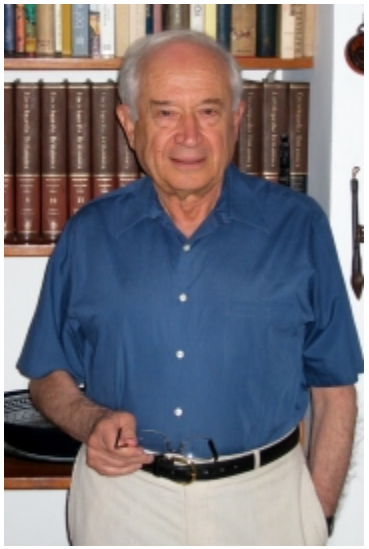
Sir:

Hashish (marihuana), the psychotomimetically active resin of the female flowering tops of *Cannabis sativa* L. is one of the most widely used illicit narcotic drugs. A number of groups have reported the isolation of active constituents.[2] Most of these substances are not fully characterized, and comparisons with or between them are difficult.

We now wish to report the isolation of an active constituent of hashish to which we assign structure I (Δ^1-3,4-*trans*-tetrahydrocannabinol).[3] This is the first active component whose constitution is fully elucidated.[4]



I

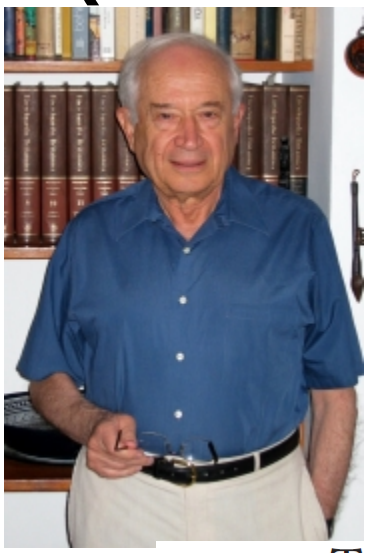


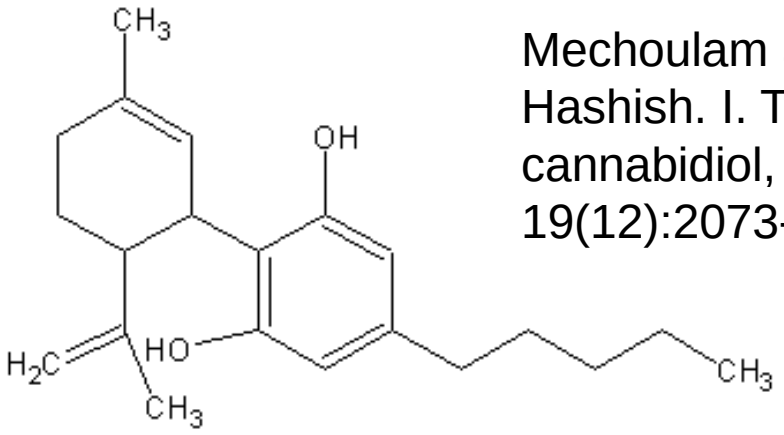
*Journal of the American Chemical Society, 86:1646-47

THC vs. Tetrahydrocannabinolic Acid (THCA)

- Cannabis produces THCA (THC precursor for THC)
- THCA does not produce psychoactive effects
- THCA is decarboxylated to THC upon drying and heating

Cannabidiol (CBD)
(Does not elicit cannabis-like effects)





Cannabidiol

Mechoulam and Shvo (1963) Hashish. I. The structure of cannabidiol, Tetrahedron 19(12):2073-8.

Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome

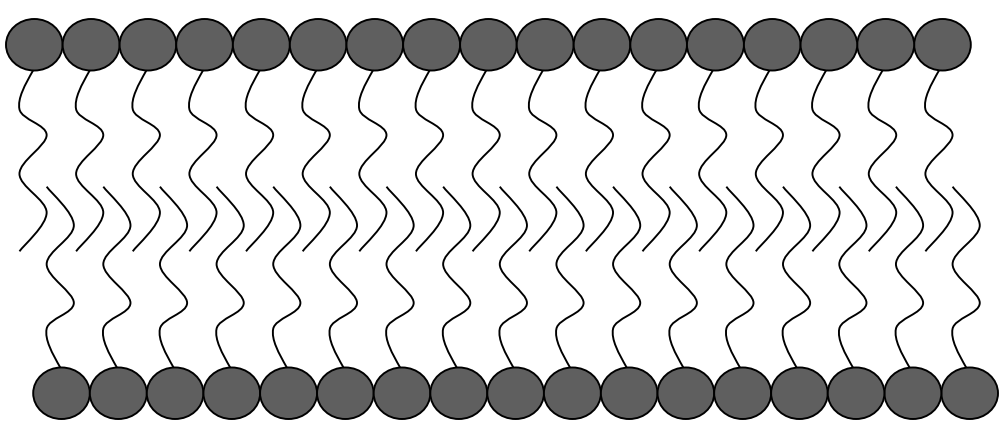
Orrin Devinsky, M.D., J. Helen Cross, Ph.D., F.R.C.P.C.H., Linda Laux, M.D., Eric Marsh, M.D., Ian Miller, M.D., Rima Nabbout, M.D., Ingrid E. Scheffer, M.B., B.S., Ph.D., Elizabeth A. Thiele, M.D., Ph.D., and Stephen Wright, M.D., for the Cannabidiol in Dravet Syndrome Study Group*

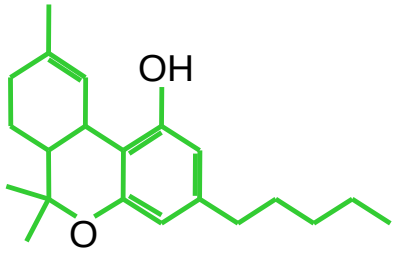
Cannabidiol attenuates seizures and social deficits in a mouse model of Dravet syndrome

Joshua S. Kaplan, Nephi Stella, William A. Catterall, and Ruth E. Westenbroek

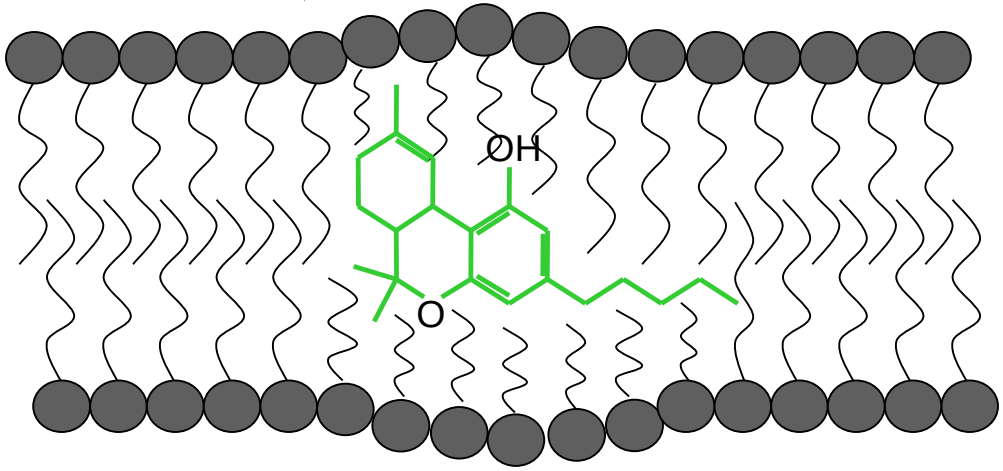
PNAS 2017 October, 114 (42) 11229-11234. https://doi.org/10.1073/pnas.1711351114

Early Hypothesis: Membrane Perturbation





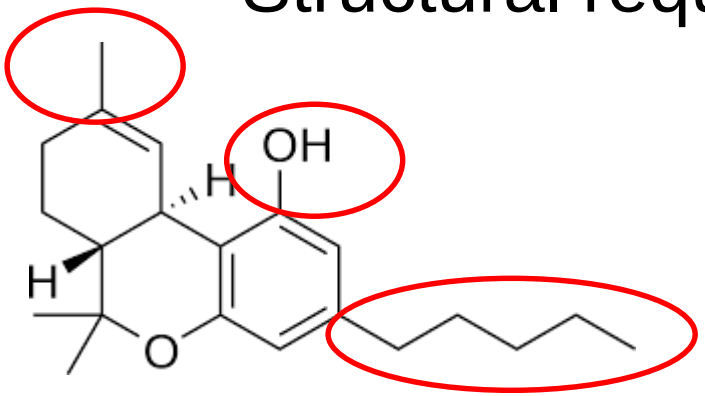
Δ^9-THC



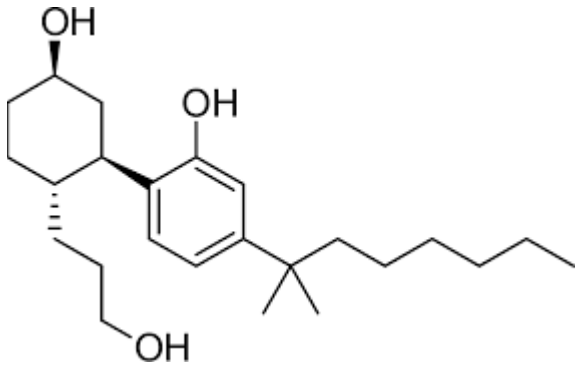
Lawrence & Gill (1975)

Structure Activity Relationship

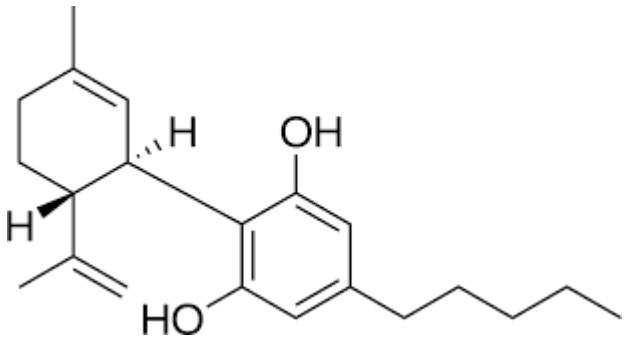
- Unique effects
- Highly potent
- Structural requirements



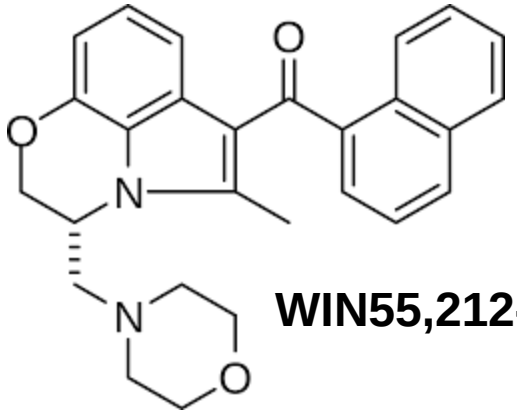
THC



CP55,940



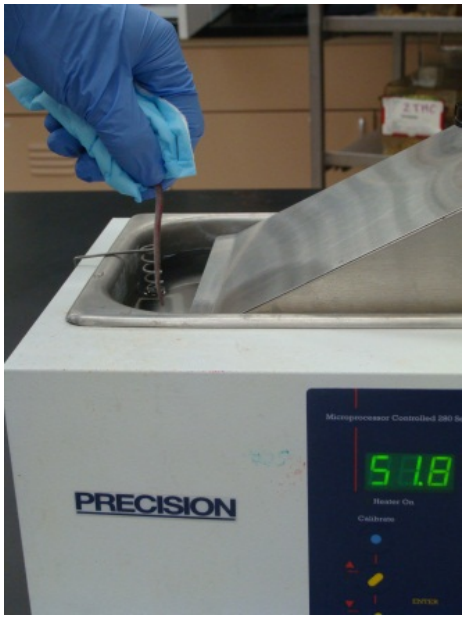
CBD



WIN55,212-2

In Vivo Screening of Cannabimimetic Activity

- **Locomotor activity** – Mice are placed in activity chambers for 5 min. Distance traveled, time immobile, and speed are recorded
- **Catalepsy (bar test) –** front paws are placed on a bar with hind paws on ground and time immobile is recorded
- **Antinociception (tail withdrawal)** – tail is submerged in 52 degree Celsius water bath and time to flick tail out of water is recorded
- **Body temperature –** temperature is recorded from rectal thermometer



Specific binding site of THC in Brain Tissue

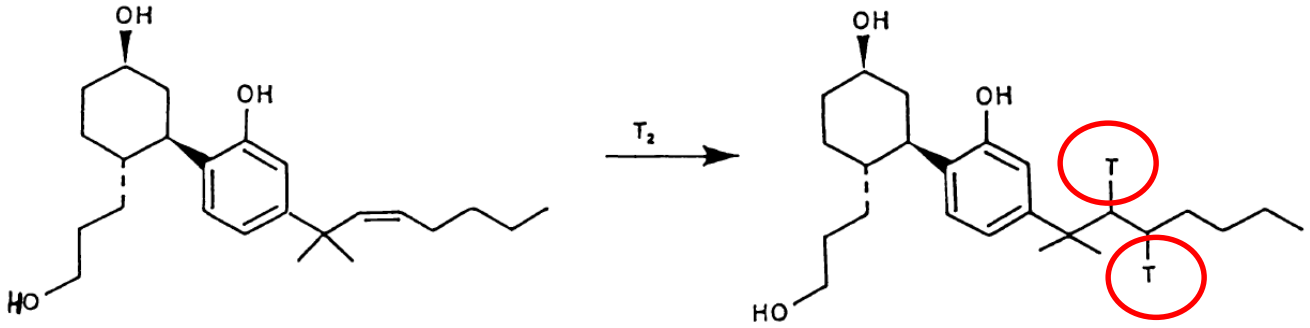
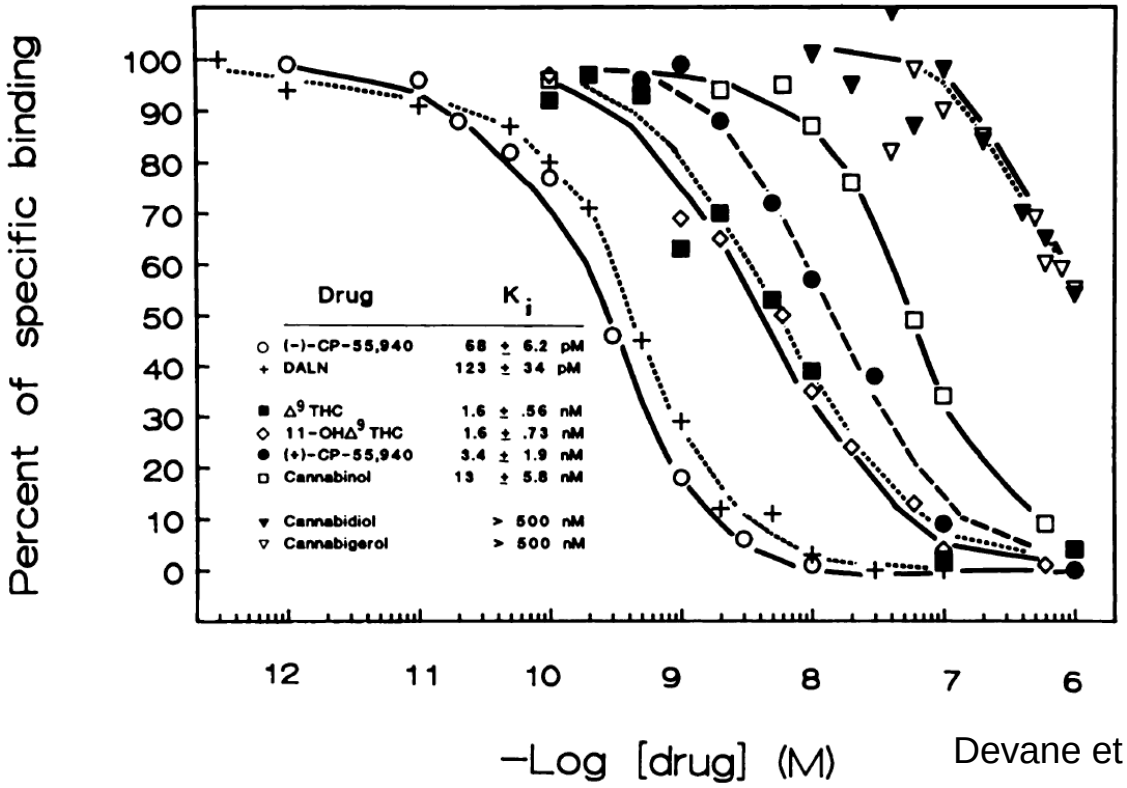


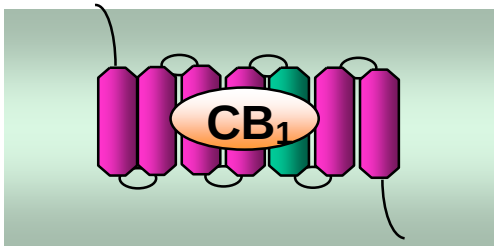
Fig. 1. The synthesis of [^{3}H] CP-55,940 by the tritium reduction of compound 1.

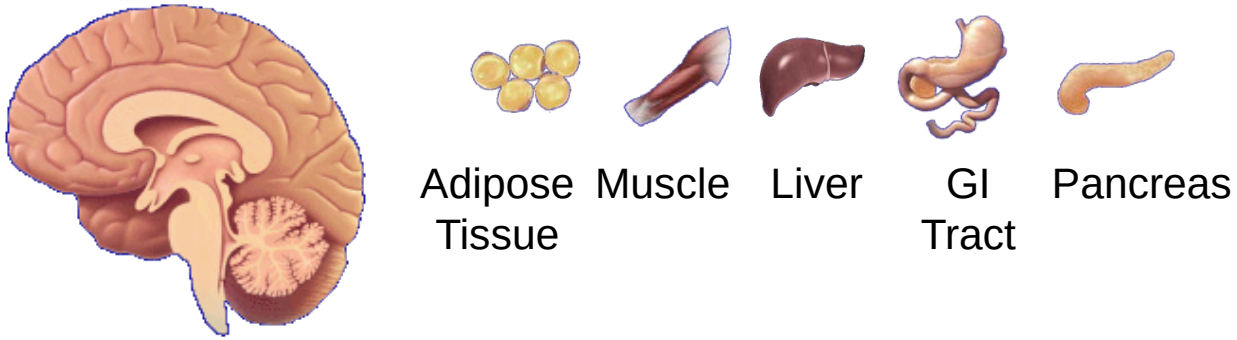
Radiolabeled CP55,940



Devane et al (1988) Mol Pharmacol, 34:605-13

CB_1 Receptors





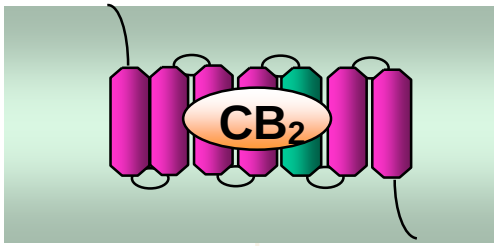
Brain

Responsible for most CNS cannabis effects

Also modulates many physiological functions

Devane et al. (1988) Mol Pharm, 34:605-613
Herkenham et al (1990) PNAS,87:1932-1936
Matsuda et al. (1990) Nature, 346: 561-4

CB_2 Receptors



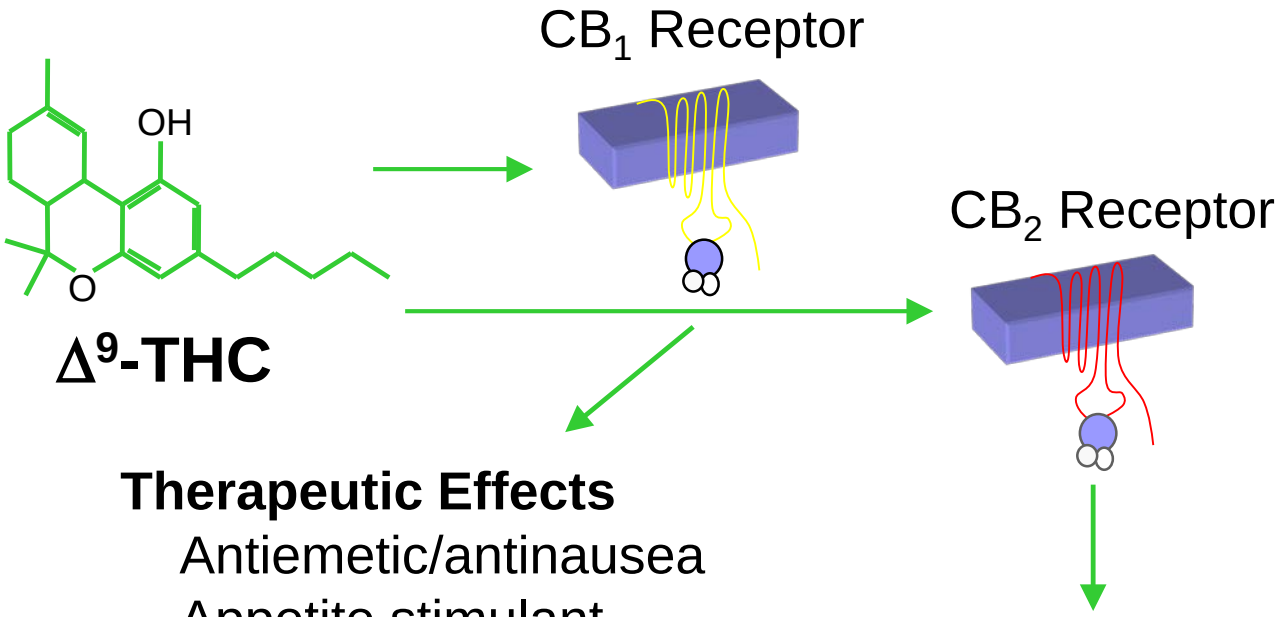
Immune System

T cells **B cells** **Monocytes**
Spleen **Tonsils**

- Expressed primarily in immune cells
- Low expression in CNS, but increased upon microglial activation, neurons
- Agonists reduce nociception, inflammation, neurodegenerative states, and cocaine reward

Munro S et al. *Nature*. 1993;365:61-65.
Van Sickle MD et al. *Science*. 2005;310:329-332.
Whiteside GT et al. *Curr Med Chem*. 2007;14:917-936.

THC Produces Its Effects Through the Activation of Two Types of Cannabinoid Receptors



Δ^9-THC

Therapeutic Effects
- Antiemetic/antinausea
- Appetite stimulant
- Increased energy storage
- Analgesia

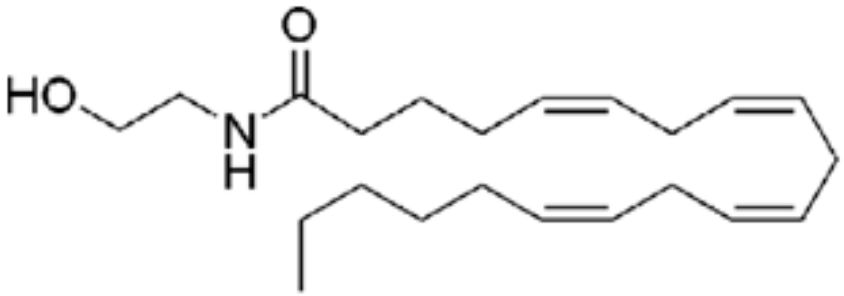
Side Effects
- Psychomimetic effects
- Abuse liability
- Dependence liability
- Memory impairment

Potential Therapeutic effects
- Analgesia
- Anti-inflammation
  - -periphery
  - -CNS (AD, ALS, etc)
- Anti-cocaine addiction

No apparent adverse side effects at the receptor

What is the evolutionary benefit of cannabinoid receptors?

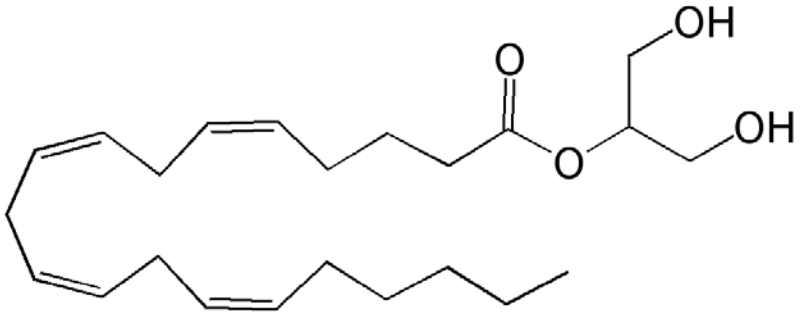
Brain's Naturally Occurring Marijuana-like Chemicals (Endogenous Cannabinoids)



Anandamide (AEA)

-1st isolated from porcine brain
-Activates CB_1 & CB_2
-Partial CB_1 agonist
-$TRPV_1$ receptor agonist
-Short half-life
-Energy regulation
-Pathological states

Devane et al. (1992) Science, 258:1946-1949



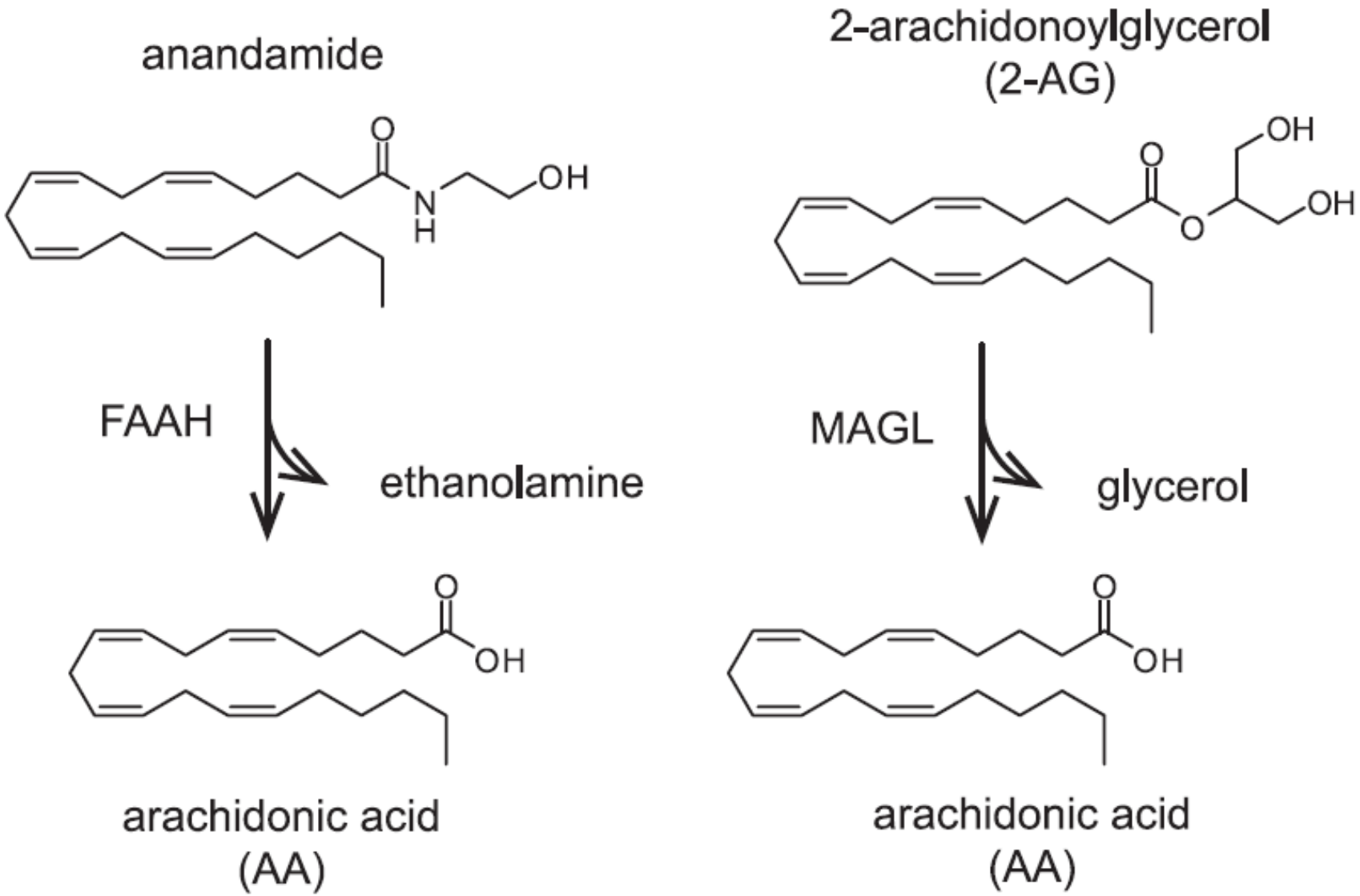
2-arachidonoylglycerol (2-AG)

-Abundant 1,000 fold>anandamide
-Activates CB_1 & CB_2
-High efficacy CB_1 agonist
-Short half-life
-Retrograde signaling molecule modulating synaptic plasticity
-Precursor for free arachidonic acid in brain

Mechoulam et al. (1995); Suigara et al. (1995) Nomura et al. 2011

Why aren’t we high on our endocannabinoids all the time?

Endocannabinoids are rapidly degraded by catabolic enzymes



Fatty Acid Amide Hydrolase (FAAH) vs. Monoacylglycerol Lipase (MAGL)

FAAH

-Expressed on post-synaptic neurons
-Major anandamide catabolic enzyme
-Hydrolyzes other FAAs
    -PEA (anti-inflammatory)
    -OEA (anti-inflammatory)
    -Oleamide (sleep-inducing)

Cravatt et al. 1996; 2001

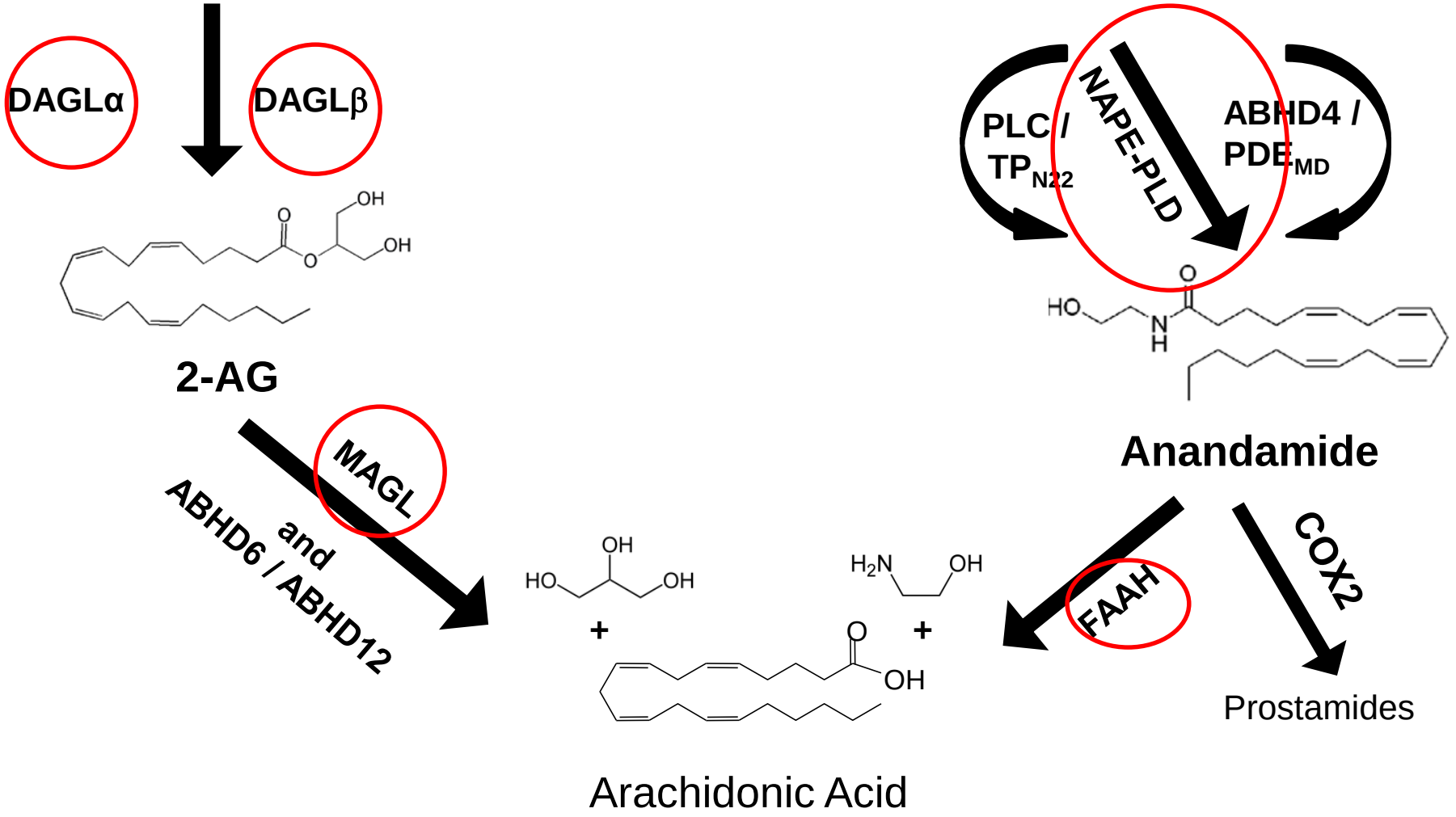
MAGL

- Expressed on pre-synaptic neurons
-Major 2-AG catabolic enzyme
-Major biosynthetic enzyme of free arachidonic acid in brain

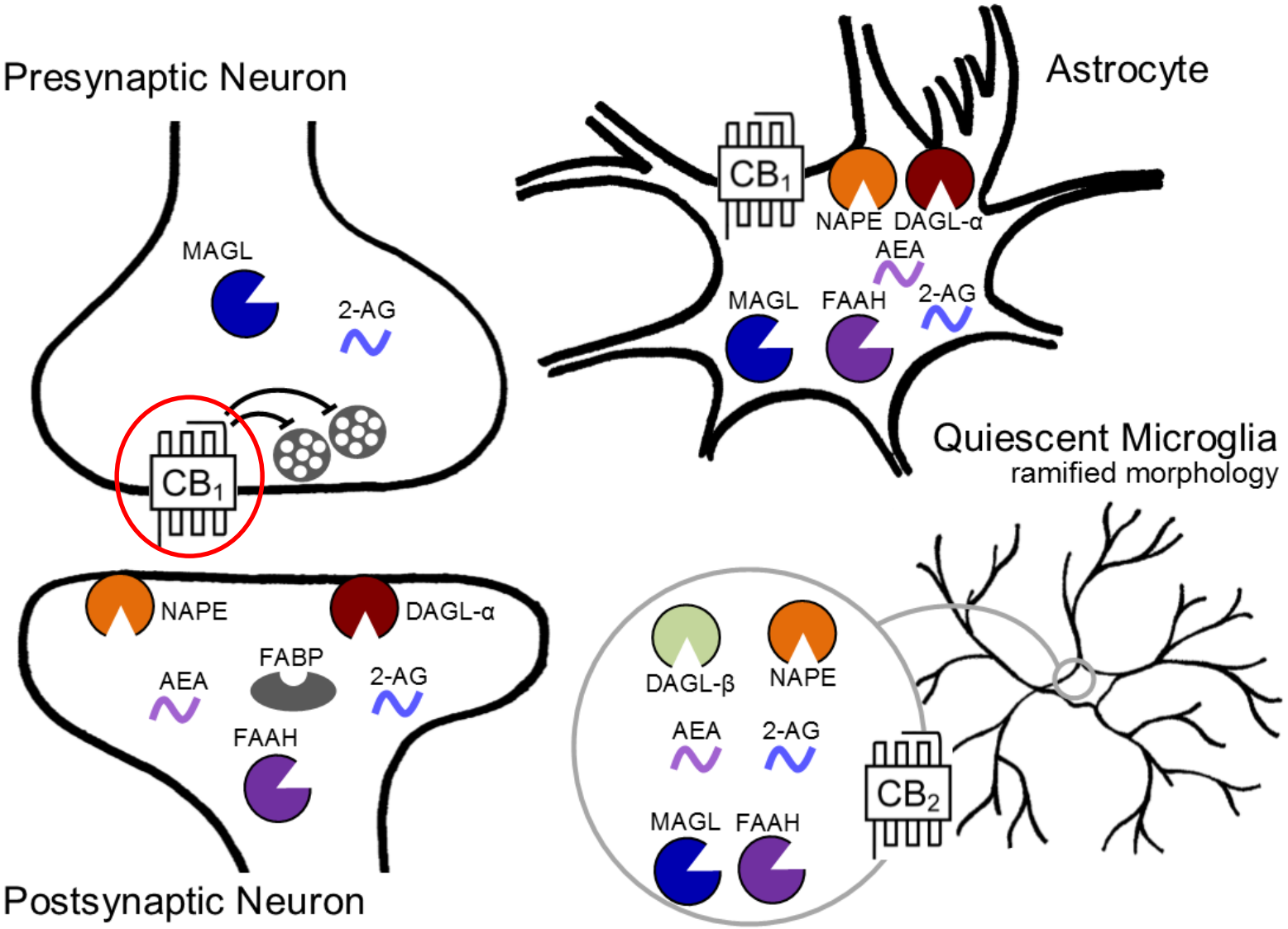
Karlsson et al. 1997; Dinh et al. 2002; Nomura et al. 2011

eCBs Produced and Released on Demand and Regulated by Hydrolytic Enzymes

Phospholipids Precursors in Cellular Membranes



Components of the Endocannabinoid System: Expressed on Cells in the CNS

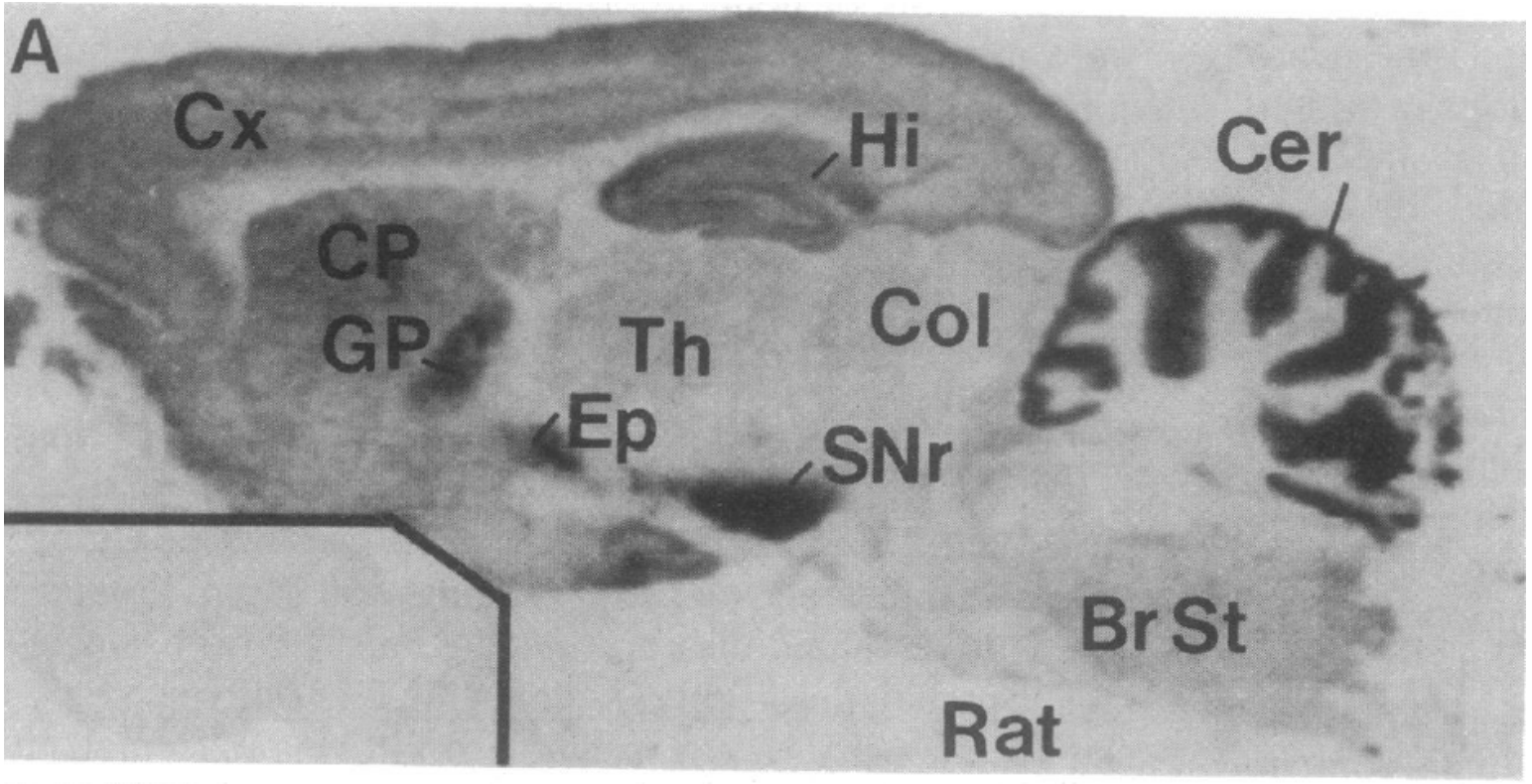


Donvito et al. (2018) Neuropsychopharm, 43:52-79

…so how does cannabis produce its pharmacological effects in the brain?

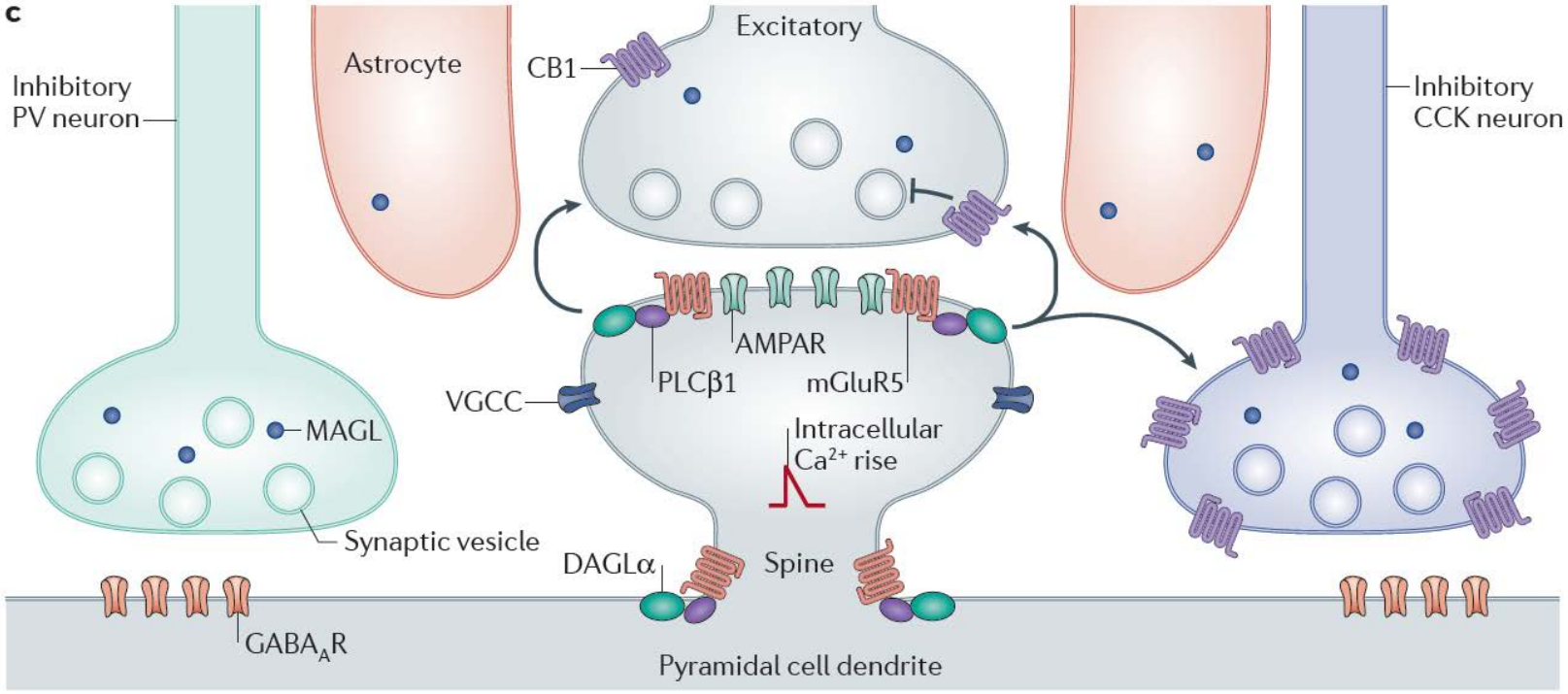
…so how does cannabis produce its pharmacological effects in the brain?

THC binds CB1 receptors heterogeneously expressed on brain regions known to mediate processes affected by cannabis



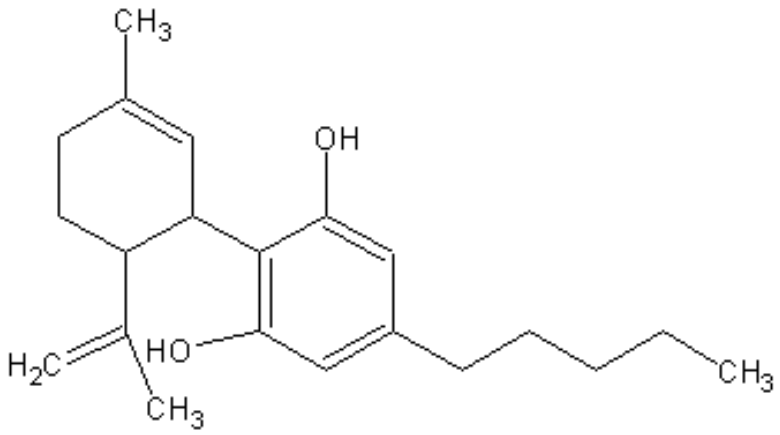
Herkenham et al (1990) Proc Natl Acad Sci, 871932-6

THC Stimulates CB1 Receptors Expressed on Presynaptic Neurons Leads to Reduced Neurotransmitter Release



Soltesz et al. (2015) Nat Rev Neurosci.16:264-77

What is/are the underlying mechanism(s) of action CBD?



Cannabidiol

CBD does not activate cannabinoid receptors, but interacts with low potency at many sites

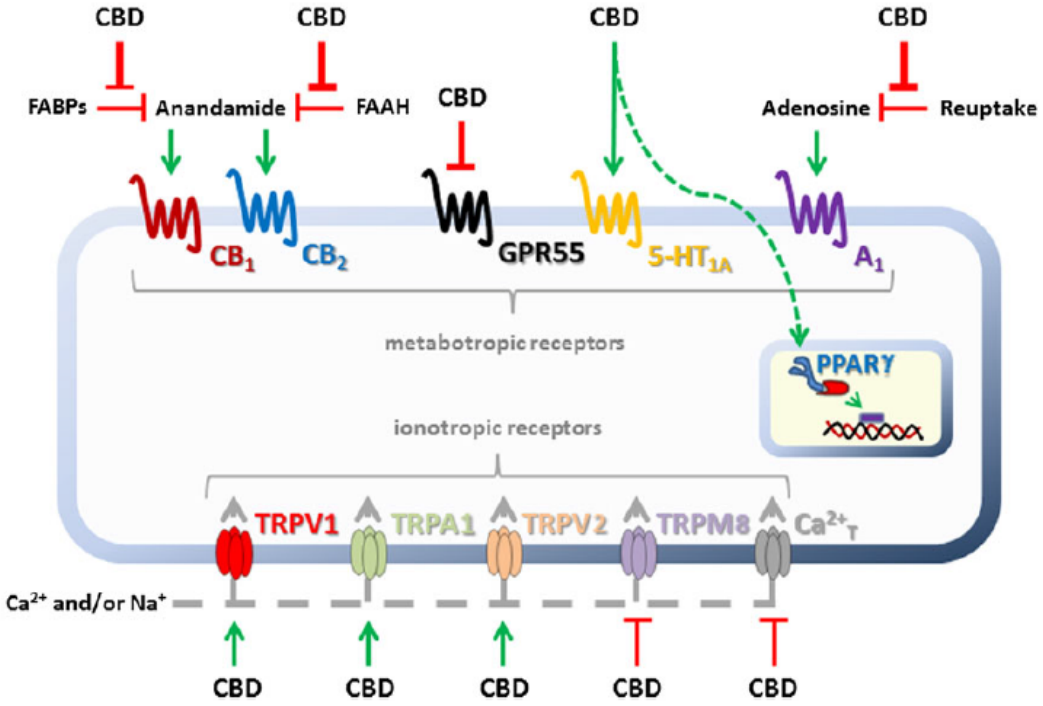


Figure 1

The main molecular targets and potential mechanisms of action of CBD. This drug inhibits both FAAH, the enzyme which metabolizes anandamide, and FABPs, which mediate the transport of anandamide to FAAH; both mechanisms ultimately result in the indirect activation of CB_1 and/or CB_2 receptors. CBD also activates the 5-HT_{1A} receptor, PPARγ and the transient receptor potential channels TRPV1, TRPA1 and TRPV2. Finally, CBD inhibits adenosine reuptake and antagonizes GPR55, TRPM8 and T-type Ca^{2+} channels. 5-HT_{1A} and (indirect) cannabinoid receptor activation are the mechanisms that have been implicated in the anxiolytic effects of CBD to date (see Ibeas Bih *et al.* (2015) and McPartland *et al.* (2015) for further details).

Lee et al (2017) Br J Pharmacol. 174:3242-3256

Endogenous Cannabinoid System: Modulates Multiple Physiological Processes

- Central Nervous system
- Peripheral nervous system
  - Dorsal root ganglia
  - Enteric nervous system
- Cardiovascular system
- Immune system
- Gastrointestinal system
- Renal system
- Bone density

- Reward
- Synaptic plasticity
- Cognition
- Stress responses
- Sleep
- Energy Regulation
  - Feeding behavior
  - Lipogenesis
- Neuroexcitability/epilepsy
- Neuroinflammation
- Neurodegeneration
- Pain and Inflammation
- Olfaction
- Eicosanoids

Endogenous Cannabinoid System
Potential Therapeutic Targets

1. **CB_1 receptor**
   a) Orthosteric site (active binding site): agonists and antagonists
   b) Allosteric site (alters confirmation binding site to increase or decrease activity): positive or negative allosteric modulators
2. **CB_2 receptor**: agonists
3. **Degradative enzymes**
   a. FAAH (anandamide): inhibitors
   b. MAGL (2-AG): inhibitors
4. **Biosynthetic enzymes**
   a. DAGL-α (2-AG: expressed on neurons and astrocytes) inhibitors
   b. DAGL-β (2-AG: expressed on microglia and macrophages) inhibitors
   c. NAPE-PLD (anandamide) inhibitors
5. **Lipid trafficking molecules**
   a) fatty acid binding proteins

Potential Therapeutic Indications: eCB System

- ✓ Cancer chemotherapy-induced nausea & emesis*
- ✓ Appetite increase in AIDS* and cancer patients
- Metabolic syndrome & weight loss (antagonists)
- Fluid regulation
- Pain and Inflammation
  - Rheumatoid arthritis
  - Spinal/Neuropathic
  - Cancer/chemotherapy
  - Migraine
  - NSAID-induced ulcers
- Pruritus (itching)
- Palliative (quality of life)
- Drug abuse disorders (e.g., cannabis, nicotine, opioids, cocaine, alcohol)
- Psychiatric diseases
  - Anxiety disorders
  - Posttraumatic Stress Disorder
  - Depression
- Brain Injury (e.g., stroke, trauma)
- ✓ Epilepsy*
- Neurodegenerative diseases
  - Spasticity/multiple sclerosis
  - Huntington's disease
  - Parkinson's disease
  - Alzheimer's disease
  - Amyotrophic lateral sclerosis
- Cancer

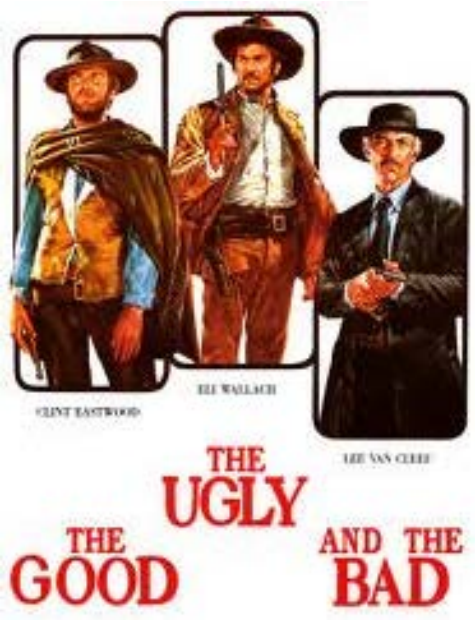
*FDA approved cannabinoid-based medications

The road to hell is paved with good intentions

"You had good intentions. Let's find you a nice job paving roads."

Unintended Consequence of Cannabinoid Research

1. Synthetic cannabinoids
   a. Emerging drugs of abuse
   b. Synthesized in clandestine labs based on scientific publications
   c. Deleterious public health consequences
2. Response
   a. Banning of synthetic cannabinoids
   b. Emergence of new ligands



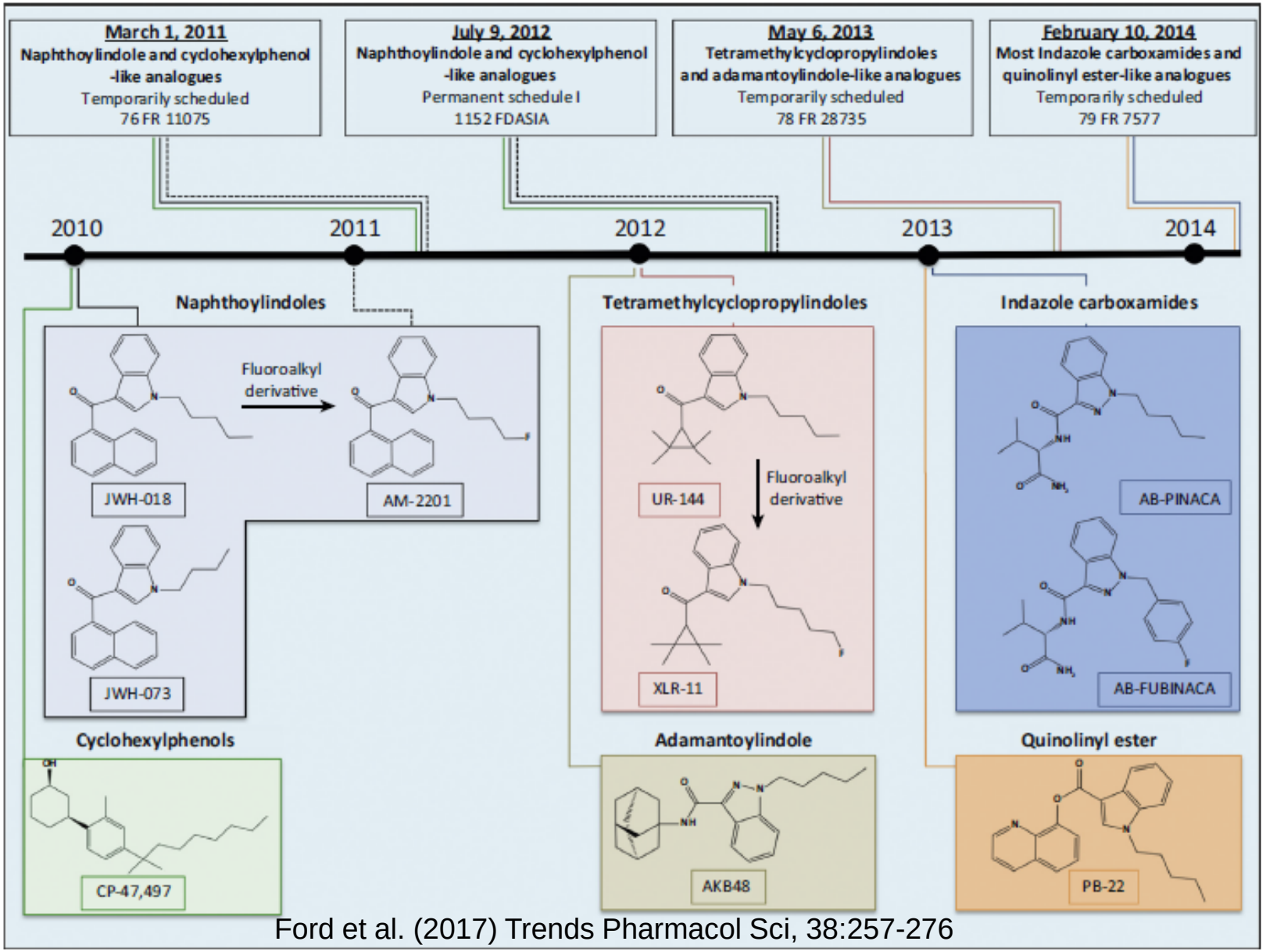
What is Synthetic Marijuana?

- Synthetic cannabinoids originally developed as research tools and potential therapeutic agents
- Mimics the effects of THC
- Synthetic cannabinoids are added to herbal products
- Predominantly sold over the internet
- Many of these chemicals are LEGAL

What is the appeal of synthetic cannabinoids?

- Produces marijuana-like effects
- Legal until recently
- Not readily detected in common drug screens
- Sophisticated marketing and shrewd branding

Rapidly Evolving Synthetic Cannabinoids



Ford et al. (2017) Trends Pharmacol Sci, 38:257-276

Comparative Adverse Neurological Effects I: Synthetic Cannabinoids vs. Cannabis

Adverse effects and toxicities	Observed with K2/Spice products (SCBs)	Observed with marijuana (THC)	Refs
• Euphoria	Common	Common	[26,29,30]
• Appetite stimulation	Common	Common	[26,31]
• Nystagmus	Reported	Reported	[32]
• Slurred speech	Reported	Reported	[33]
• Ataxia/lethargy	Reported	Reported	[34]
• Psychosis in susceptible individuals	Extreme	Mild	[3,35]
• Hypothermia	Reported	None reported	[188]
• Hallucinations	Common	Rare	[3,36]
• Delusions	Common	Rare	[3]
• Confusion	Common	Rare	[33]

Ford et al. (2017) Trends Pharmacol Sci, 38:257-276

Comparative Adverse Neurological Effects II: Synthetic Cannabinoids vs. Cannabis

Adverse effects and toxicities	Observed with K2/Spice products (SCBs)	Observed with marijuana (THC)	Refs
• Anxiety	Common	Rare	[37,38]
• Panic attacks	Common	Rare	[34]
• Agitation	Common	Rare	[3,34]
• Irritability	Common	Rare	[39]
• Confusion	Common	Rare	[33]
• Memory disturbances	Reported	Common	[26]
• Self-mutilation	Reported	None reported	[40]
• Seizures	Reported	None reported	[41]
• Catatonia	Reported	Very rare	[42]
• Acute cerebral ischemia	Reported	None reported	[28]

Ford et al. (2017) Trends Pharmacol Sci, 38:257-276

Comparative Adverse Effects III: Synthetic Cannabinoids vs. Cannabis

Adverse effects and toxicities	Observed with K2/Spice products (SCBs)	Observed with marijuana (THC)	Refs
Renal			
• Acute tubular necrosis	Reported	None reported	[47,48]
• Acute interstitial nephritis	Reported	None reported	[48]
• Acute kidney failure	Reported	None reported	[49]
Effects of chronic use			
• Tolerance	Common	Common	[50,51]
• Marked withdrawal	Reported	Mild	[52]
• Dependence	Reported	Rare	[51,52]
Deaths (between 2011 and 2014)	Over 20 deaths reported	None reported	[53]

Ford et al. (2017) Trends Pharmacol Sci, 38:257-276

Summary

1. Endogenous cannabinoid system
   a) Components
      i. Cannabinoid CB1 and CB2 receptors
      ii. Endogenous cannabinoids (anandamide and 2-AG)
      iii. Endocannabinoid regulating enzymes
   b) Modulates a multitude of physiological processes
   c) Target for FDA-approved medications and potential new drugs
2. Cannabis
   a) THCA (THC precursor devoid of psychoactive activity)
   b) THC (responsible for psychoactive effects): activates CB1 & CB2 receptors
   c) CBD (lacks intoxicating actions): does not activate CB receptors
   d) Contains 100+ other minor/trace cannabinoids and terpenoids
3. Synthetic cannabinoids
   1. Medicines and potential medicines
   2. Experimental tools
   3. Dangerous emerging drugs of abuse that represent a significant public health concern

Conclusions

- The FDA approved constituents of cannabis (THC and CBD) in medicines
- The endocannabinoid system modulates many physiological systems and contains potential therapeutic targets
- Cannabis and synthetic cannabinoids can produce untoward side effects
- A great need exists for outcome-based research for cannabinoid-based medications

Acknowledgements

NIH National Institute on Drug Abuse
The Science of Drug Abuse & Addiction


Any Questions?

Medical Marijuana Dispensary Operations

Presented By:

Al Domeika, R.Ph

Northeast Pharmacy Operations

Acreage Holdings, LLC

LEARNING OBJECTIVES

- Outline the history of cannabis based medicine
- Discuss state and federal laws regarding the usage and dispensing of marijuana products.
- Overview Virginia's cannabis laws
- Discuss the role of the pharmacist in dispensing cannabis products, including:
  - Analyzing the pharmacology of the different components of the cannabis plant
  - Discussing drug interactions and safety concerns
  - Learning the different modes of delivery a patient may use cannabis
  - Picking appropriate dosing regimens

History

2900 B.C.

Chinese Emperor Fu Hsi references cannabis as a popular medicine

Robert Deitch *Hemp: American History Revisited: The Plant with a Divided History*, 2003

History

First recorded use in 2737 B.C. by Chinese emperor Shen-Nung

Effective in treating pain associated with rheumatoid arthritis and gout

greenrushdaily.com/cannabis-history/

History

MA

Chinese word for cannabis

Earliest written reference to medical marijuana in Chinese Pharmacopeia (Rh-Ya)

National Institute on Drug Abuse (NIDA) *Marijuana Research Findings: 1976*, 1977

History

Throughout ancient history, many writings suggest that cannabis was used to treat numerous diseases

Even the Bible suggests that cannabis was used in anointing oils.

Chris Bennett "Was Jesus a Stoner?," *High Times Magazine*, Feb. 10, 2003

History

1611: Jamestown settlers brought hemp to North America

Useful in making clothing, sails, and rope.

1762: Virginia government proposed incentives to manufacture products from hemp

Bernard Segal, PhD Perspectives on Drug Use in the United States, 1986

History

George Washington known to have grown hemp at Mount Vernon

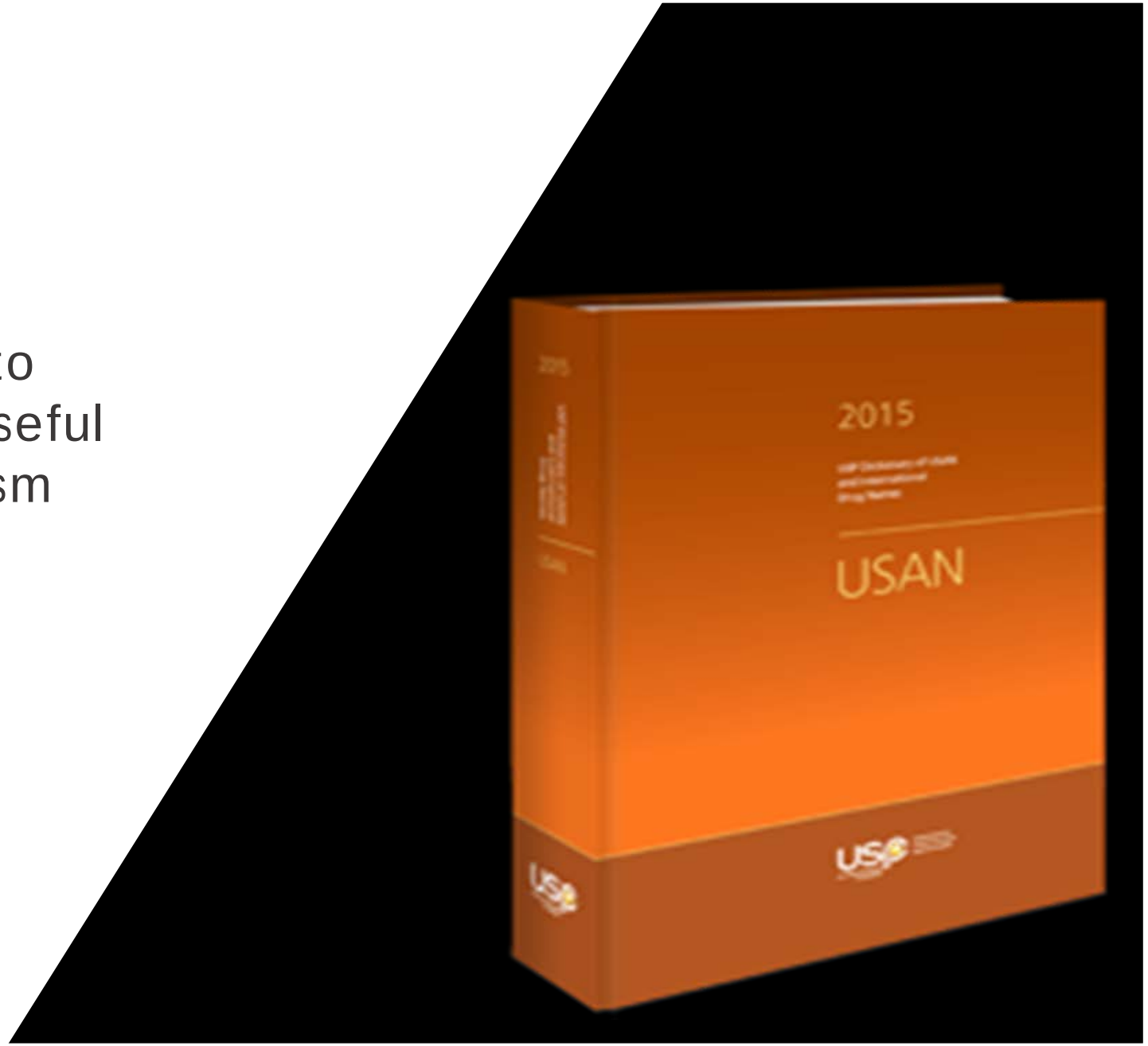
Thomas Jefferson grew hemp at Monticello

Robert Deitch *Hemp American History Revisited: The Plant with a Divided History*, 2003

History

In 1850, marijuana was added to the U.S. Pharmacopoeia as a useful medicine for nausea, rheumatism and labor pains

Easily accessible in pharmacies and local stores



Richard Glen Boire, JD and Kevin Feeney, JD *Medical Marijuana Law*, 2007

History

1906: President Theodore Roosevelt signs the Pure Food and Drug Act

Required the labeling of all medicine, including cannabis-based products

https://www.politico.com/story/2014/06/fda-theodore-roosevelt-108164

History

1911: Massachusetts becomes 1st state to outlaw recreational cannabis

1913: Maine, Wyoming, Indiana follow

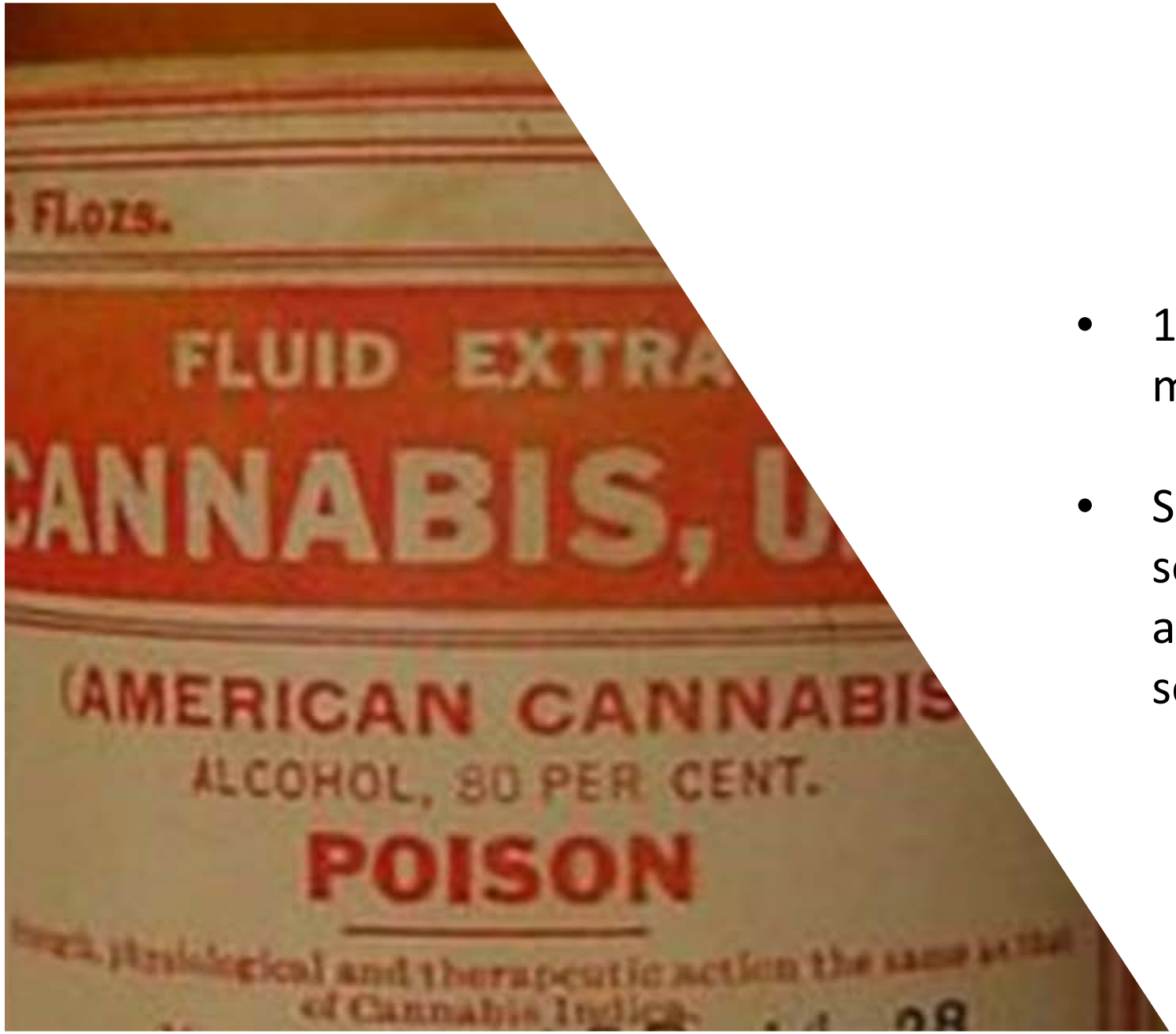
1914: New York City

1915: Utah, Vermont

1917: Colorado, Nevada

1917 – 1927: 10 other states pass marijuana prohibition laws

Dale Gieringer, PhD "The Forgotten Origins of Cannabis Prohibition in California," *Contemporary Drug Problems*, Summer 1999



History

- 1930's: Demand for cannabis based medications rise.
- Several pharmaceutical companies sold marijuana extracts as an analgesic, antispasmodic, and sedative.

Janet Joy, PhD Alison Mack *Marijuana as Medicine: Beyond the Controversy*, 2001

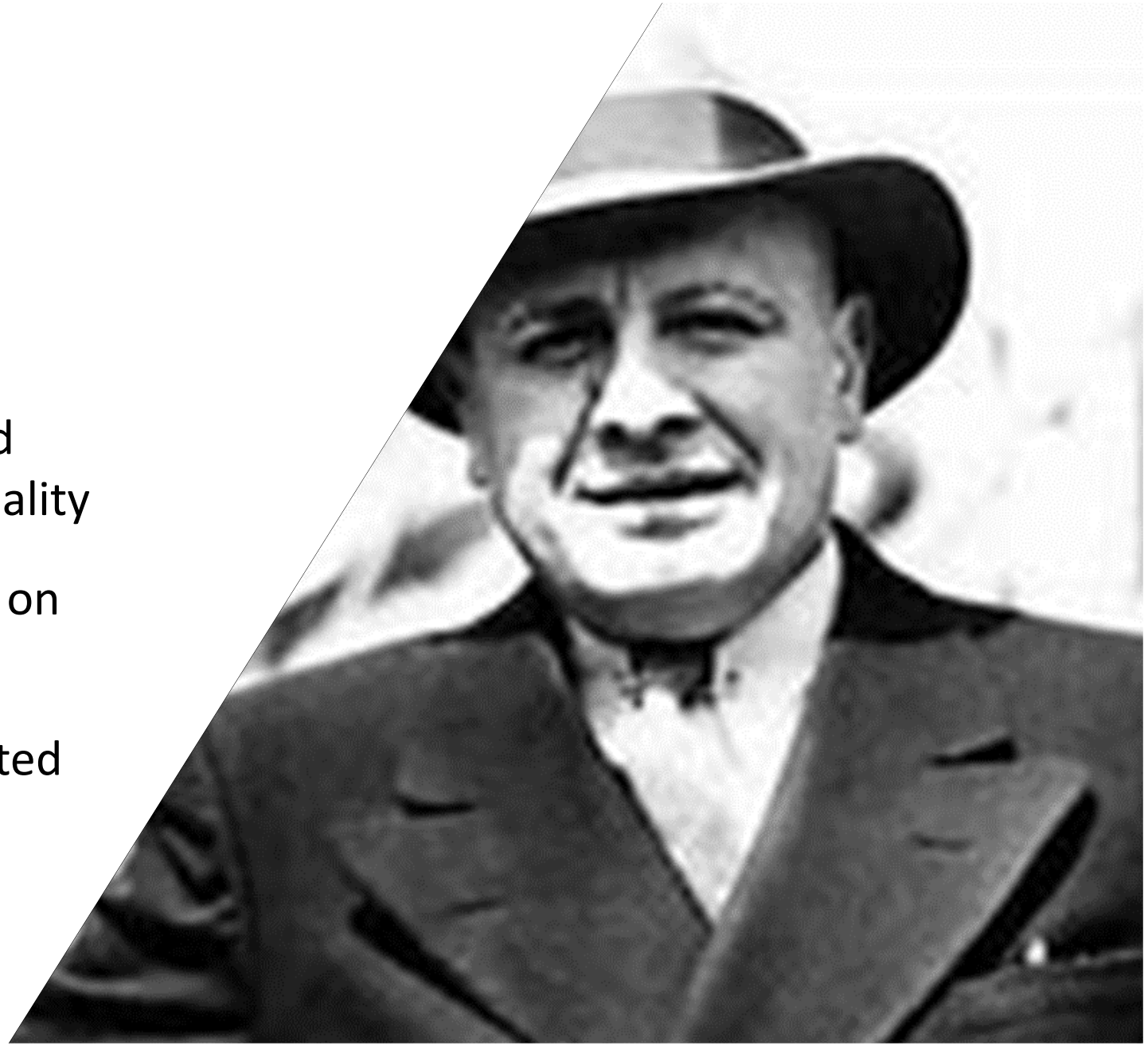
History

1930: Harry J. Anslinger appointed Commissioner of Federal Bureau of Narcotics

Believed cannabis caused insanity and pushed people towards acts of criminality

In 1936, urged to put federal controls on cannabis.

By the end of 1936, all 48 states enacted laws to regulate marijuana



Michael Schaller, PhD "The Federal Prohibition of Marihuana," *Journal of Social History*, Autumn 1970

History

1936: Reefer Madness released

Describes marijuana as a drug that leads to people getting killed, committed to insane asylums

Originally titled *Tell Your Children,* financed by small church group

Purchased by a producer of exploitation films, edited and changed title to *Reefer Madness*

http://blog.dominionstage.org/2009/12/15/the-history-behind-reefer-madness/

History

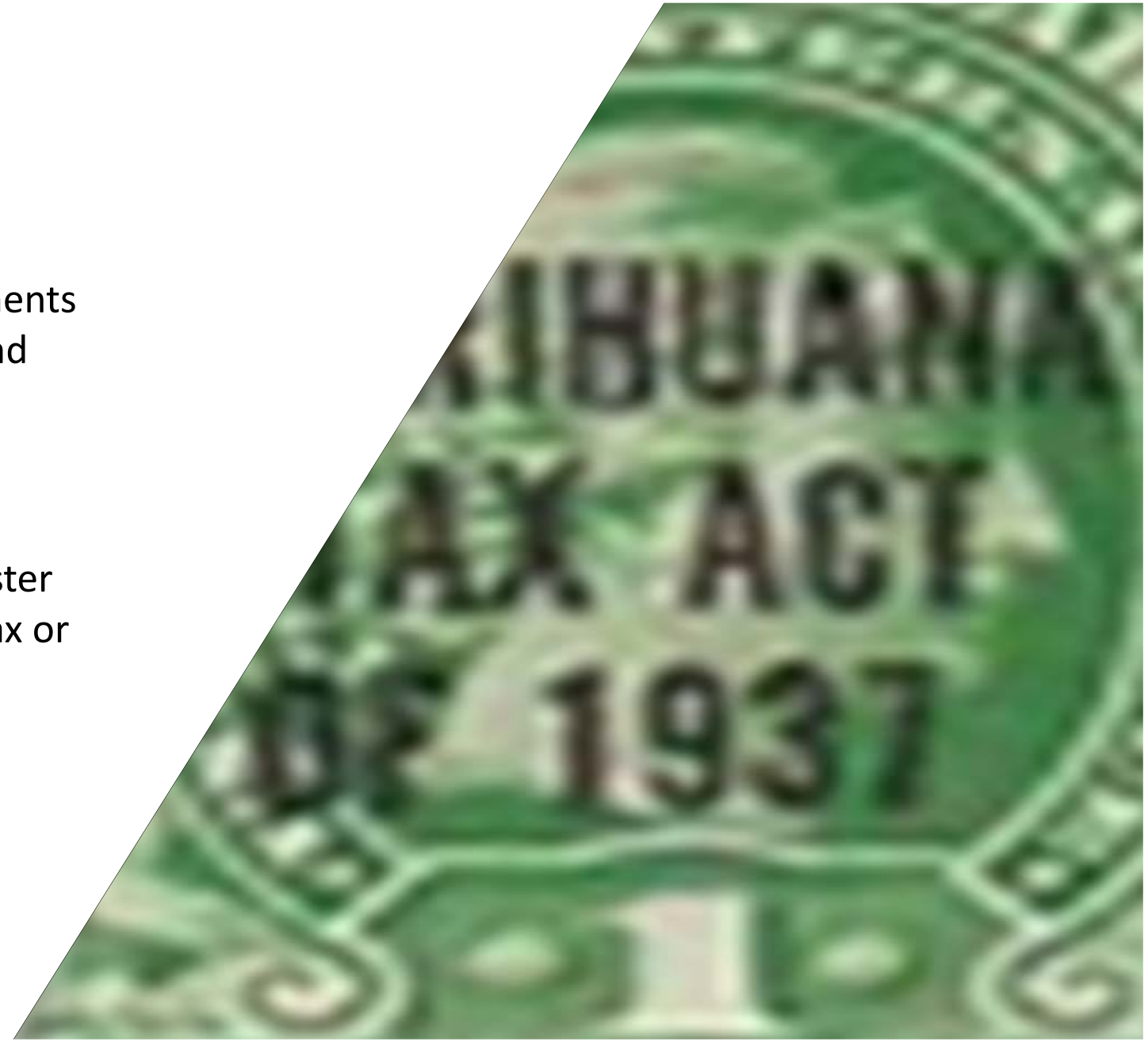
MARIJUANA TAX ACT OF 1937

Imposed registration and reporting requirements and imposed large tax on growers, sellers, and buyers

American Medical Association opposed bill

Required physicians and pharmacists to register with federal authorities and pay an annual tax or license fee

Prescriptions of marijuana products reduced



Marijuana Tax Act Law and Legal Definition | USLegal, Inc.
definitions.uslegal.com/m/marijuana-tax-act%20/

History

October 2nd, 1937

1st day Marijuana Tax Stamp Act was enacted

Samuel R. Caldwell:
1st marijuana seller arrested and convicted under U.S. Federal Law

Sentencing:
$1000 fine
4 years hard labor in Leavenworth

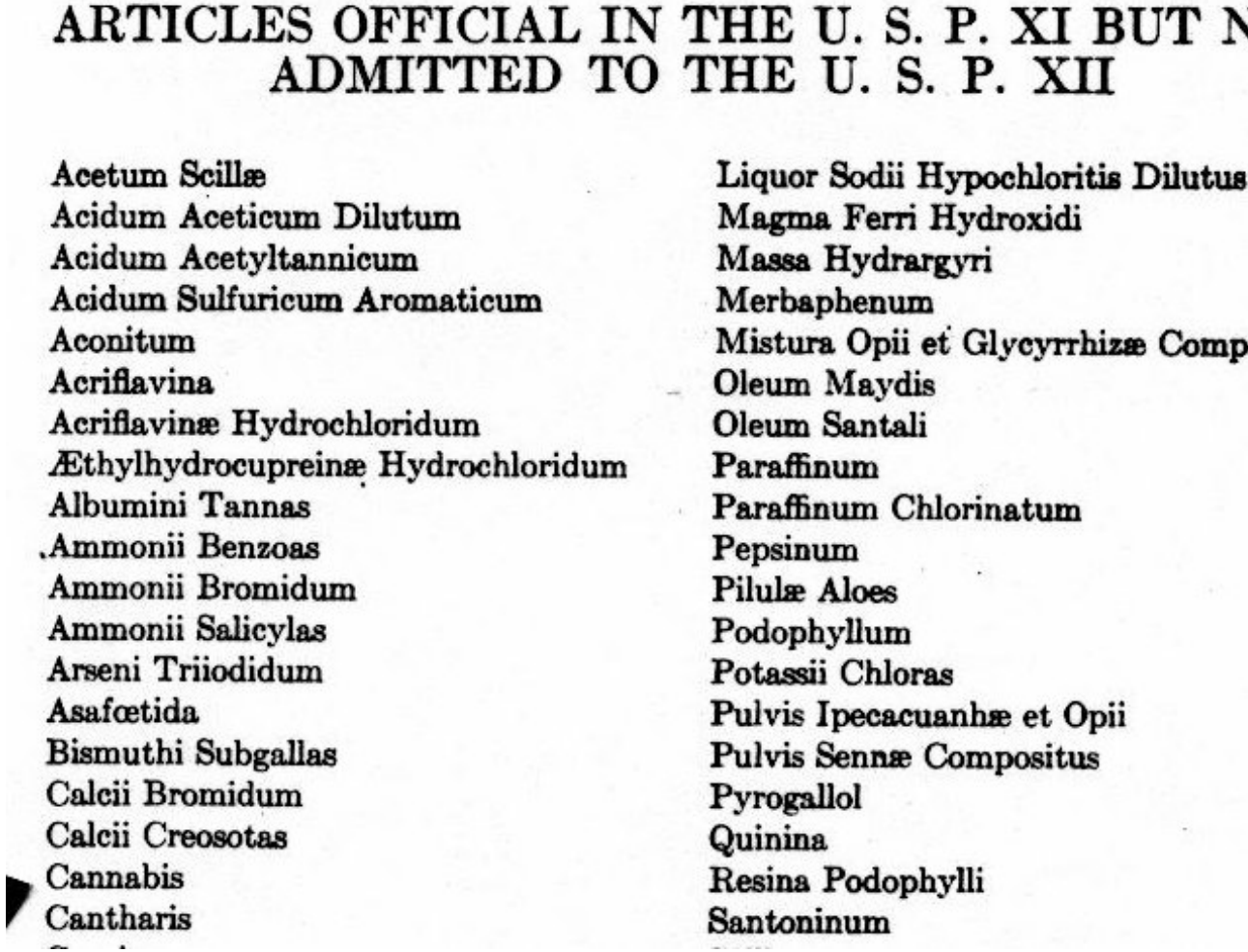
National Organization for the Reform of Marijuana Laws (NORML) "The First Pot POW," norml.org

History

1942

Cannabis removed from US Pharmacopeia

Lost any sort of medicinal legitimacy



ARTICLES OFFICIAL IN THE U. S. P. XI BUT N
ADMITTED TO THE U. S. P. XII

Acetum Scillæ
Acidum Aceticum Dilutum
Acidum Acetyltannicum
Acidum Sulfuricum Aromaticum
Aconitum
Acriflavina
Acriflavinæ Hydrochloridum
Æthylhydrocupreinæ Hydrochloridum
Albumini Tannas
Ammonii Benzoas
Ammonii Bromidum
Ammonii Salicylas
Arseni Triiodidum
Asafœtida
Bismuthi Subgallas
Calcii Bromidum
Calcii Creosotas
Cannabis
Cantharis
Liquor Sodii Hypochloritis Dilutus
Magma Ferri Hydroxidi
Massa Hydrargyri
Merbaphenum
Mistura Opii et Glycyrrhizæ Comp
Oleum Maydis
Oleum Santali
Paraffinum
Paraffinum Chlorinatum
Pepsinum
Pilulæ Aloes
Podophyllum
Potassii Chloras
Pulvis Ipecacuanhæ et Opii
Pulvis Sennæ Compositus
Pyrogallol
Quinina
Resina Podophylli
Santoninum

http://antiquecannabisbook.com/Appendix/USP1942.htm

History

1956

Congress includes marijuana in the Narcotics Control Act of 1956

Imposed stricter penalties and mandatory sentences for drug related offenses.

lawbrain.com/wiki/Narcotics_Acts

History

1968

University of Mississippi becomes official grower of marijuana for the Federal Government

Cultivates cannabis for government use and research studies

Researchers must be approved by the DEA and a representative from NIDA

https://technical420.com/cannabis-article/university-mississippi-sole-provider-marijuana-medical-research-us

History

The Controlled Substance Act of 1970 classified marijuana as a Schedule I drug

Made it illegal to possess, use, buy, sell, and grow marijuana

US Drug Enforcement Administration (DEA) span> "Marijuana," DEA website

History

1985

Marinol approved by FDA

Originally approved for nausea and vomiting associated with cancer chemotherapy

Placed as a Schedule II drug

Later approved (1992) for anorexia in patients with AIDS

Rescheduled to a Schedule III drug in 1999

https://en.wikipedia.org/wiki/Dronabinol

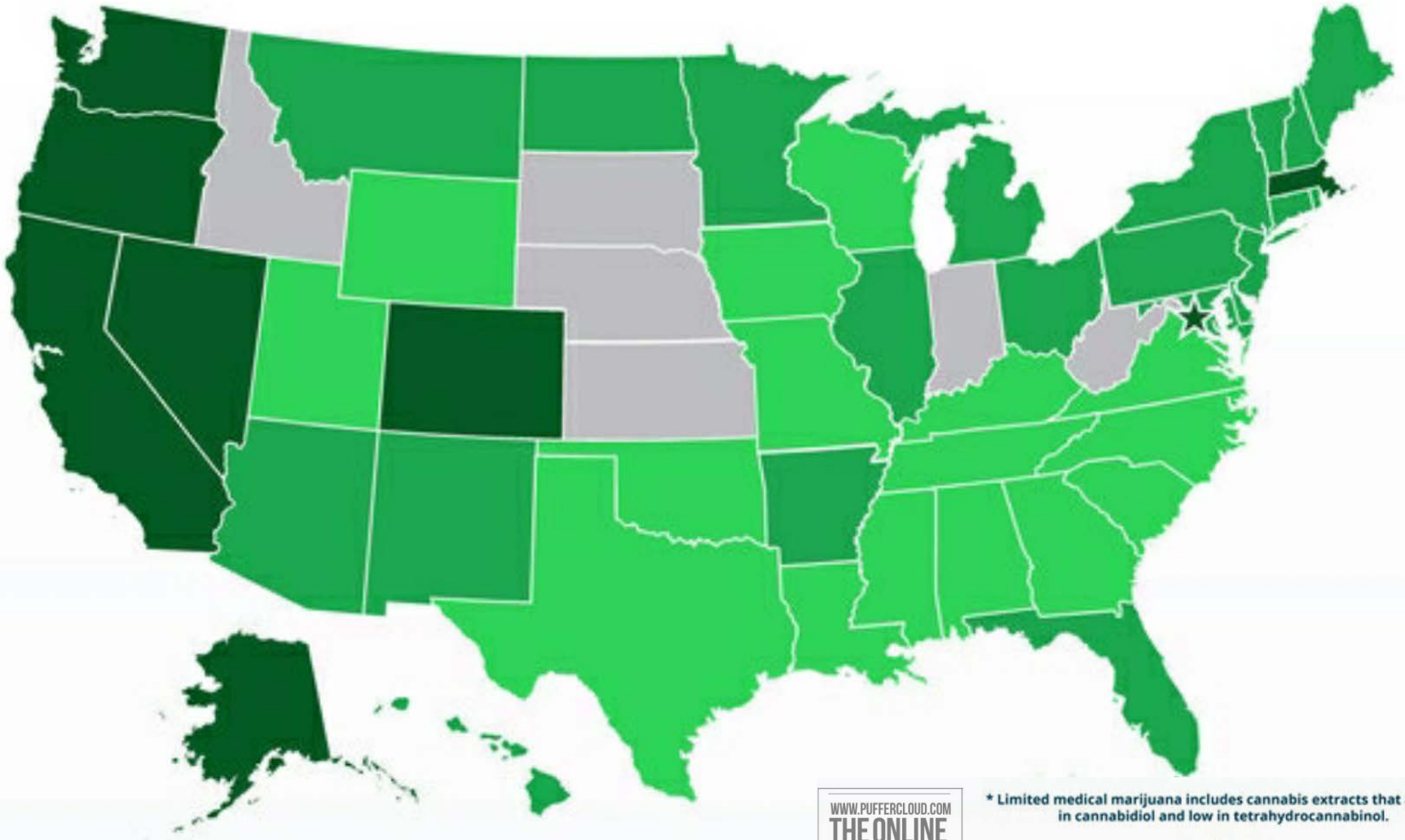
History

In 1996, California became the first state to allow medical marijuana for patients with a valid doctor's recommendation.

Other states followed…

en.wikipedia.org/wiki/California_Proposition_215_(1996)

Marijuana Legalization by State



Recreational Marijuana

- Alaska
- California
- Colorado
- Massachusetts
- Nevada
- Oregon
- Washington
- Washington, D.C.

Medical Marijuana

- Arizona
- Arkansas
- Connecticut
- Delaware
- Florida
- Hawaii
- Illinois
- Maine
- Maryland
- Michigan
- Minnesota
- Montana
- New Hampshire
- New Jersey
- New Mexico
- New York
- North Dakota
- Ohio
- Pennsylvania
- Rhode Island
- Vermont

Limited Medical Marijuana*

- Alabama
- Georgia
- Iowa
- Kentucky
- Louisiana
- Mississippi
- Missouri
- North Carolina
- South Carolina
- Tennessee
- Texas
- Utah
- Virginia
- Wisconsin
- Wyoming

* Limited medical marijuana includes cannabis extracts that are high in cannabidiol and low in tetrahydrocannabinol.

Source
National Conference of State Legislatures
http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx

FEDERAL LAWS

FEDERAL LAW

Cannabis still federally illegal

Within the White House, many differences in opinion

Cole Memo

Adopted in 2013, urged federal prosecutors to not use resources to prosecute people and businesses who are compliant with their state's marijuana laws

Federal prosecutors should shift their focus on:

- Distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana to criminal enterprises
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana;
- Preventing the growing of marijuana on public lands; and
- Preventing marijuana possession or use on federal property.

Jeff Sessions rescinded this memo on January 4th, 2018

https://www.biotrack.com/cole-memo/

ROHRABACHER-FARR AMENDMENT

- Prohibits Justice Department from using funds to be used to prevent states from implementing medical cannabis laws
- Ends federal medical marijuana raids, arrests, criminal prosecutions, and civil asset forfeiture lawsuits
- Provides current medical cannabis prisoners a way to petition their release
- Current version expires on September 30th, 2019 (must be renewed annually each fiscal year.

Jeff Sessions sent a letter to Congress asking legislators to deny recertification

https://www.safeaccessnow.org/federal_marijuana_law

William Barr

- “Untenable”
- Pledged not to enforce federal marijuana policies against states that are compliant under the Cole Memo guidelines.
- Supports Federal regulation
- Does not support Federal legalization.

https://www.cbsnews.com/news/william-barr-on-marijuana-legalization-attorney-general-nominee/

CONNECTICUT MARIJUANA LAWS

- Changed classification from a Schedule I drug to a Schedule II drug.
- Only pharmacy technicians that have had an active Connecticut pharmacy technician license within 5 years may apply for a dispensary technician license and sell marijuana product.
- Only pharmacists may apply for a dispensary license and dispense marijuana product.

https://www.safeaccessnow.org/house_bill_no_5389

STATES THAT UTILIZE PHARMACISTS TO DISPENSE CANNABIS

Minnesota

New York

Arkansas

Pennsylvania

Oklahoma

VIRGINIA LAWS AND PENALTIES

Offense	Penalty	Incarceration	Max. Fine
Possession			
Less than 1/2 oz. (first offense)	Misdemeanor	30 days	$500
Less than 1/2 oz. (subsequent offenses)	Misdemeanor	1 year	$2500
Sale/Manufacture/Trafficking			
½ ounce to 5 pounds	Felony	1* to 10 years	$2500
5 pounds to 100 kg	Felony	5* to 30 years	$1000
More than 100 kg	Felony	20* years to life	$100,000
To a minor who is at least 3 years younger	Felony	2* to 50 years	$100,000
Within 1000 feet of school or school bus stop	Felony	1* to 5 years	$100,000
Manufacture of marijuana	Felony	5* to 30 years	$10,000
Transporting more than 5 lb into the state	Felony	5* to 40 years	$1,000,000

*Mandatory Minimum Sentence

https://norml.org/laws/item/virginia-penalties-2

Virginia Hemp Law

Year Passed

1 2015

Statute

2 Va. Code. Ann. § 3.2-4112 (2015)

Summary

3 Senate Bill 955 allows for the cultivation of industrial hemp by licensed growers of industrial hemp as part of a university-managed research program. The Department of Agriculture and Consumer Services is in charge of regulating and establishing industrial hemp research programs by public institutions of higher education.

https://norml.org/legal/item/virginia-hemp-law

VIRGINIA CBD-SPECIFIC MARIJUANA LAW

1 Law Signed

2015

2 Qualifying Condition

Intractable Epilepsy

3 Summary

- Gives protection to those who are in possession of cannabidiol oil or THC-A oil (contains at least 15% of CBD or THC-A and less than 5% of THC)
- Must have a written valid certification issued from a practitioner in the realm of practice to treat epilepsy
- No current dispensaries, but in 2016, legislation was passed to establish regulations for the manufacturing of therapeutic oils containing CBD and/or THC-A.

https://www.mpp.org/states/virginia/

VIRGINIA CBD-SPECIFIC MARIJUANA LAW

1 Law Signed

2018

2 Qualifying Condition

Any Condition

3 Summary

- HB 1251 & SB 726
- Bills to expand certifications to include “any diagnosed condition or disease determined by the practitioner to benefit from such use.”
- HB 1251 also increases supply of CBD oil or THC-A oil a processor may dispense from a 30 day supply to a 90 day supply

https://www.mpp.org/states/virginia/

VIRGINIA CBD-SPECIFIC MARIJUANA LAW

Summary

1

- Only oils permitted, not whole plant cannabis
- Must contain at least 15% of either CBD or THC-A, and no more than 5% THC
- “Written Certification” must be provided by physician, available online from the Department of Health Professions
  - Any physician licensed to practice medicine or osteopathy in Virginia
  - Practitioners must register with the Board of Pharmacy
  - Only be permitted to issue a set number of certifications
- Patients, parents/legal guardians apply through the Board of Pharmacy
  - $50 application fee
  - Certifications are good for 1 year

https://www.mpp.org/states/virginia/virginias-limited-cbd-and-thc-a-oil-law/

VIRGINIA CBD-SPECIFIC MARIJUANA LAW

Summary

1

Pharmaceutical Processors

- Responsible for cultivating, manufacturing and dispensing
- Pharmacist must be in charge of each facility
- Cannabis oils cannot be sold in pharmacies
- Conditional approval for 5 initial pharmaceutical processors, one for each health service area
  - Pharmacann (Health Service Area I)
  - Dalitso (Health Service Area II)
  - Dharma (Health Service Area III)
  - Green Leaf (Health Service Area IV)
  - Columbia Care (Health Service Area V)

https://www.dhp.virginia.gov/pharmacy/PharmaceuticalProcessing/docs/PPPReferenceNov2018.pdf

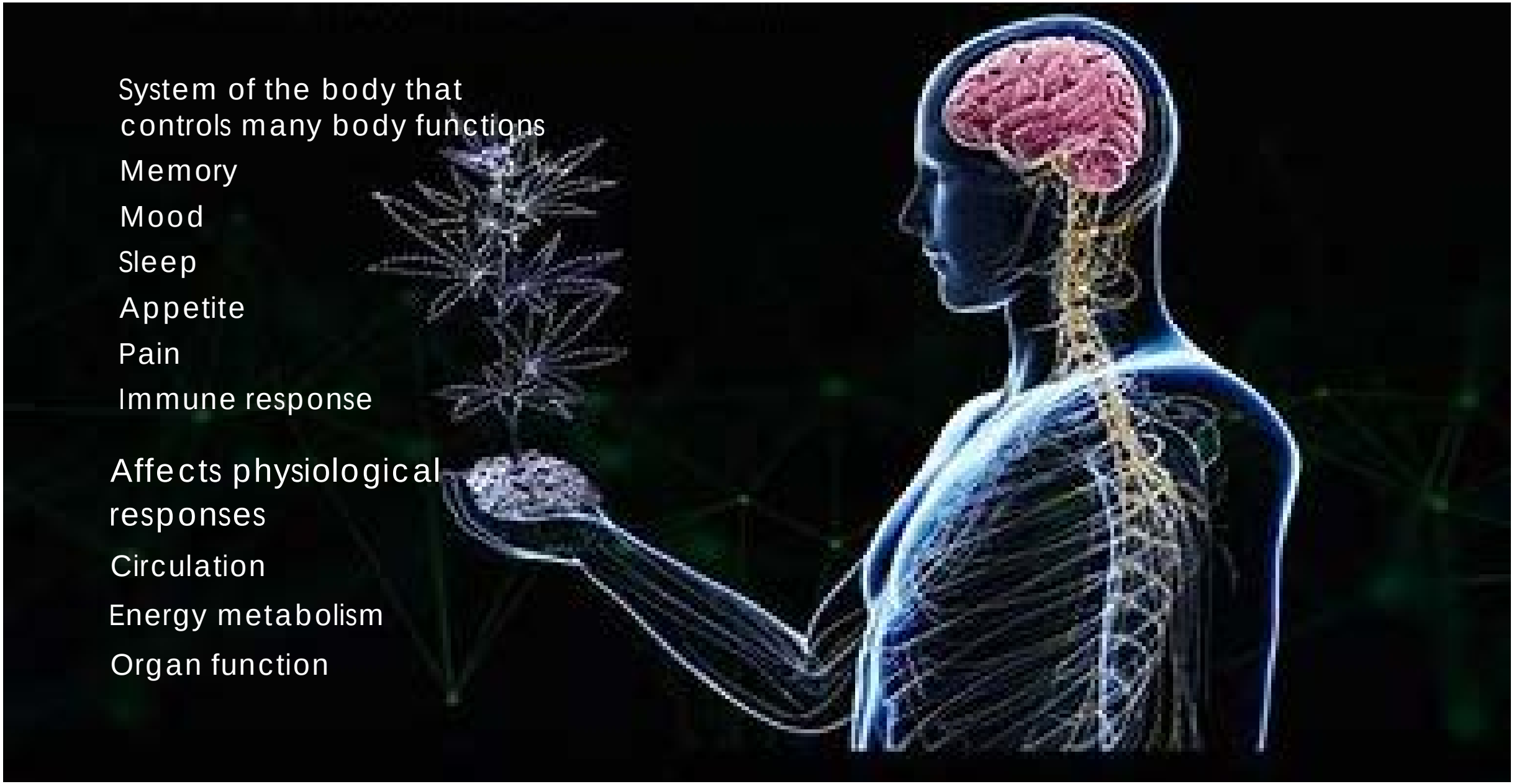
The Dispensary Pharmacist

Component Analysis

CANNABINOIDS

Group of chemical compounds that interact with the endocannabinoid system

THE ENDOCANNABINOID SYSTEM



System of the body that controls many body functions

Memory

Mood

Sleep

Appetite

Pain

Immune response

Affects physiological responses

Circulation

Energy metabolism

Organ function

CANNABINOID RECEPTORS

CB1 Receptors

Primarily present in the brain and spinal cord

Found in areas concerned with movement, postural control, pain, memory, cognition, and emotion

Also found in appetite controlling areas like the hypothalamus

Are NOT present in cardiopulmonary centers in the brain

CB2 Receptors

Expressed primarily in immune tissues

Can mediate regulation of cytokine release from immune cells

May modulate clinical conditions such as inflammatory pain, post-operative pain, chronic pain

ENDOCANNABINOID SYSTEM

INTEGRATED *Hemp* SOLUTIONS

THE HUMAN ENDOCANNABINOID SYSTEM

CB1 CB2 and THC fit like a lock and key into existing human receptors. These receptors are part of the endocannabinoid system which impacts physiological processes affecting pain modulation, memory and appetite plus anti-inflammatory effect and other immune system responses. The endocannabinoid system comprises two type of receptors, CB1 and CB2, which serve distinct functions in human health and well-being.

TETRAHYDROCANNABINOL

CANNABIDIOL

CANNABINOL

CB1

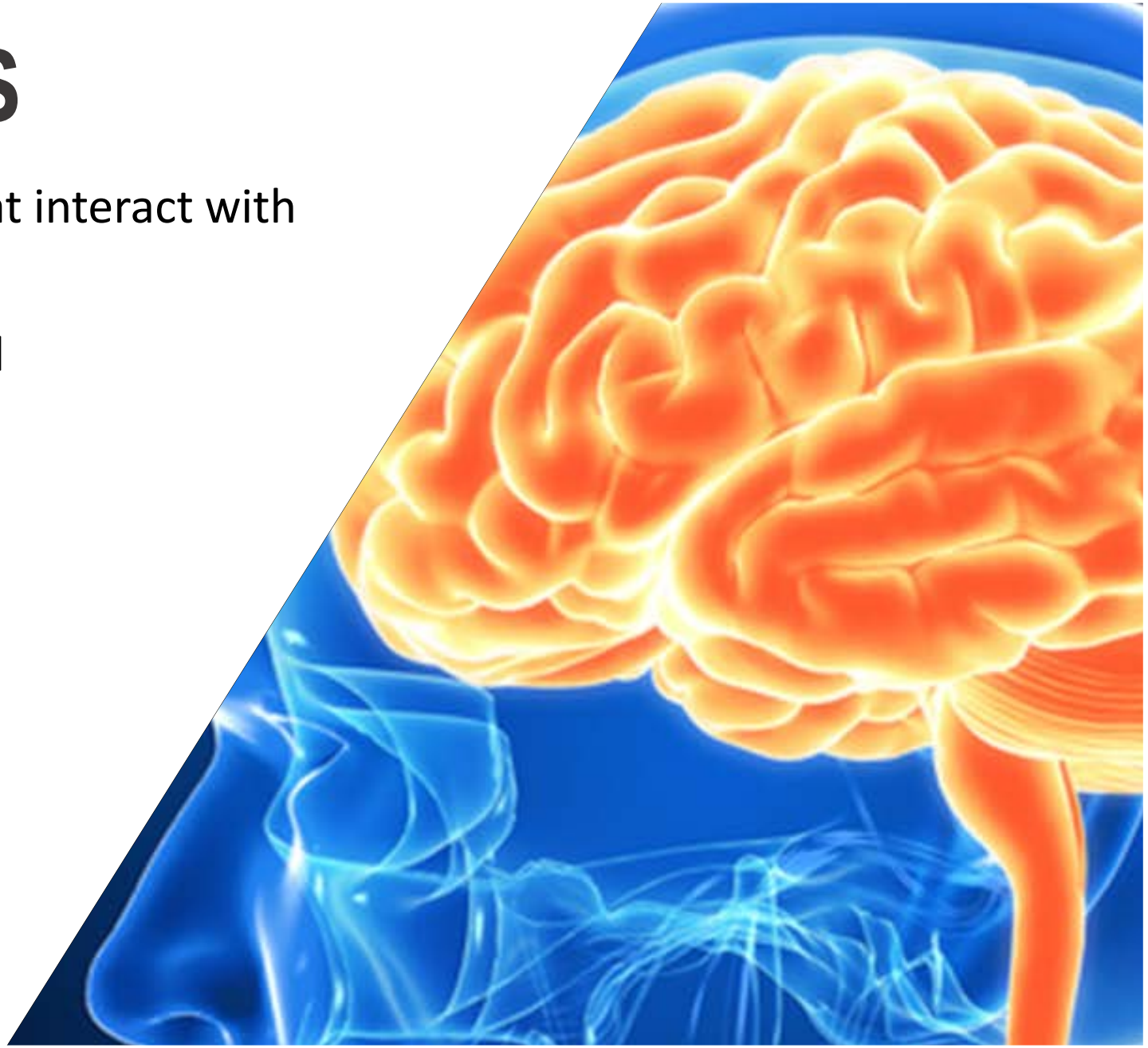
CB2

RECEPTORS ARE FOUND ON CELL SURFACES

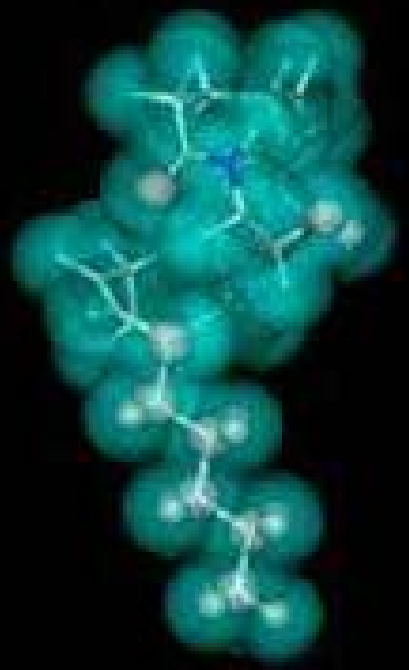
The recent identification of cannabinoid receptors has triggered an exponential growth of studies exploring the endocannabinoid system and its regulatory functions in health and disease. This system has been implicated in a growing number of physiological functions, both in the central and peripheral nervous systems and in peripheral organs.

CANNABINOIDS

- Group of chemical compounds that interact with the endocannabinoid system
- Found naturally in the body, called endocannabinoids
  - Anandamide
  - 2-Arachidonoylglycerol (2-AG)

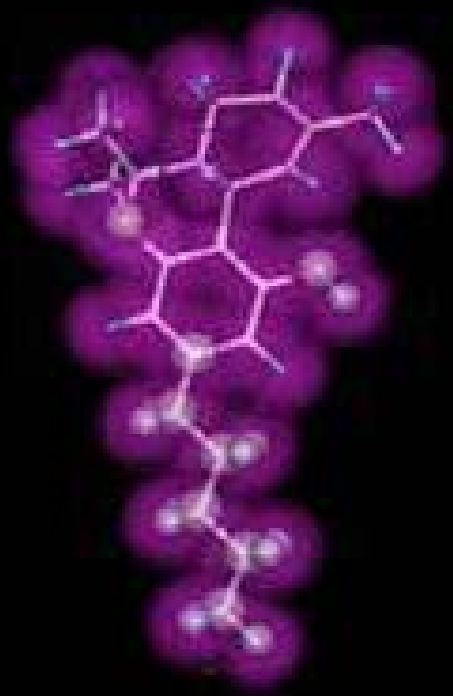


Brain's Chemical



Anandamide

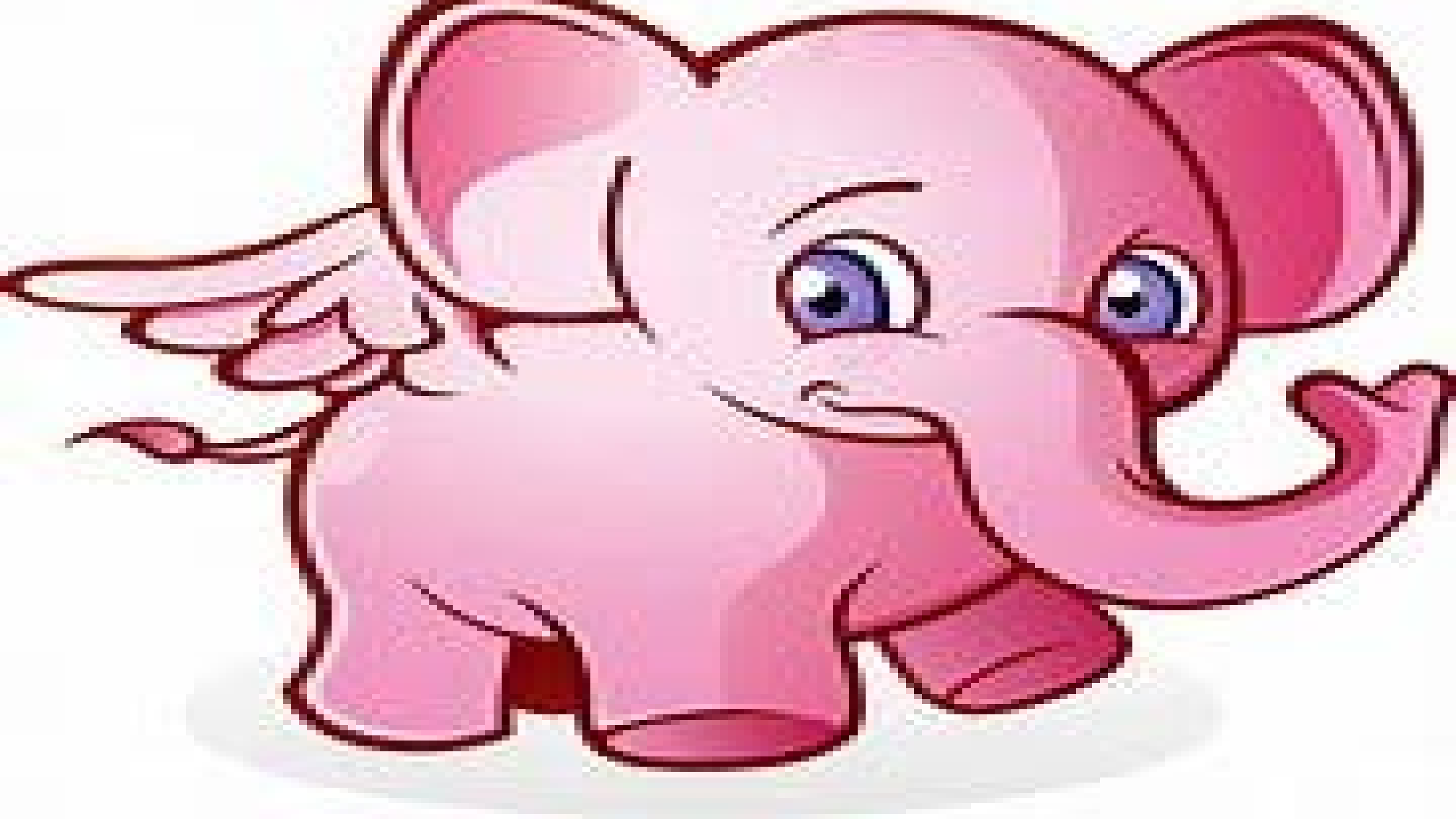
Drug



THC

CANNABINOIDS

- Found in high concentrations in cannabis (phytocannabinoids)
- Each cannabinoid may have its own or shared therapeutic benefit

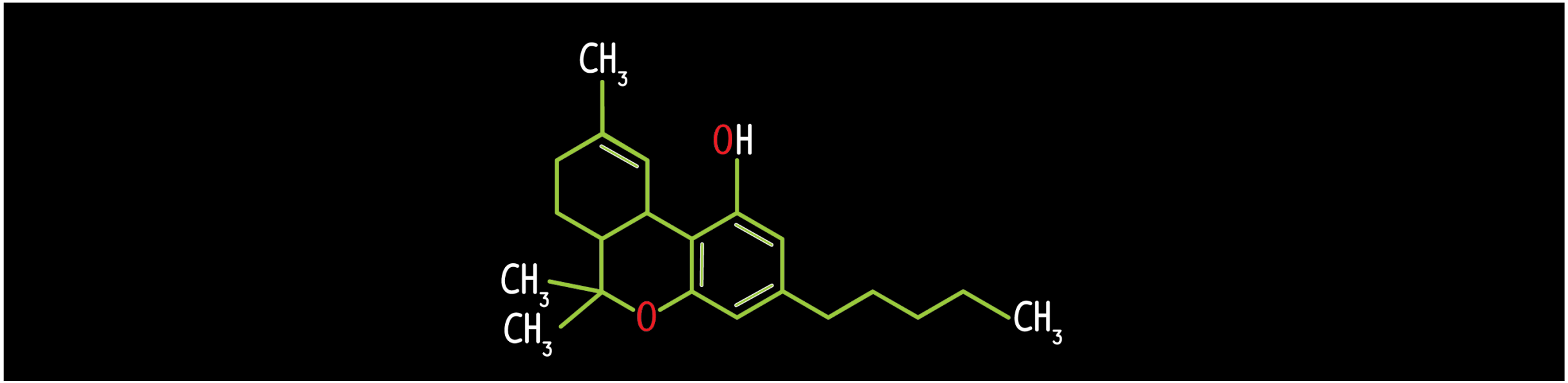


CANNABINOIDS

THC (d-9 Tetrahydrocannabinol)

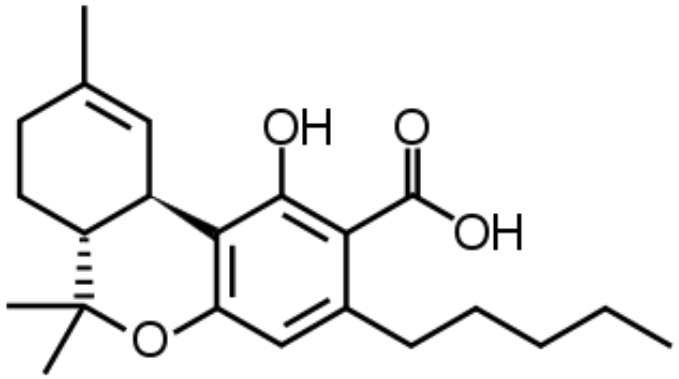
- Known for being strongly psychoactive
- Stimulates endocannabinoid system by binding to CB1 and CB2 receptors

- Health Benefits
  - > Analgesic
  - > Sleep
  - > Antidepressant
  - > Antispasmodic
  - > Antiemetic
  - > Appetite stimulant
  - > Antioxidant
  - > Reduces intraocular eye pressure



Cannabis Pharmacy (2014); 34-41 Michael Backes

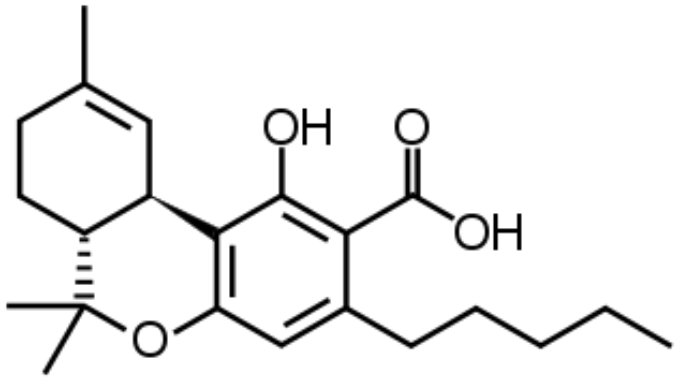
Tetrahydrocannabinolic Acid (THC-A)



- Acid precursor to THC
- Non-intoxicating cannabinoid found in raw and live cannabis
- THCA will convert to active THC as plant dries or heat is applied → Decarboxylation

http://www.cbdscience.com/uploads/1/3/9/3/13931495/thc_thca_cbd_comparison.pdf

Tetrahydrocannabinolic Acid (THC-A)

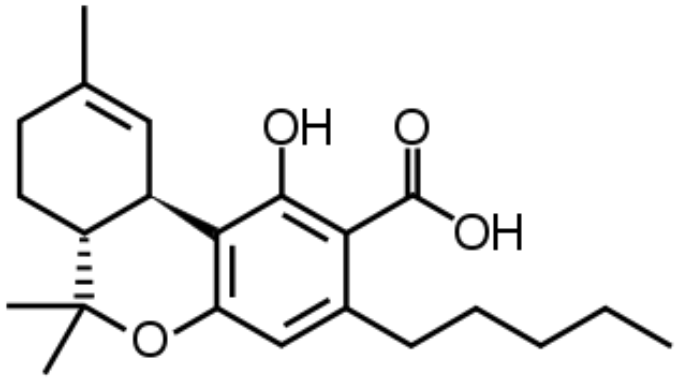


- Affects 4 functions of the endocannabinoid system
  - Releases COX-1
  - Inhibits COX-2
  - Inhibits TNF-Alpha
  - Releases Interleuken-10

- Wider spectrum of effects than THC and CBD

http://www.cbdscience.com/uploads/1/3/9/3/13931495/thc_thca_cbd_comparison.pdf

Tetrahydrocannabinolic Acid (THC-A)

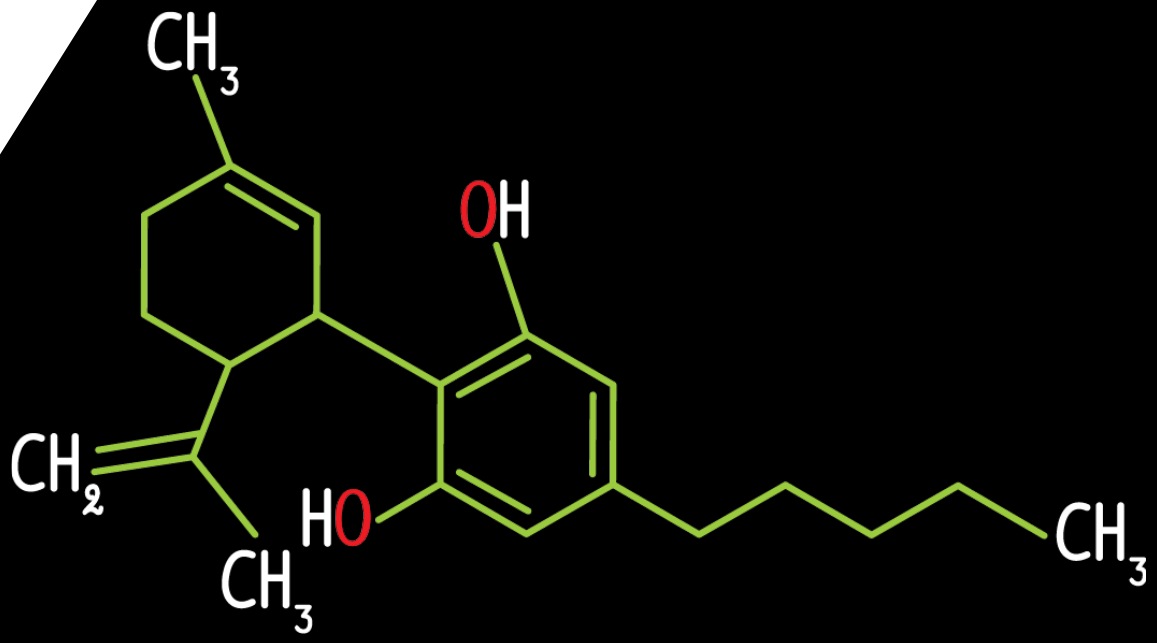


- Modulates:
  - Autonomic nervous system
  - Auto-immune system
  - Microcirculation
- Anti-inflammatory, Anti-convulsant, Anti-spasmodic, and Anti-oxidant properties
- Aniproliferative?

http://www.cbdscience.com/uploads/1/3/9/3/13931495/thc_thca_cbd_comparison.pdf

CBD (Cannabidiol)

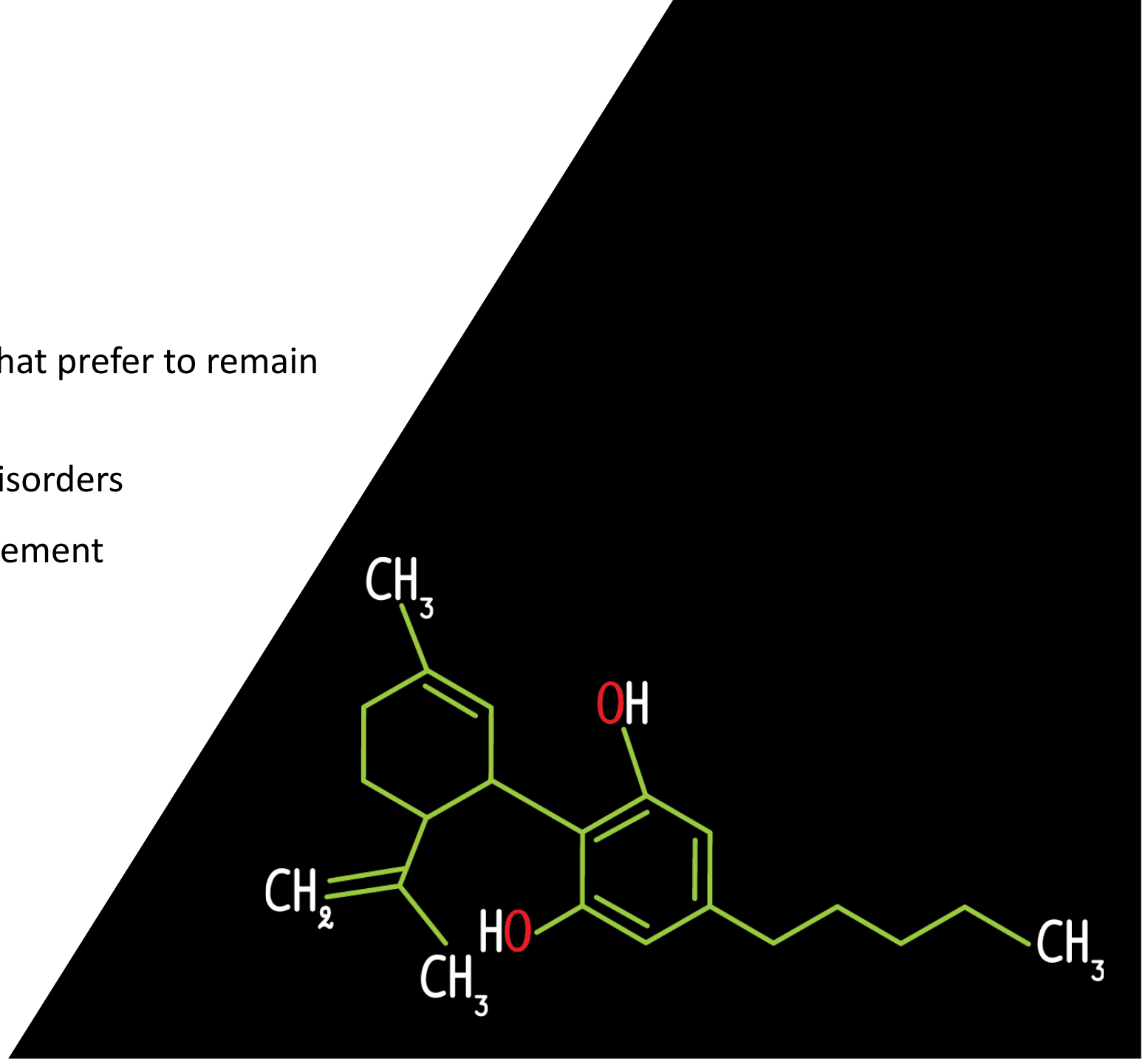
- Does not bind directly to CB1 or CB2 receptors
- Stimulates activity in both receptors
  - > Causes increased release in 2-AG
  - > Inhibits activity of fatty acid amide hydroxylase (FAAH) which slows deterioration of anandamide
- Inhibits THC's effects on CB1 receptors
- Binds directly to G-protein coupled receptor : TRPV-1
- Activates 5-HT1A serotonin receptor
- Affinity to histamine receptors
- Found to inhibit ID-1 gene



Cannabis Pharmacy (2014); 34-41 Michael Backes

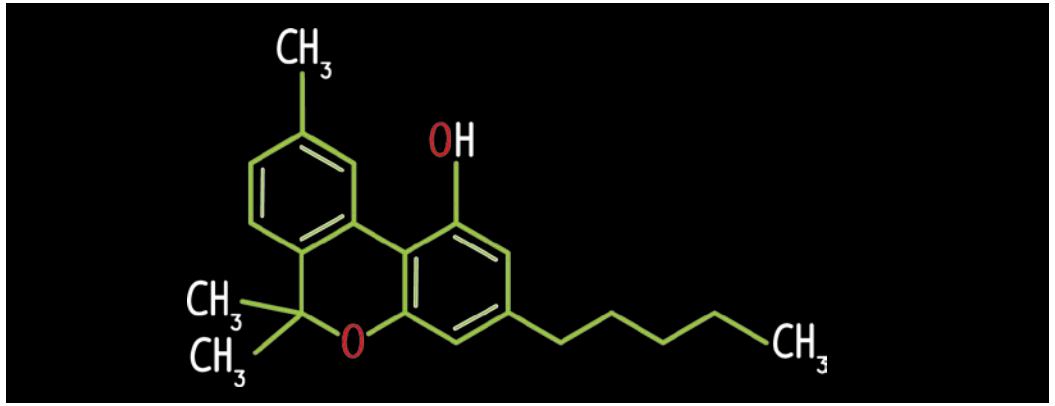
CBD (Cannabidiol)

- Non-psychoactive
- Suppresses psychoactivity of THC
- Ideal for elderly, children and patients that prefer to remain clear-headed
- Extremely valuable in treating seizure disorders
- Often as effective as THC in pain management
- Calming effect
- Can provide a focusing effect



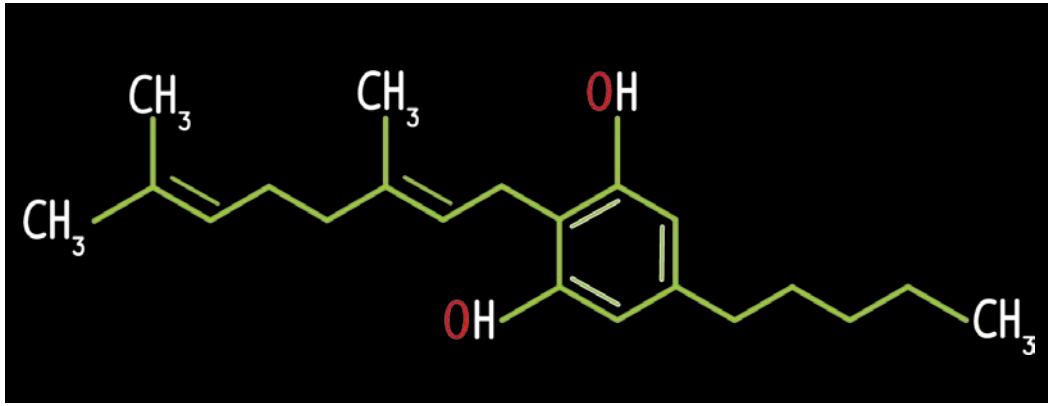
***Cannabis Pharmacy* (2014); 34-41 Michael Backes**

CANNABINOIDS



CBN (Cannabinol)

- Oxidation process of THC
- Partial agonist of CB2 receptors and weak agonist of CB1 receptors
- Strongly sedative
- Useful in treatment of insomnia

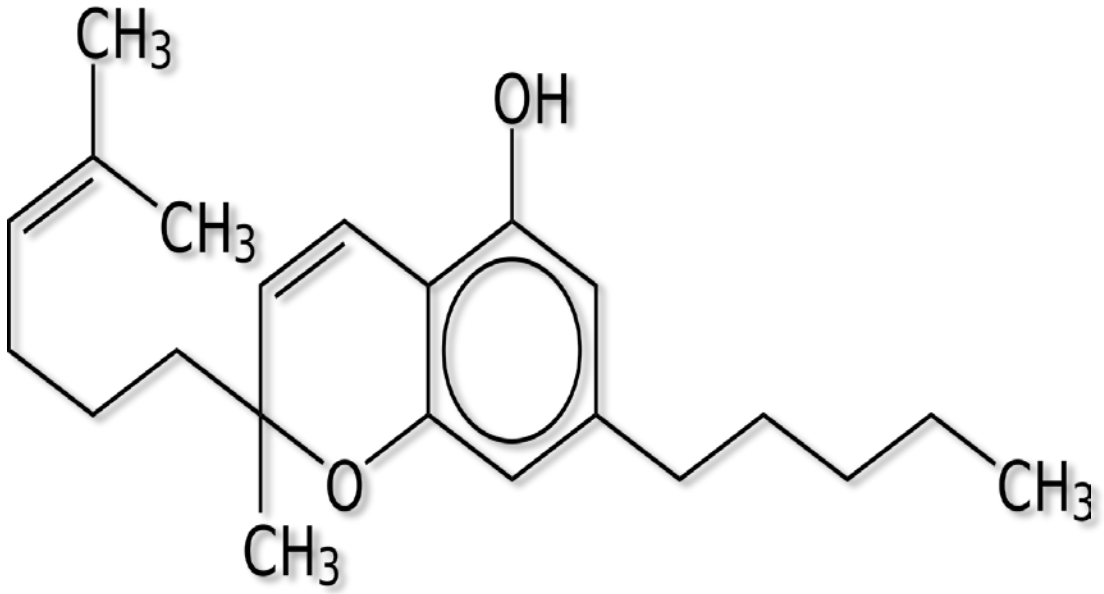


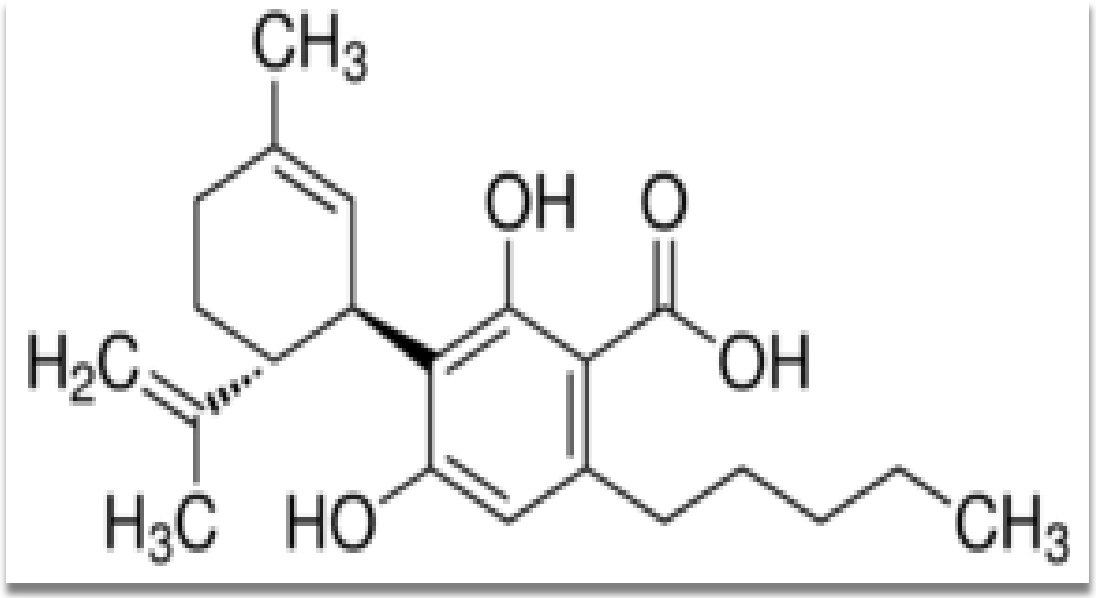
CBG (Cannabigerol)

- Non-psychoactive
- Inhibits uptake of GABA – decreases anxiety and muscle tension
- Anti-inflammatory

Cannabis Pharmacy **(2014); 34-41 Michael Backes**

CANNABINOIDS





CBC

- **Non-psychoactive**
- **Inflammation, Pain, Anxiety, Stress**

CBD-A

- **Acid precursor to CBD**
- **Anti-inflammatory, Digestive aid**

Cannabis Pharmacy **(2014); 34-41 Michael Backes**

Terpenes

- Organic hydrocarbons found in the essential oils in plants that give cannabis it’s aroma
- Contained in many familiar plants found in the natural world
- Every strain has a unique terpene profile
- Works in synergy with cannabinoids (entourage effect)
- Contain separate therapeutic effects

http://steephilllab.com/terpenes-and-cannabis/

Pinene

Aroma: Pine

Also found in: pine needles, rosemary, basil, dill

Medicinal value: bronchodilator, antiseptic, anti-inflammatory

http://steephilllab.com/terpenes-and-cannabis/

Myrcene

Aroma: Musky, Earthy

Also found in: Mango, Thyme, Hops

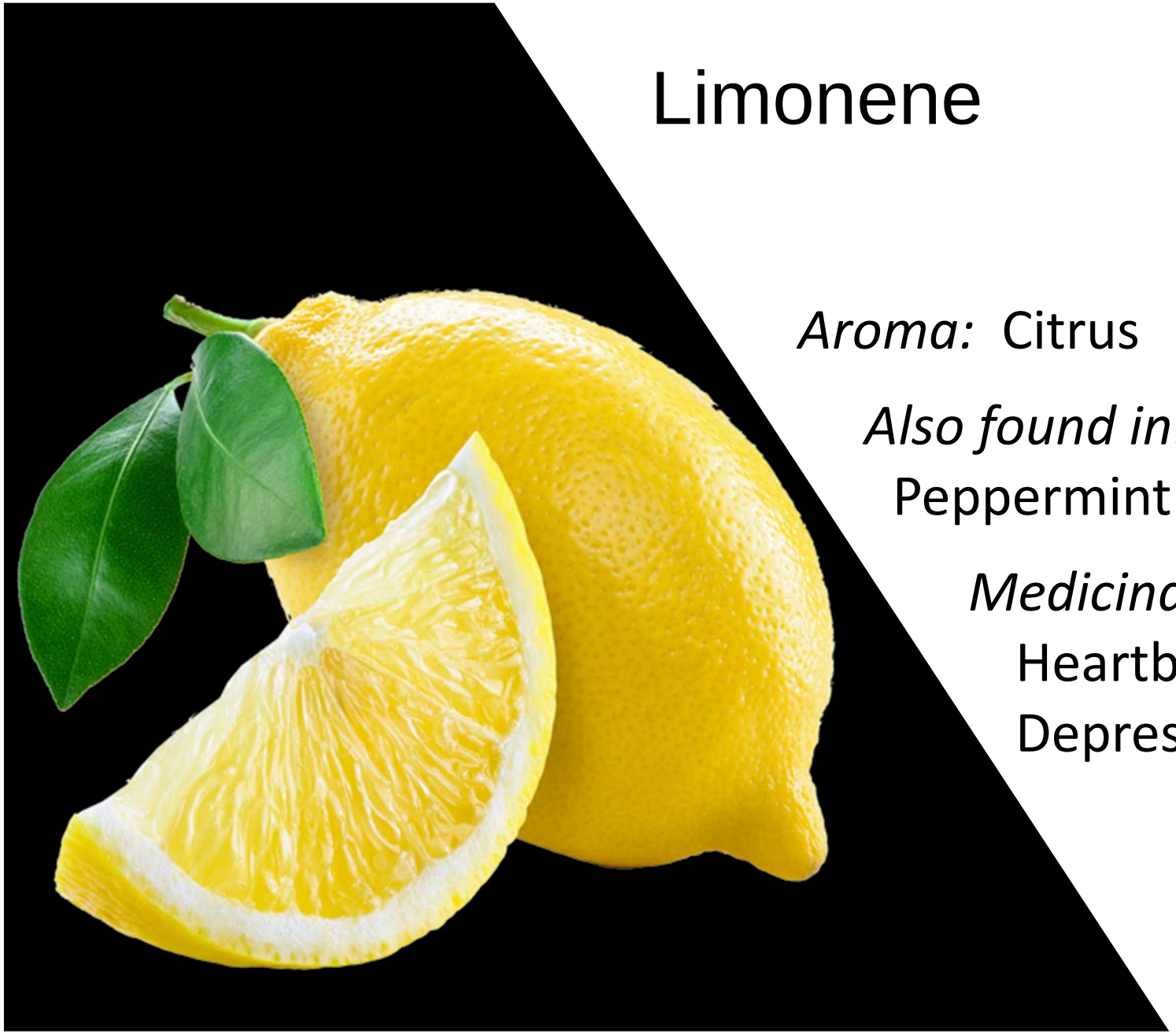
Effects: Relaxing, Sedating, "Couch-lock"

Medical value: Anti-oxidant, Muscle tension, Pain, Inflammation, Depression, Sleep

Allows THC to take effect more quickly by allowing it to cross the blood-brain barrier more easily

http://steephilllab.com/terpenes-and-cannabis/

Limonene



Aroma: Citrus

Also found in: Fruit rinds, Rosemary, Peppermint

Medicinal value: Anti-fungal, Heartburn, GI complications, Depression, Anxiolytic

http://steephilllab.com/terpenes-and-cannabis/

Caryophyllene

Aroma: Peppery, Spicy

Also found in: Black pepper, Basil, Cloves, Cotton

Medical value: Gastro-protective, Anti-inflammatory, Pain relief

May selectively activate CB2 receptors

http://steephilllab.com/terpenes-and-cannabis/

Linalool

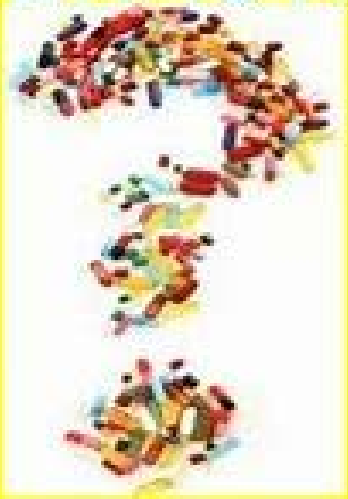
Aroma: Floral

Also found in: Lavender, Spring Flowers, Rosewood

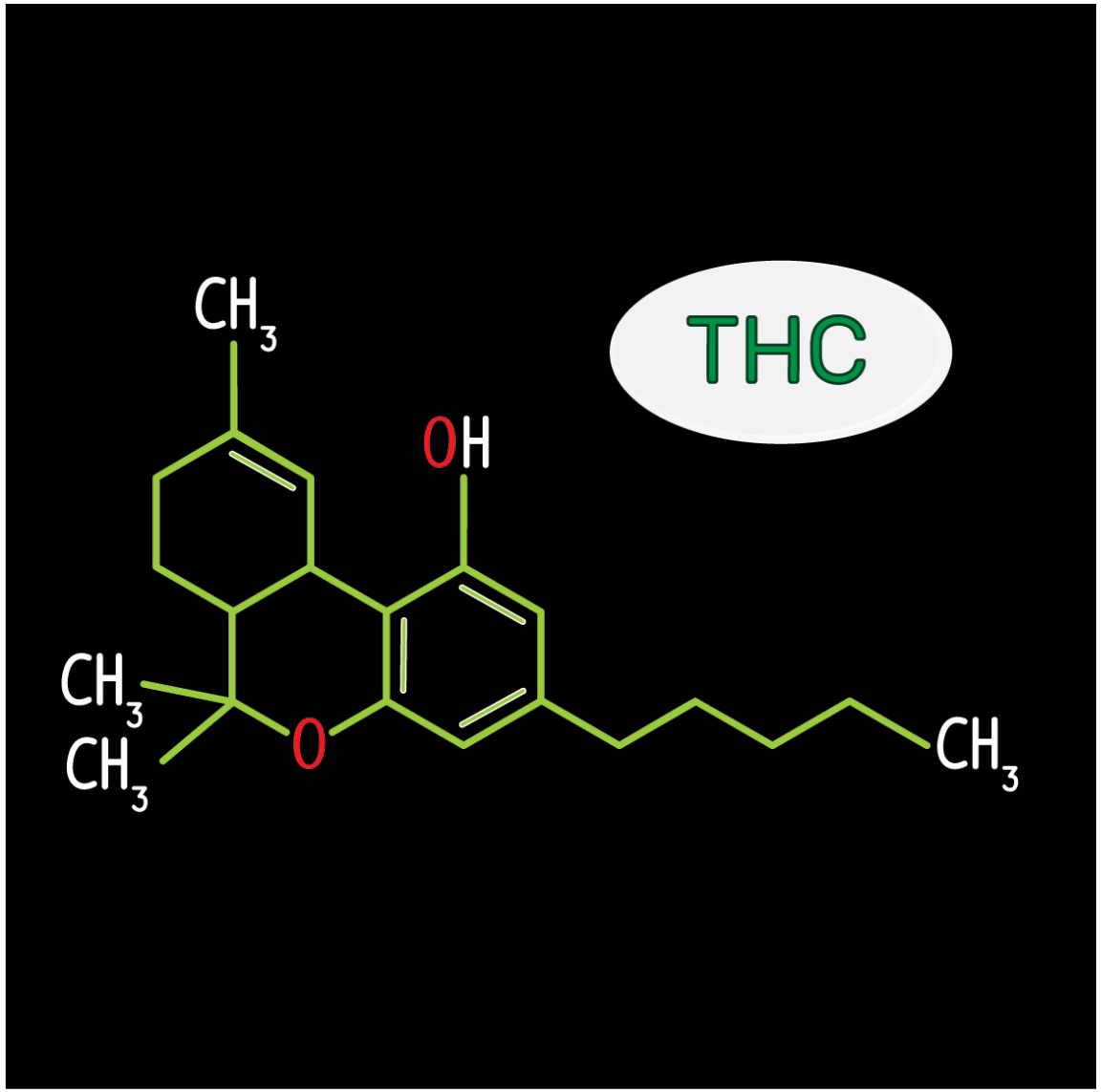
Medicinal value: Calming Effect, Anti-Anxiety, Sedative Effect, Analgesic, Anti-Epileptic

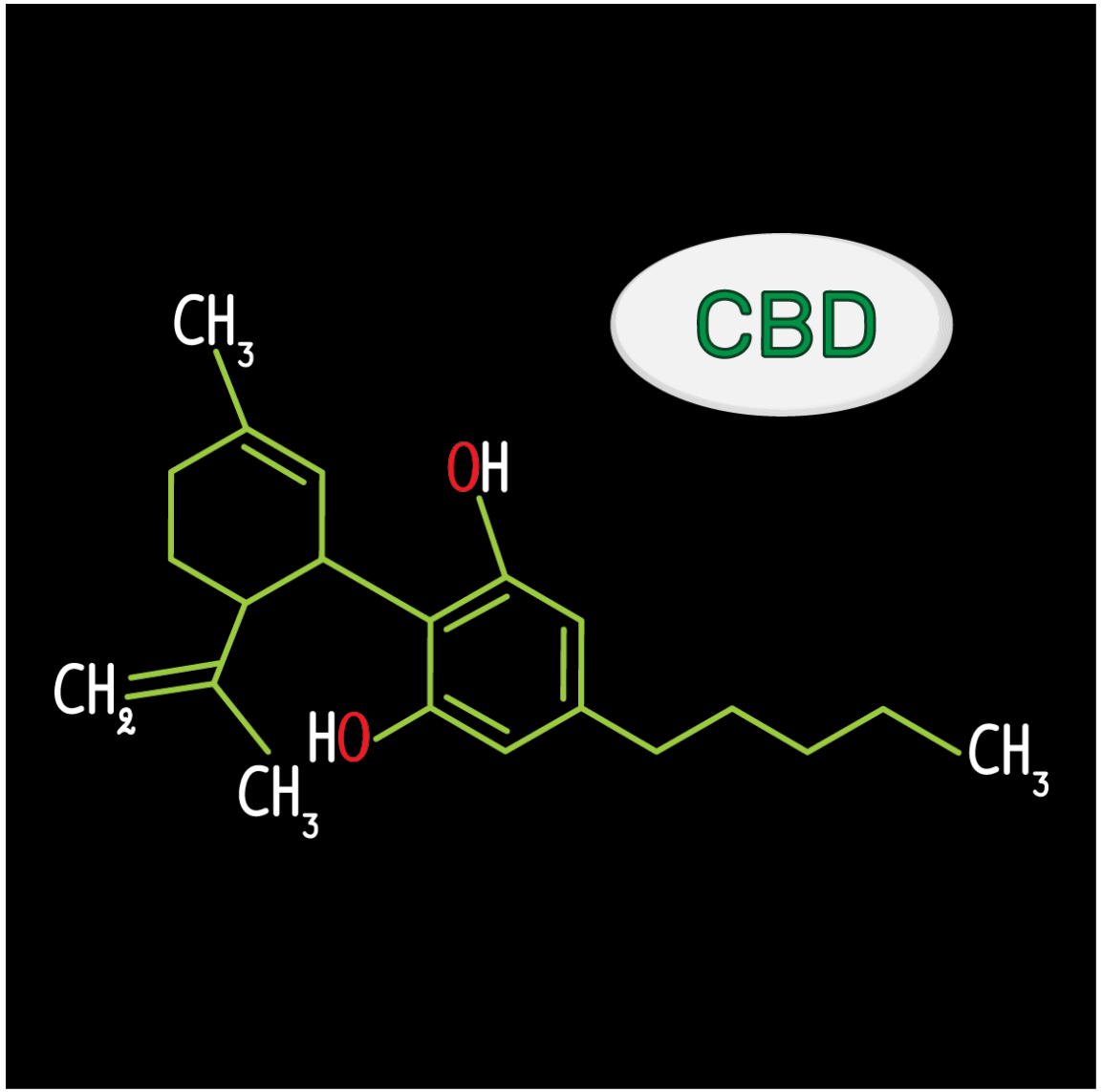
http://steephilllab.com/terpenes-and-cannabis/

DRUG INTERACTIONS

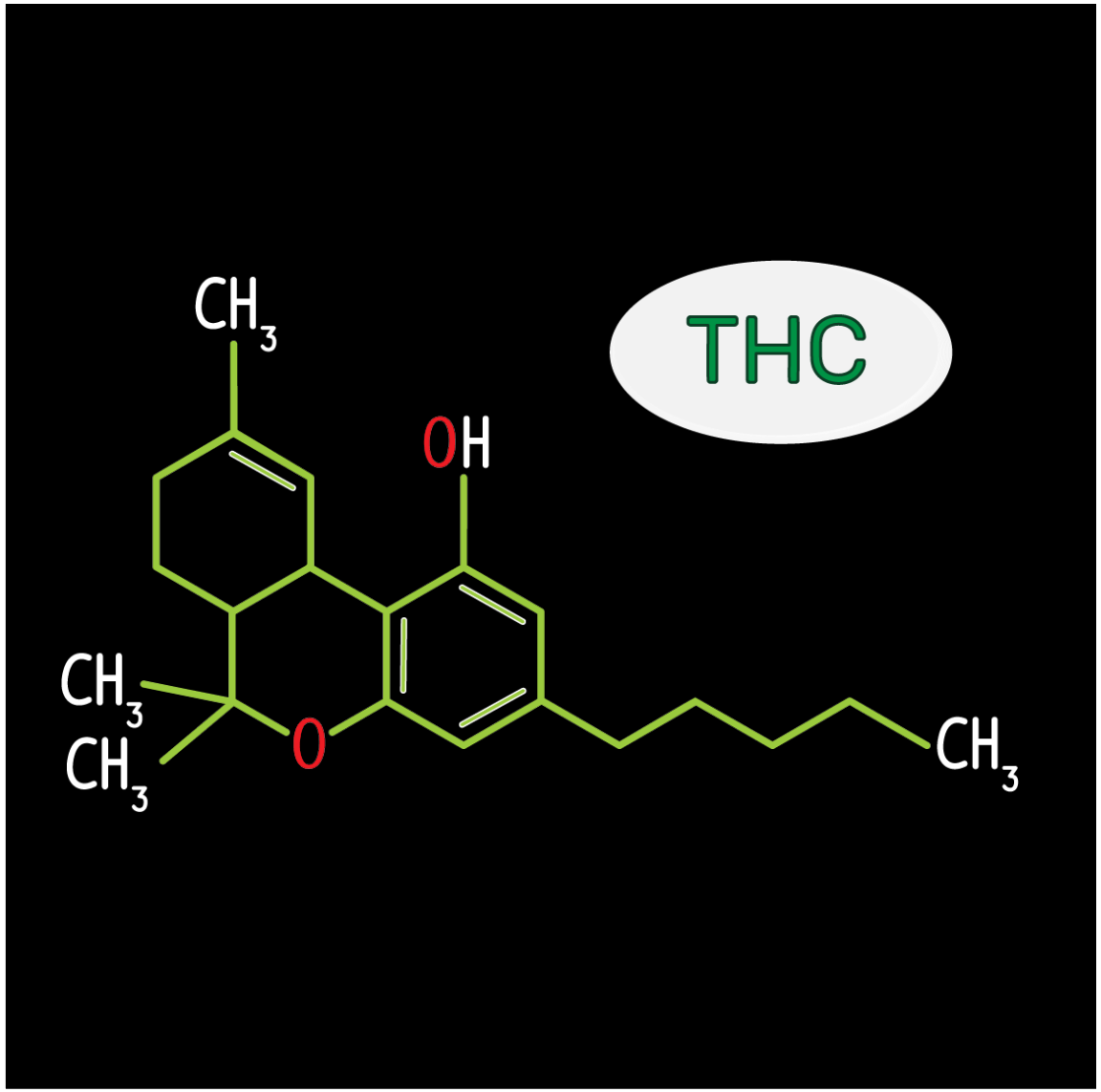


Drug Interactions





Drug Interactions

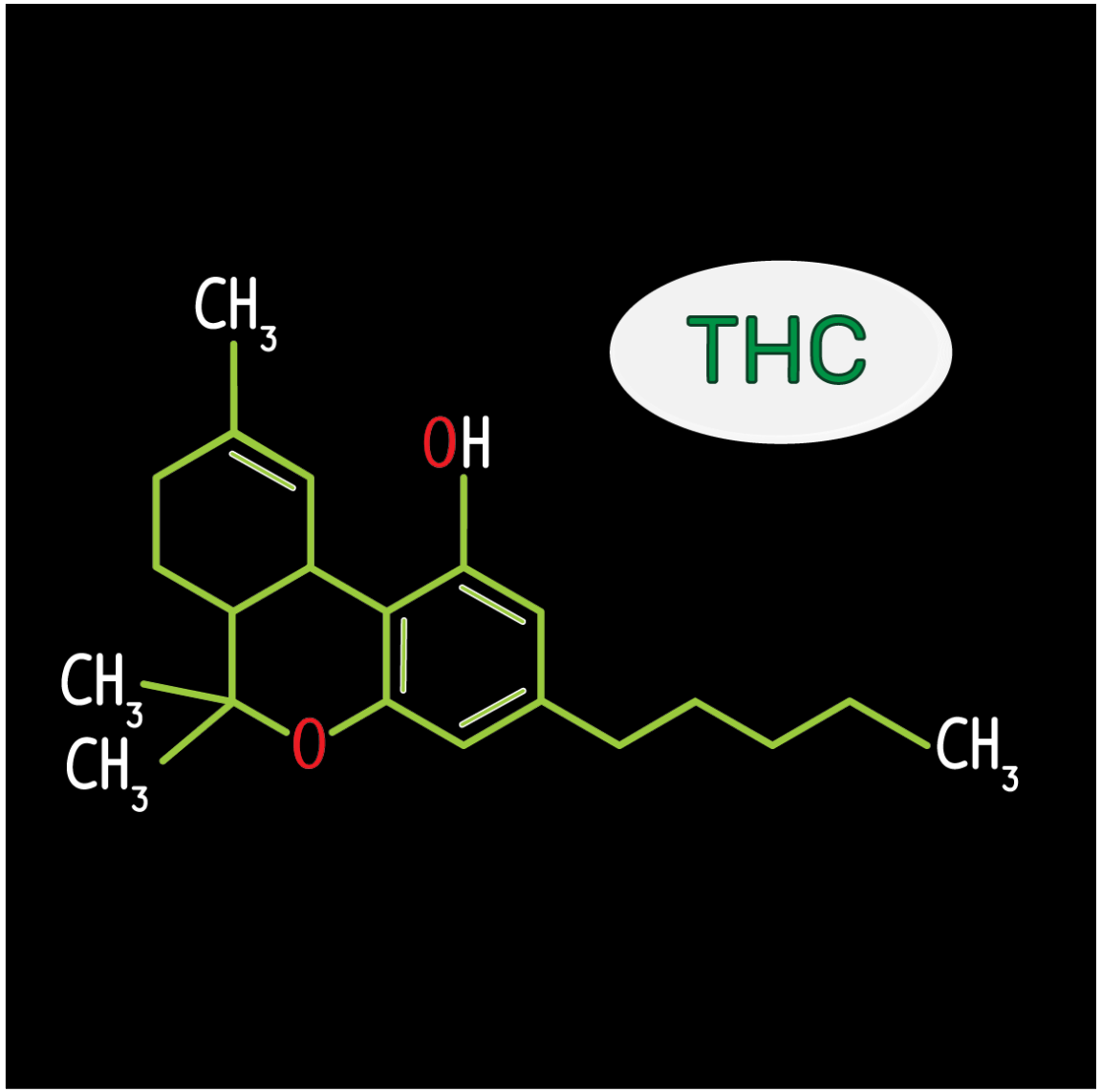


THC metabolized by CYP2C9 and CYP3A4 enzymes

- Medications that may be increased by THC administration: Amiodarone, Atorvastatin, Carvedilol, Metoprolol, Ritonavir, Simvastatin, Verapamil
- Clopidogrel effects may be decreased
- Amiodarone, Metronidazole, Fluoxetine, Fluconazole may inhibit THC elimination
- Ketoconazole has been shown to increase peak concentrations of THC
- Poor metabolizers of CYP2C9 can have THC concentrations increase three-fold

http://www.pharmacytimes.com/publications/issue/2014/December2014/Drug-Interactions-with-Marijuana

Drug Interactions

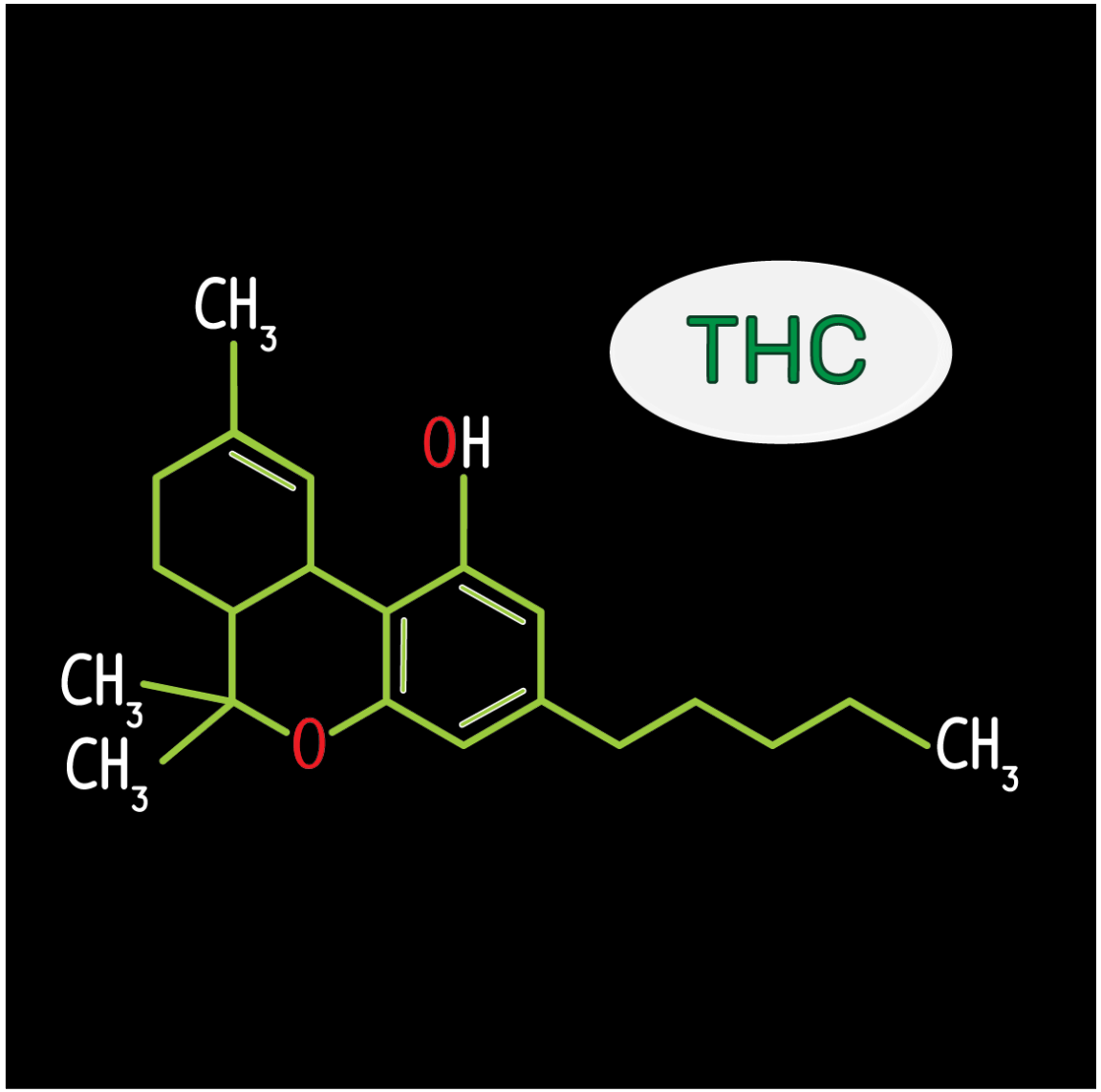


THC may also induce CYP1A2 enzyme

- Smoked cannabis has been shown to increase the metabolism of theophylline and chlorpromazine
- 50% decrease in plasma concentrations
- Induction seems to be occur in smoked marijuana, not oral administration, and is dose specific

http://www.pharmacytimes.com/publications/issue/2014/December2014/Drug-Interactions-with-Marijuana

Drug Interactions



THC strongly binds to blood plasma proteins

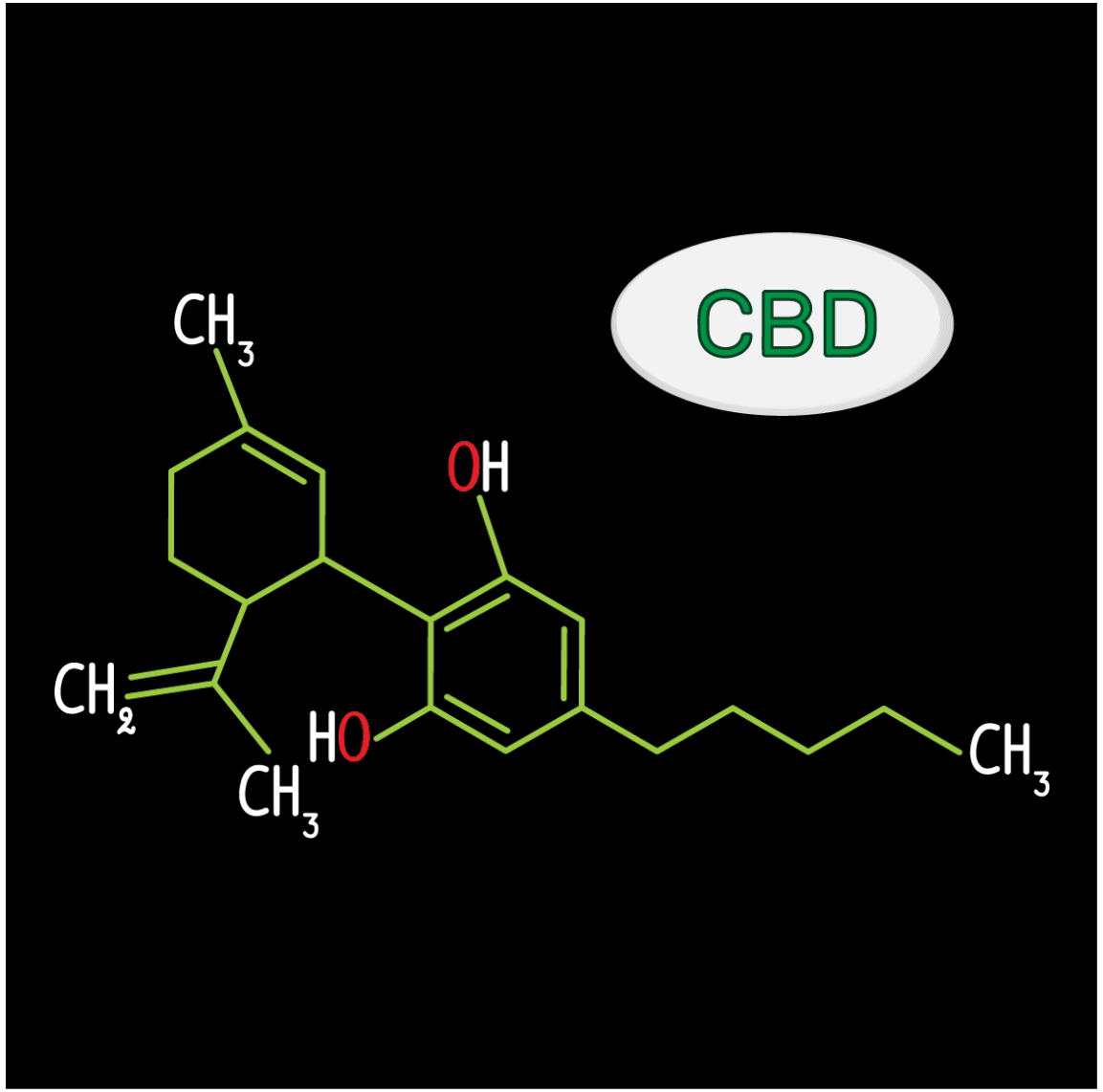
- Caution patients on warfarin
- One study has shown an increased response with a patient smoking 4 to 5 marijuana cigarettes per week

http://www.pharmacytimes.com/publications/issue/2014/December2014/Drug-Interactions-with-Marijuana

Drug Interactions

CBD is a substrate of CYP3A4 and CYP2C19 enzymes

- Medications that may have an increased effect
  - ❖ Amitriptyline
  - ❖ Clobazam
  - ❖ Diazepam
  - ❖ Propranolol
  - ❖ Warfarin



http://www.pharmacytimes.com/publications/issue/2014/December2014/Drug-Interactions-with-Marijuana

Drug Interactions

Pharmacodynamic interactions should be expected between marijuana and:

- Drugs with sympathomimetic activity (tachycardia, hypertension)
- Central nervous system depressants (drowsiness, ataxia), and
- Drugs with anticholinergic effects (tachycardia, drowsiness).

Cannabis medicines (smoked, oral, sublingual, or vaporized) may increase effects of:

- Alcohol
- Benzodiazepines
- Opiates

http://www.pharmacytimes.com/publications/issue/2014/December2014/Drug-Interactions-with-Marijuana

The Pharmacist's Role

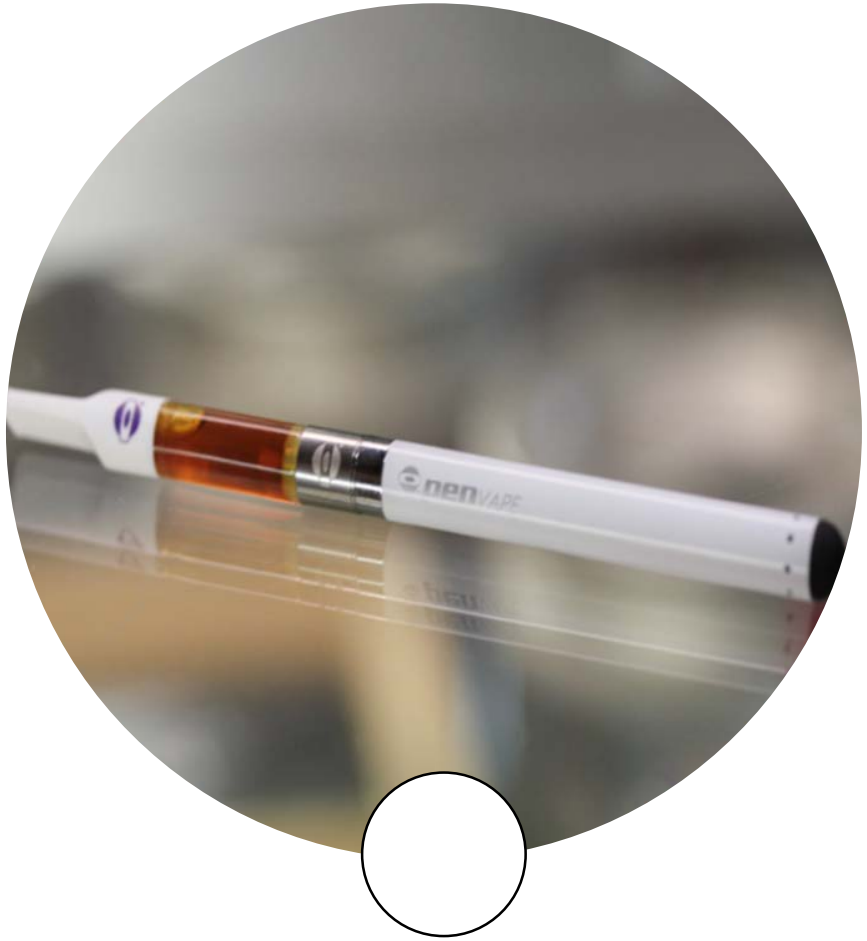
Prescription Monitoring Program (PMP)

- Controlled substances as well as marijuana card activation and marijuana purchases will show up on the report
- Physicians can monitor patient's usage.
- Before dispensing any marijuana product, the pharmacist checks the PMP.
  - Double check to make sure patients remain with one dispensary and are not over their monthly limit
  - Review any new controlled medications that may have been added since last visit and counsel if appropriate

COUNSELING

DOSAGE FORMS

INHALANTS

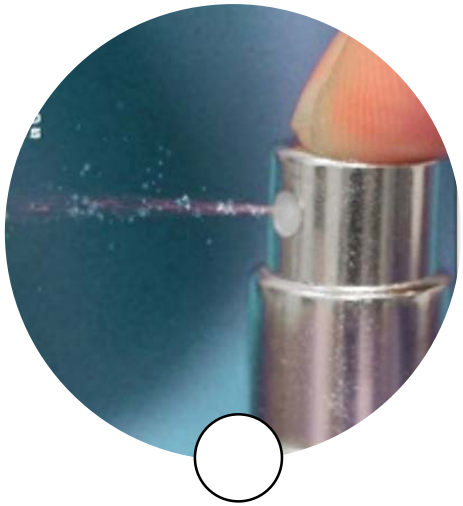


INHALANTS

- ✓ Fast-acting; produces an effect within 5 minutes.
- ✓ Effects last for approximately 2 hours.
- ✓ Easy to titrate dose.
- ✓ Can cause throat irritation.
- ✓ Hard to determine dosage.
- ✓ Appropriate for patients who need instant relief and to minimize side effects.

Sublinguals

Tinctures



Sprays

Dissolvable Strips

SUBLINGUALS

- ✓ Under the tongue application.
- ✓ Delayed action (takes approximately 30 minutes before effect).
- ✓ Longer duration of action (three to four hours).
- ✓ Specific dosing.
- ✓ Beware of added ingredients (alcohol, coconut oil)
- ✓ Appropriate for those individuals who need quick relief who cannot inhale cannabis.

Consumables

Edibles

Capsules

Oils

CONSUMABLES

- ✓ Effects delayed (30 minutes to 2 hours).
- ✓ Effects can last anywhere from 4 to 8 hours.
- ✓ Effects are much stronger.
- ✓ Specific dosing.
- ✓ Beware of added ingredients (food additives, coconut oil)
- ✓ Bioavailability can range from 10-20%
- ✓ Appropriate for those patients who need long term relief.

Other Routes of Administration

Topical

Rectal

DOSING

DOSING

- Ask about marijuana experience
- Focus on symptoms
- Fit cannabis therapy in a patient's lifestyle - compliance
- Start low and slow
- Gradually increase dose every 3-5 days
- Note adverse effects as well as symptom relief
- Individualized medicine – different doses for different patients

PRODUCT A – VAPE OIL

CANNABINOID CONTENT	
THC-A	<0.10%
THC	2.57%
CBD-A	2.81%
CBD	47.7%
CBG-A	0.17%
CBG	0.75%
CBN	0.12%
CBC	2.42%

TERPENE CONTENT	
a-Pinene	0.75%
b-Pinene	0.33%
b-Myrcene	0.32%
Limonene	0.75%
b-Caryophyllene	0.50%
Humulene	0.17%

PRODUCT B – TINCTURE

CANNABINOID CONTENT (mg per mL)	
THC-A	30.30mg
THC	0.9mg
CBD-A	0.3mg
CBD	<0.1mg
CBG-A	0.34mg
CBG	<0.1mg
CBN	0.10mg
CBC	0.23mg

TERPENE CONTENT	
a-Pinene	<0.01%
b-Pinene	<0.01%
b-Myrcene	0.96%
Limonene	<0.01%
b-Caryophyllene	0.12%
Humulene	0.15%

PRODUCT C - CAPSULES

CANNABINOID CONTENT (mg per pill)	
THC-A	<0.10mg
THC	2.73mg
CBD-A	<0.10mg
CBD	50.0mg
CBG-A	<0.10mg
CBG	<0.10mg
CBN	<0.10mg
CBC	2.07mg

TERPENE CONTENT	
a-Pinene	<0.01%
b-Pinene	<0.01%
b-Myrcene	<0.01%
Limonene	<0.01%
b-Caryophyllene	<0.01%
Humulene	<0.01%

PRODUCT D - TOPICAL

CPS Lotion

CANNABINOID CONTENT (mg per container)	
THC-A	<0.10mg
THC	0.21mg
CBD-A	<0.10mg
CBD	263mg
CBG-A	<0.10mg
CBG	<0.10mg
CBN	<0.10mg
CBC	0.02mg
TERPENE CONTENT	
a-Pinene	<0.01%
b-Pinene	<0.01%
b-Myrcene	<0.01%
Limonene	<0.01%
b-Caryophyllene	<0.01%
Humulene	<0.01%

CASE STUDY #1

- Patient A comes into the dispensary for the first time and sits down with the pharmacist. He is diagnosed with severe back pain from an accident he suffered last year. His major complaints are pain in the evening time, as it keeps him up at night. He also has COPD and high blood pressure. His current medications include Furosemide, Amlodipine, and uses a ProAir inhaler prn. After looking at PMP, you also find he has been prescribed Percocet and Carisoprodol as well. He states he has used marijuana in the past, but not regularly.
- A: What should the pharmacist go over with Patient A?
- B: What product would best suit Patient A?
- C: What dose should the pharmacist recommend?

CASE STUDY #2

- Patient B comes into the dispensary for the first time and presents with PTSD symptoms, mainly social anxiety and fatigue. She has been using cannabis for some time, but she sometimes feels that she gets more anxious after she smokes. She takes an alprazolam 0.5mg prn and amitriptyline 50mg hs. She does not have any other health conditions.
- A: What should the pharmacist go over with Patient B?
- B: What product(s) would be most appropriate for Patient B?
- C: What dose should the pharmacist recommend?

CASE STUDY #3

- Patient C comes into the dispensary to speak with the pharmacist. She has been diagnosed with severe psoriasis and psoriatic arthritis. She has chronic angina, high blood pressure, high cholesterol, and recently suffered a stroke. Her current medications include Plavix, Lipitor, Ranexa, Ibuprofen prn, and uses Triamcinolone cream. Her symptoms are more local, but needs something to help with her pain and inflammation. She has not used cannabis before.
- A: What should the pharmacist go over with Patient C?
- B: What products should the pharmacist recommend?
- C: What dose should Patient C start out with?

THE PHARMACIST'S ROLE

- Follow up with patients
  - Track symptom relief
  - Note medication changes
  - Document adverse effects
- Change strain / dose to optimize therapy
- Outreach
- Research

SIDE EFFECTS

Short-Term Side Effects

Mood reactions (euphoria, relaxation, anxiety, time-distortion)

Rapid heartbeat

Facial flushing

Red eyes

Dry mouth

Headaches

Dizziness

Coughing

Long-Term Side Effects

Severe, chronic bronchitis

Range of cognitive deficits

Receptor down-regulation (decline in receptor density)

Risks/Warnings

Contraindications

- Pregnancy / nursing
  - Lower birth weights
  - Endocannabinoids involved in several aspects of fetal and childhood development
  - Cannabinoids are passed along breast milk
- Serious mental disorders (i.e. schizophrenia)

Use with caution for patients with:

- Heart conditions
- Respiratory conditions
- History of drug / alcohol abuse

Risks/Warnings

In case of overmedication:

- May potentiate / worsen side effects
- Will resolve after stopping medication
- Drinking water and eating may help, as well as fresh air

- Do not consume cannabis in a public place or where it may pose harm to others
- Never operate a vehicle after consuming marijuana
- Keep this medicine out of reach of children or pets

Number of Deaths from

Cannabis


THANK
YOU

Virginia Department of Health Professions

Virginia Board of Pharmacy Pharmaceutical Processor Update

Board of Pharmacy Retreat

April 16, 2019

DHP Staff

Virginia Department of Health Professions

Pharmaceutical Processor

- Facility permitted by Board of Pharmacy
- Vertical operation
- Cannabidiol (CBD) oil or THC-A oil as defined in Code
- Pharmacist oversight
- Any diagnosed condition or disease determined by practitioner to benefit from such use

Pharmaceutical Processor, cont.

- Independent laboratory tested for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue, and active ingredient analysis
- Laboratory results available to registered patients, parents, guardians, and physicians upon request
- Board quarterly inspections required.

Virginia Department of Health Professions

Five Conditional Approval Awardees

- HSA I = PharmaCann Virginia LLC
- HSA II = Dalitso LLC
- HSA III = Dharma Pharmaceuticals
- HSA IV = Green Leaf Medical of Virginia LLC
- HSA V = Columbia Care Eastern Virginia LLC

Virginia Department of Health Professions

Five Conditional Approval Awardees

- Anticipated to be operational by December 2019
- Approximately 4-6 months to cultivate and produce oils

Virginia Department of Health Professions

Affirmative Defense

- Law provides for an affirmative defense for a patient, parent/legal guardian to possess CBD oil or THC-A oil as defined in §54.1-3408.3
- ….who has been issued a valid written certification from a Board of Pharmacy-registered physician
- ….and who maintains a current registration with the Board of Pharmacy.

Virginia Department of Health Professions

Written Certification Form

- Authorized since 2015
- Developed by Board of Medicine and Virginia Supreme Court
- Physician is provided access to the written certification once registered with Board of Pharmacy
- Nurse practitioners and Physician Assistants may obtain registration and issue written certifications after July 1, 2019

Virginia Department of Health Professions

Registrations as of 4/12/19

- 256 registered physicians
- 420 registered patients; 120 pending
- 7 registered parent/legal guardians

Status of Regulations

- Revised emergency regulations effective 10/1/18 and scheduled to expire 8/5/19.
- Proposed replacement regulations adopted by board in September 2018.
  - Public comment period ends May 17, 2019
  - Regulation Committee to discuss on May 3, 2019
  - Board to adopt final regulations June 5, 2019

Action Items

- Amend physician registration application and written certification to include nurse practitioners and physician assistants
- Develop form for physician to inform board of change in patient's eligibility
- Draft regulations for number of patients for whom registered agent may represent and regulations for wholesale distributing oils between processors
- Develop application for registered agent

Action Items

- Develop form for registering oils, processes for assigning “NDC-like” number and reporting dispensed oils to PMP
- Create mechanism for processors to verify status of registrations
- Continue educating on law
- Finalize opening and routine inspection forms
- Train staff

Virginia Department of Health Professions

Update on Inspection Form & Training

- Development of form
- cGMPs for dietary supplements
- Visit to Connecticut

Virginia Department of
Health Professions

Questions?