What is the Current Status of Cannabis Research?

Aidan Hampson, Special Content Expert: Cannabis, National Institute on Drug Abuse, National Institutes of Health

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Moderated by **Christina M. Markus**, Partner, King & Spalding LLP

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FEDERAL CANNABIS RESEARCH

Aidan Hampson, Ph.D.

Special Expert on Cannabis

Division of Therapeutics and Medical Consequences

National Institute on Drug Abuse

National Institute on Drug Abuse

CURRENT FEDERAL POLICY

US is Signatory to **Single Convention on Narcotics (1961, 1972 update)** –International treaty covering opium (poppy plants), coca leaves, and cannabis

- Cannabis is illegal to grow, possess, or distribute
- Each nation can designate a single source of marijuana for research purposes
- The DEA has designated *NIDA* to be that source using a contract with the University of Mississippi

NIDA's Marijuana Farm

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WHY IS CANNABIS SCHEDULE 1 (C I)?

- Controlled Substances Act (1970) weighs the risk of abuse / dependence against *accepted* medical use (eg FDA approval)
- Synthetic THC (Dronabinol) and natural CBD (Epidiolex) have accepted medical uses (CIII, CV respectively).
- Cannabis is not a single "drug product" and its make up varies substantially, so Cannabis as a category has no accepted medical use
- "Marihuana" is rewarding, has a *risk* for abuse / dependence and no accepted medical use.
- Botanical drug designation is possible and so a cannabis product *could* be shown to have medical use.
  - The product would need records of cultivation and manufacturing controls, analytical batch quality data and clinical data to support efficacy. Any Approval given to that product would not cover all cannabis.

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NIH / FDA AND CANNABIS RESEARCH

FDA U.S. FOOD & DRUG ADMINISTRATION

NIH National Institutes of Health
Turning Discovery Into Health

August 27, 2019

The Honorable Brian Schatz
United States Senate
Washington, DC 20510-1105

Dear Senator Schatz:

Thank you for your March 20 letter requesting information on research and regulatory issues related to the therapeutic use of cannabis and cannabinoid compounds. The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are committed to advancing research on the risks and potential benefits of cannabis for therapeutic uses, and we are pleased to share the following information about this important area of inquiry with you.

Sincerely yours,

Norman E. Sharpless, M.D.
Acting Commissioner of
Food and Drugs

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health

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LETTER HIGHLIGHTS

- NIDA is the only source of research marijuana, and we do not have the capacity to manufacture an array of cannabis-derived formulations. The diversity of available products is limited.
- ***NIH and FDA support licensing additional entities to supply cannabis & / extracts*** so to make products available to researchers that reflect what is currently consumed,.
- Under federal law, researchers are unable marijuana products from state dispensaries (even with non-federal funds). This limits our understanding of these products and their impact on health.
- **NIH and FDA support enabling researchers** with DEA CI licenses for marijuana **to obtain products from state authorized dispensaries.**
- Dispensary products could be used for basic or clinical research, but clinical materials would need to comply *Chemistry, Manufacturing and Control* requirements for Investigational New Drug applications
- ***NIH and FDA*** recognize the complexity in demonstrating equivalency between plant extracts derived from NIDA cannabis used in clinical trials and a commercial product seeking FDA approval

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AREAS OF NIDA CANNABIS RESEARCH

NEUROSCIENCE:

- **Endocannabinoid System** eg PA-18-917.html **Developing the Therapeutic Potential of the Endocannabinoid System for Pain Treatment**
- **Impact on Brain** Cognition; motivation; mood; fetal and adolescent development NOT-DA-17-065

TREATMENT of Substance Use Disorders. eg PAR-19-327 Grand Opportunity in Medications Development for Substance-Use Disorders

- **Medications and psychosocial behavioral treatments**
  - Withdrawal; Relapse prevention
  - Co-morbid conditions (e.g. psychosis)
- **Cannabis Use Disorder :** PAR-18-221 Fast-Track Development of Medications to Treat Cannabis Use Disorders
- **Use of cannabinoids in Opioid Use Disorder:** Opioid Sparing pain medications (THC, CBD) Reduced anxiety and Craving (CBD). Reduced withdrawal (THC) RFA-DA-19-002 Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose
- **Use of cannabinoids in Nicotine Use Disorder:** Reduced anxiety and Craving.

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AREAS OF NIDA CANNABIS RESEARCH

- **PREVENTION**: ABCD-study Adolescent Brain Cognitive development study Longitudinal study 10k children 9,10 YO- followed into adulthood. Dissemination of evidence based programs results; Effective messaging in current legal environment
- **EPIDEMIOLOGY**: National and Local Surveys, eg Monitoring the Future Drug and alcohol use and attitudes in adolescent students. participants report drug use across past month, year, lifetime. 44,482 students from 392 schools participated in 2018.
- **POLICY:** PA-17-135: **Public Policy Effects on Alcohol-, Marijuana, and Other Substance-Related Behaviors and Outcomes**
  - Surveillance measures that are sensitive, reliable, and report meaningful (i.e., actionable) outcomes
  - Impact of different regulatory models, marketing, taxes, etc.
  - Social, Cultural, Academic, and Health Impacts

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NEW TERRITORY: AGRICULTURAL IMPROVEMENT ACT 2018

- Removed Hemp (Cannabis sativa plants containing less than 0.3% THC) from Controlled Substances Act
- Assigned USDA as regulator of Hemp production and affirmed the regulatory role of the FDA for hemp derived products intended to be Medications (treatments), Dietary Supplements (wellness), Food Additives
- May 28: USDA OGC: "*decontrolling of hemp is self-executing. neither the publication of those updated regulations [to the CSA], nor any other action is necessary*" – **Research using Hemp products therefore no longer requires a DEA license or NIDA supply (although NIDA can still supply CBD if needed**
- ***Universities remain cautious about research with CBD or cannabis (in states where it is legal)*** UNCERTAINTY around DOJ Enforcement and potential loss of Federal funding
- NIDA is actively investigating use of hemp-derived products in clinical investigations

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NIH/NIDA CANNABIS RESEARCH EXPENDITURES

RCDC Categories	NIH FY 16 (in Millions)	NIH FY17 (in Millions)	NIH FY18 (in Millions)	NIH FY19* (in Millions)	NIDA FY17 (in Millions)	NIDA FY18 (in Millions)	NIDA FY19* (in Millions)
Cannabinoid Research	$115	$140	$147	$164	$88	$90	$100
Therapeutic Cannabinoid	$28	$36	$37	$50	$16	$20	$27
Cannabidiol	$12	$15	$19	$20	$11	$14	$15
Endocannabinoid System Research	$51	$63	$63	$65	$30	$28	$29

BARRIERS TO CONDUCTING RESEARCH WITH C I SUBSTANCES

- DEA registration process can take more than a year. C I licenses cover only specific compounds, and additions may trigger further inspections
- Implementing security requirements can be challenging.
  - **Researchers need safes**, locking refrigerators and freezers, surveillance systems, etc. Installation may require facility remodeling and space constraints maybe untenable for *each* licensed investigator to have their own secure storage.
  - **There is variability in the application of rules and regulations (local DEA agents / State requirements):**
    - The need for Schedule I registrations for all agents and employees of a research laboratory
    - When / whether campus-wide registrations are possible
    - Redundancies result in additional burdens and delays. Protocol amendments need to be submitted to the DEA for review and approval prior to implementation, after having already been submitted to an IRB and FDA

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HOW CAN *SCIENCE* INFORM *POLICY*?

- Recognize that there are *polarized views* and we need to be explicit and clear about what we know, what we think we know, and what we don't know.
- Need to be precise in our terminology: distinguish cannabis (the plant) from cannabinoids (plant derived or synthetic); cannabidiol (CBD) vs. other medicinal preparations
- Research needs to answer real world questions: E.g., does cannabis legalization impact the opioid epidemic? Is there a potency limit that should be imposed? Should certain products be prohibited. How dangerous is prenatal exposure to cannabis?
- Need to better disseminate the knowledge that we have.
- Help ensure that the public health interests are front and center when policies are implemented.

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A GW Pharmaceuticals PLC Company

How & Why to obtain FDA-approval of cannabis-based medicines

Angelique Lee-Rowley VP, Global Chief Compliance & Ethics Officer, R&D Legal Lead

November 19, 2019

Disclosures

- Employee of Greenwich Biosciences, Inc., the US subsidiary of GW Pharmaceuticals PLC, a publicly traded UK-based company (NASDAQ: GWPH)
- I do not intend to give any material nonpublic information
- I am a lawyer, but nothing in this presentation should be construed as legal advice.

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About GW Pharmaceuticals / Greenwich Biosciences

GW's vision is to be the global leader in **cannabinoid science and medicines** – helping seriously ill patients through developing and delivering rigorously tested cannabis-derived medicines with proven safety and efficacy profiles, manufactured to consistently high standards and approved by regulators.

RESEARCH

20 years experience in researching and developing novel Rx cannabinoid medicines

- 14 cannabinoids evaluated in pre-clinical research
- >80 peer-reviewed publications
- Cannabinoids exported to >35 countries for research

DEVELOPMENT

~800 person in-house team with expertise in bringing drugs to regulatory approval in US and ROW

- >50 Phase 2/3 clinical trials
- >55,000 patient-years of human safety data
- Sativex® (nabiximols) approved in >25 countries (ex-US) for MS spasticity
- Complex botanical mixture (approx. 1:1 cannabidiol (CBD) to tetrahydrocannabinol (THC) ratio with other minor cannabinoids and non-cannabinoid plant components)
- Planning clinical trials and NDA submission in

COMMERCIALIZATION

- Epidiolex® (cannabidiol) approved by FDA in June 2018 for two types of intractable, childhood onset epilepsies—Dravet syndrome and Lennox-Gastaut syndrome
- Comprised of cannabidiol (CBD)
- Oral liquid 100 mg/ml

World Leader in Cannabinoid Science

Our Values:

- **PATIENT-DRIVEN** – patients motivate everything we do
- **PASSIONATE** – we are here to change lives
- **INNOVATIVE** – we challenge ourselves to find new and better approaches
- **COLLABORATIVE** – we accomplish more through working together
- **ACCOUNTABLE** – we take responsibility and deliver on our commitments
- **INTEGRITY** – we are fair, honest, and ethical
- **EXCELLENCE** – we strive to work to the highest standards

Health Authority Approved, Plant Derived Cannabis Medicines

- **Epidiolex® (cannabidiol) oral solution – approved by the FDA in June 2018**, DEA scheduled (CV) September 2018.
- Available in the United States, District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.

- Sativex® (nabiximols) is an oromucosal spray of a formulated complex botanical extract of the cannabis sativa plant that contains the principal cannabinoids delta-9-tetrahydrocannibinol (THC) and cannabidiol (CBD) in an aprroximate 1:1 ratio as well as specific minor cannabinoids and other non-cannabinoid components.

- Prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. It is not known if it is safe and effective in children under 2 years of age.
- Known important identified **safety risks / warnings and precautions:** Hepatocellular injury, somnolence and sedation, pneumonia, rash, and hypersensitivity reactions.

- Received positive CHMP opinion in July and **Approved by European Commission in September 2019** for adjunctive use in conjunction with clobazam.

- **Approved > 25 countries outside the US**; currently an investigational product in the US.
- Prescription medicine that is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.
- **Special warnings and precautions for use**: Mild or moderate dizziness, alterations in pulse rate and blood pressure, psychiatric symptoms (anxiety, illusions, changes in mood, and paranoid ideas), disorientation /confusion, hallucinations and delusional beliefs or transient psychotic reactions.

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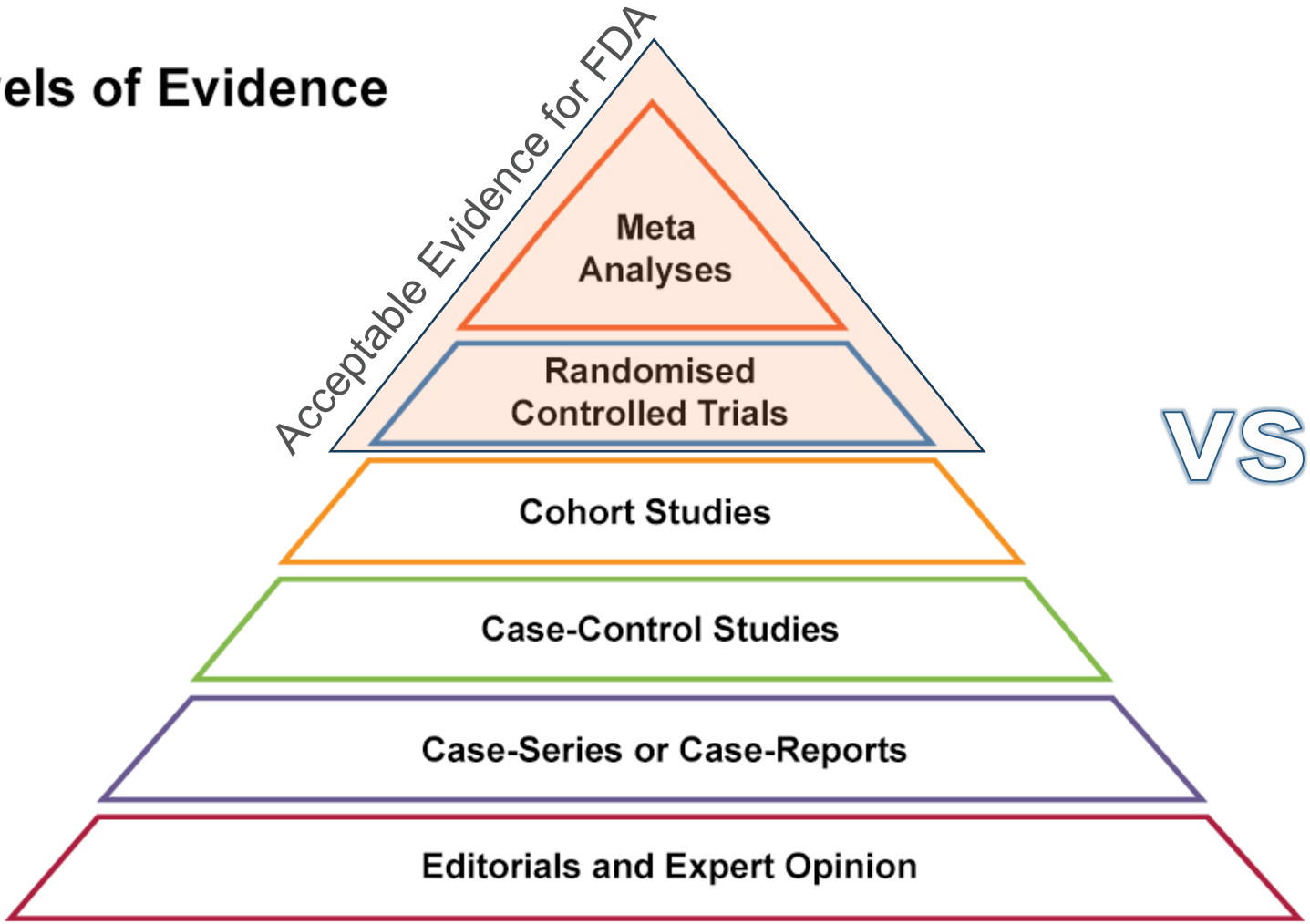
Medicines Require Proof



VS

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FDA-Approved Plant-Based Cannabis Medicines

- ✓ WHAT?
- ✓ HOW?
- ✓ WHY?
- ✓ How to ensure their future?

Cameron
Living with Lennox-Gastaut syndrome,
Being treated with Epidiolex®

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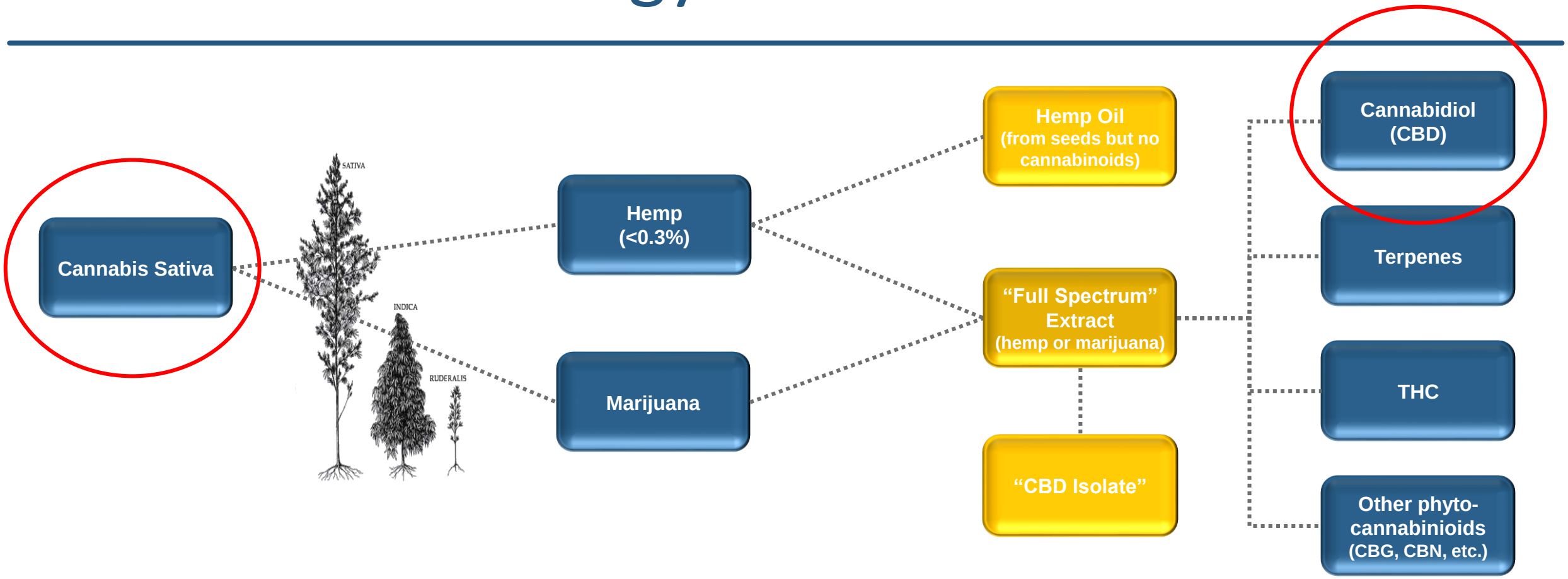
What? Terminology



Scientific Terms | Legal Terms | Marketing Terms | Scientific Terms

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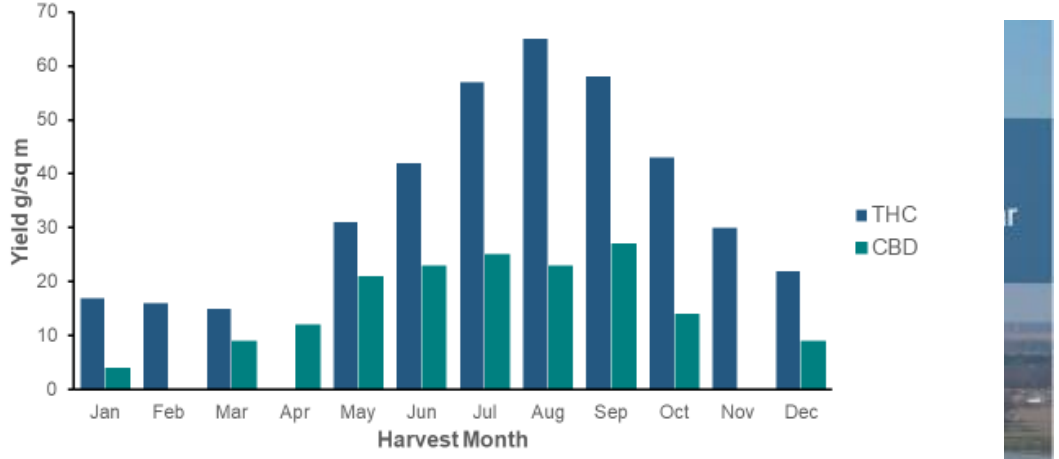
What: The Epidiolex® (cannabidiol) Process

Variability in Production[1]

Variations in growing conditions can significantly impact plant consistency and composition, i.e. production season, soil, plant genetics, seed vs. cutting, etc.



1. The Propagation, Characterisation and Optimisation of Cannabis Sativa L as a Phytopharmaceutical, PhD Thesis Dr. David Potter 2009

DRUG SUBSTANCE

CBD Botanical Raw Material

Milling

Decarboxylation

Extraction

CBD Botanical Drug Extract (Crude Form)

Multi-step Crystallisation

Pure CBD

Filtration & Drying

Extraction

HOW: The Epidiolex® Story.
Schedule I Research & Development, It Can be Done!

Pre-2012

Pre-clinical research

2012

- **Dec** – First child treated with CBD-OS in UK

Engaged DEA & FDA consultants

2013

- **Feb** – EAP "industrialized" / facilitation of DEA requirements
- **Nov** – US Orphan Designation for Dravet Syndrome (DS)

DEA import permits obtained

2014

- **Feb** – Pre-IND Meeting
- **Feb** – US Orphan Designation for Lennox-Gastaut Syndrome (LGS)
- **Mar** –**GW IND 120055 activated & development program begins**
- **Jun** – Fast-Track granted
- **Jun** –FDA Meeting Clinical
- **Oct** – EU Orphan Designation for DS
- **Dec** – FDA Meeting Clinical

2015

- **4 Phase 3 studies in DS and LGS started and enrolled**
- **Jun** – EMA Protocol Assistance
- **Aug** – FDA CMC Meeting
- **Oct** – FDA Guidance Meeting, various

Each site & investigator must secure special Schedule I research licenses (registrations) from DEA and **additionally** from the state controlled drugs authority.

Special security provisions for handling, storage (safe), recordkeeping, disposal, etc.

2016

Results from three of the four clinical trials available

Jul – Pre-NDA Meeting

Nov – Pre-NDA CMC Meeting

2017

- **March** – EU Orphan designation for LGS
- **Apr** – Rare pediatric disease designations received
- **Jun** – Rolling submission started
- **Jul** – Meeting with Rapporteur
- **Oct** – Rolling submission complete
- **Dec** – FDA files NDA and PDUFA clock starts
- **Dec** – MAA submitted to EMA

2018

- **Jan to Mar** – FDA PAI for GCP and GMP
- **Feb** – Mid-cycle meeting with FDA
- **Mar** – Late-cycle meeting with FDA
- **Apr** – FDA Advisory Committee Meeting
- **Jun** – NDA approval
- **Sep** – DEA rescheduling

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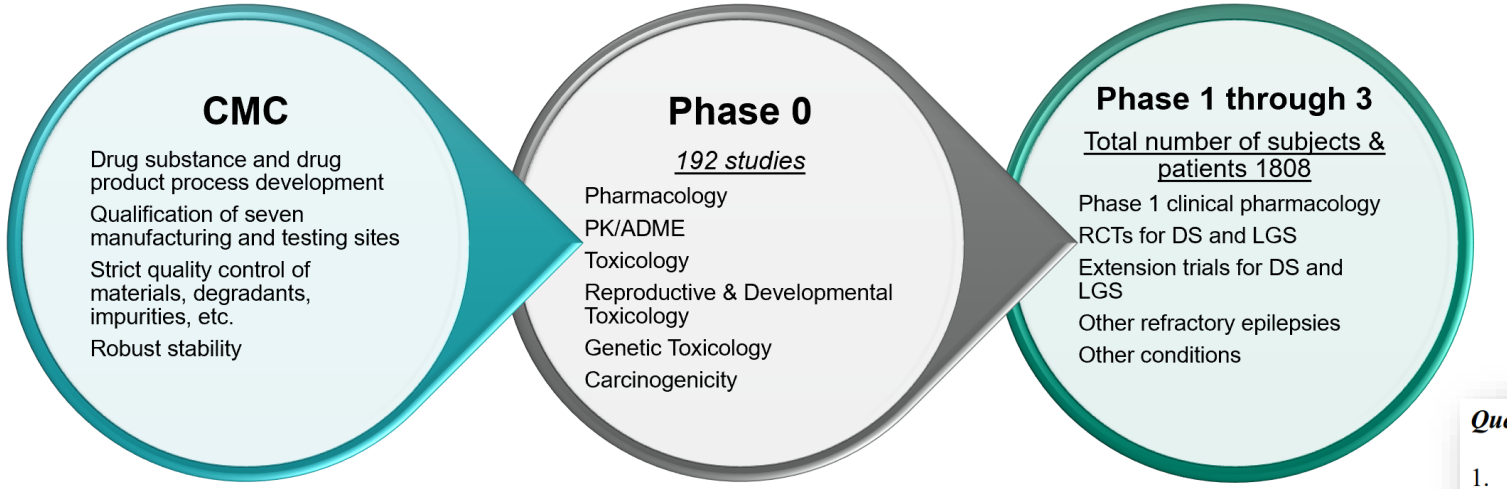
The Epidiolex® NDA Submission, PAIs & Ad Com



Amount of data submitted with initial NDA

- Number of PDF documents + all of the SAS and Program files was **2,309**
- Total number of PDF pages across all sequences was **704,301**
- Full submission size was **35 GB** of information, equivalent to 35,000 pictures being uploaded to your computer
- If this had been a paper submission, that is equivalent to **~ 2,012** volumes of information

CO-1

Cannabidiol Oral Solution (CBD-OS) for Treatment of Seizures Associated with Lennox–Gastaut Syndrome (LGS) and Dravet Syndrome (DS)

April 19, 2018
GW Pharmaceuticals (GW)
Peripheral and Central Nervous System Drugs
Advisory Committee

Question to the Committee:

1. **VOTE:** Is the benefit-risk profile of cannabidiol favorable for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients 2 years of age and older?

Vote Result: Yes: 13 No: 0 Abstain: 0

***Committee Discussion**: The committee unanimously agreed that the benefit-risk profile of cannabidiol was favorable for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients 2 years of age and older. The committee members agreed that efficacy was well demonstrated in the studies and that the safety concerns could be managed with labeling, education and monitoring. Please see the transcript for details of the committee discussion.*

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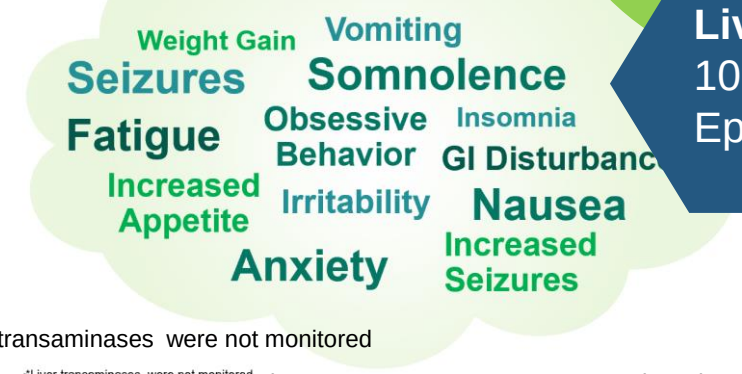
Balance of Benefit and Risk

Why go the FDA approval route?

- CBD can alter the effect of other medications
- CBD could decrease or increase the potency of the other drugs the patient is taking

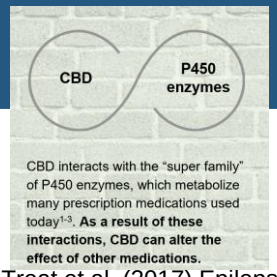
RISK?

Self-reported side effects of CBD products and oral cannabis extracts* (>10% of patents)[1-3]



Controlled studies with regular monitoring

Liver toxicity was found in 10% of participating patients in Epidiolex trials



OR

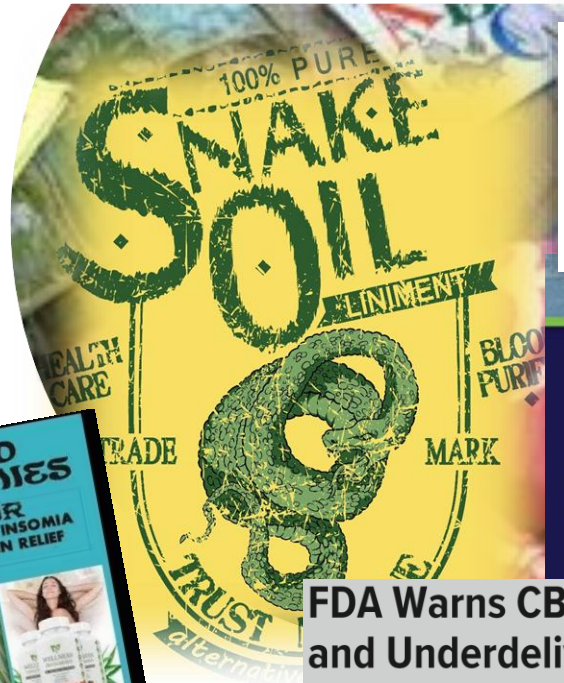
Therapeutic Benefit?

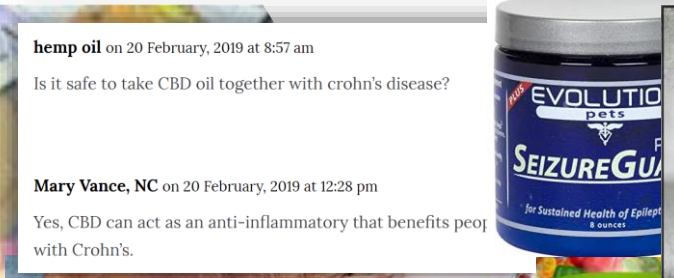
Intended Use??

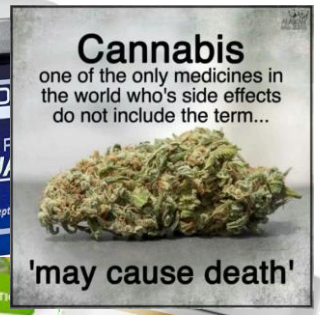
*Liver transaminases were not monitored

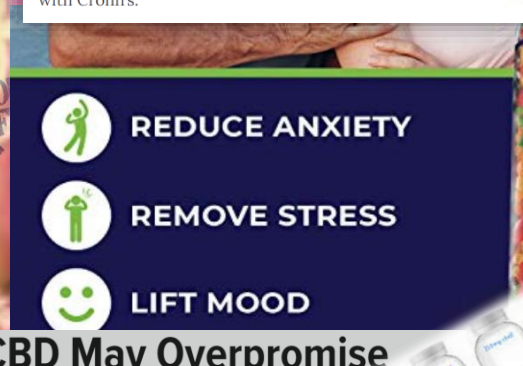
1. Hussain et al. (2015) Ep & Beh. 47: 138-141; 2. Press & Knupp. (2015) Epi & Beh. 45:49-52; 3. Treat et al. (2017) Epilepsia; 58(1): 123-127.

Why go the FDA approval route?









Carl's Jr is selling a CBD-infused burger on 420

FDA Warns CBD May Overpromise and Underdeliver

One manufacturer has been warned, but experts say growing problem.

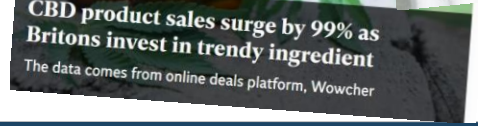
Tapee Paws Hemp Oil for Dogs and Cats 250 mg - Pain Relief, Calming, Fights Cancer, Remedies - Arthritis, Stress, Seizures, Muscle Spasms, Epilepsy, Separation Anxiety, Itching & Skin Allergies

by Tapee Organics

52 customer reviews | 19 answered questions

Price: $25.97 & FREE Shipping. Details & FREE Returns

Hemp has historically been used for many things, including sewing, making rope and even clothes, and now it's the star botanical in a gin!



AMERICAS

Meet the nuns who make £850k a year growing and selling marijuana

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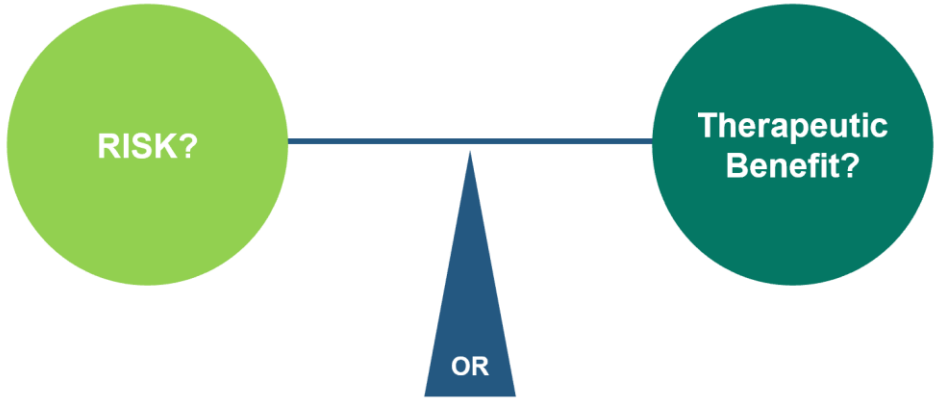
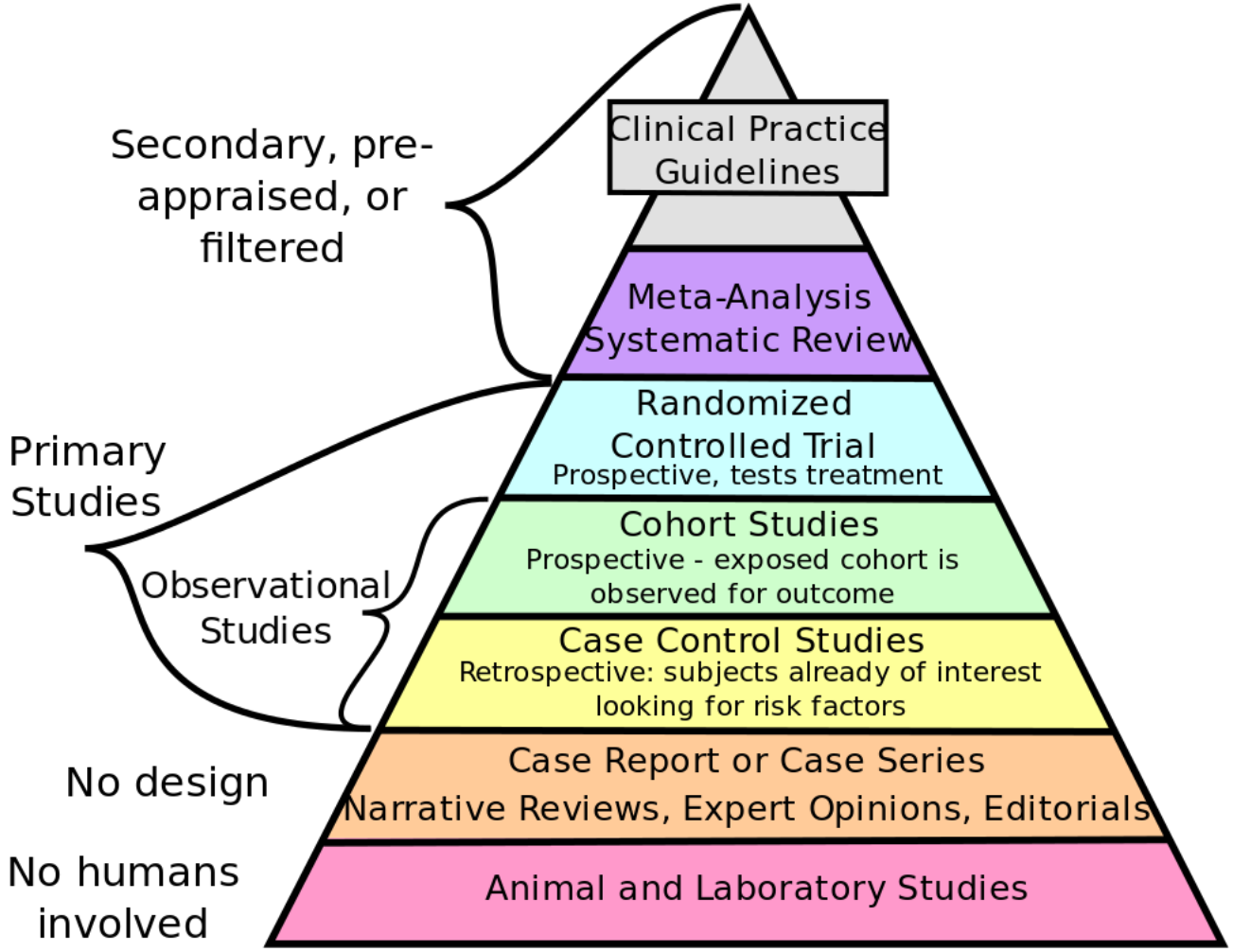
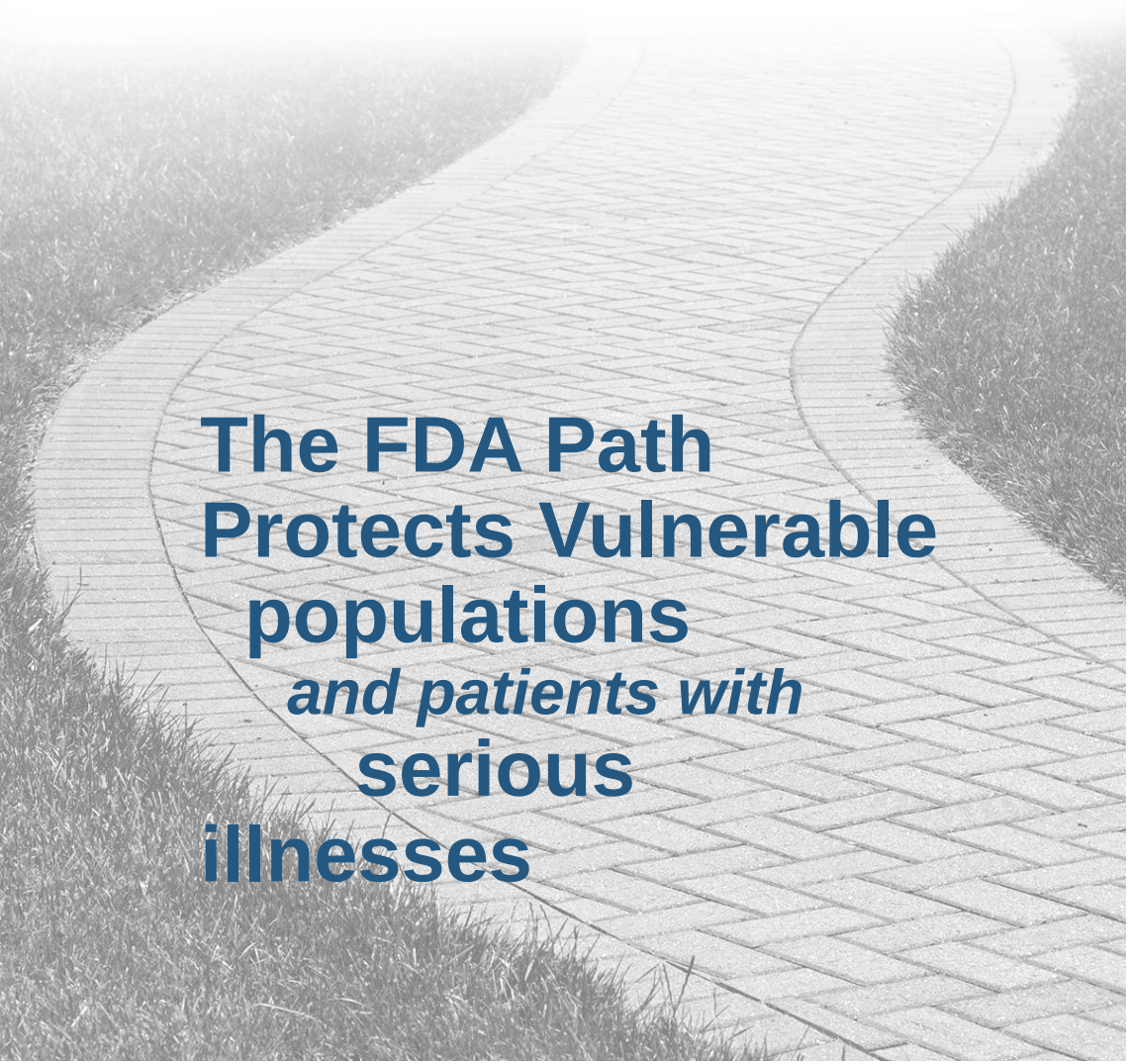
Levels of Evidence





While Developing Products for FDA Approval is Difficult, It is the Structure in Place to Ensure Medications are Safe and Effective



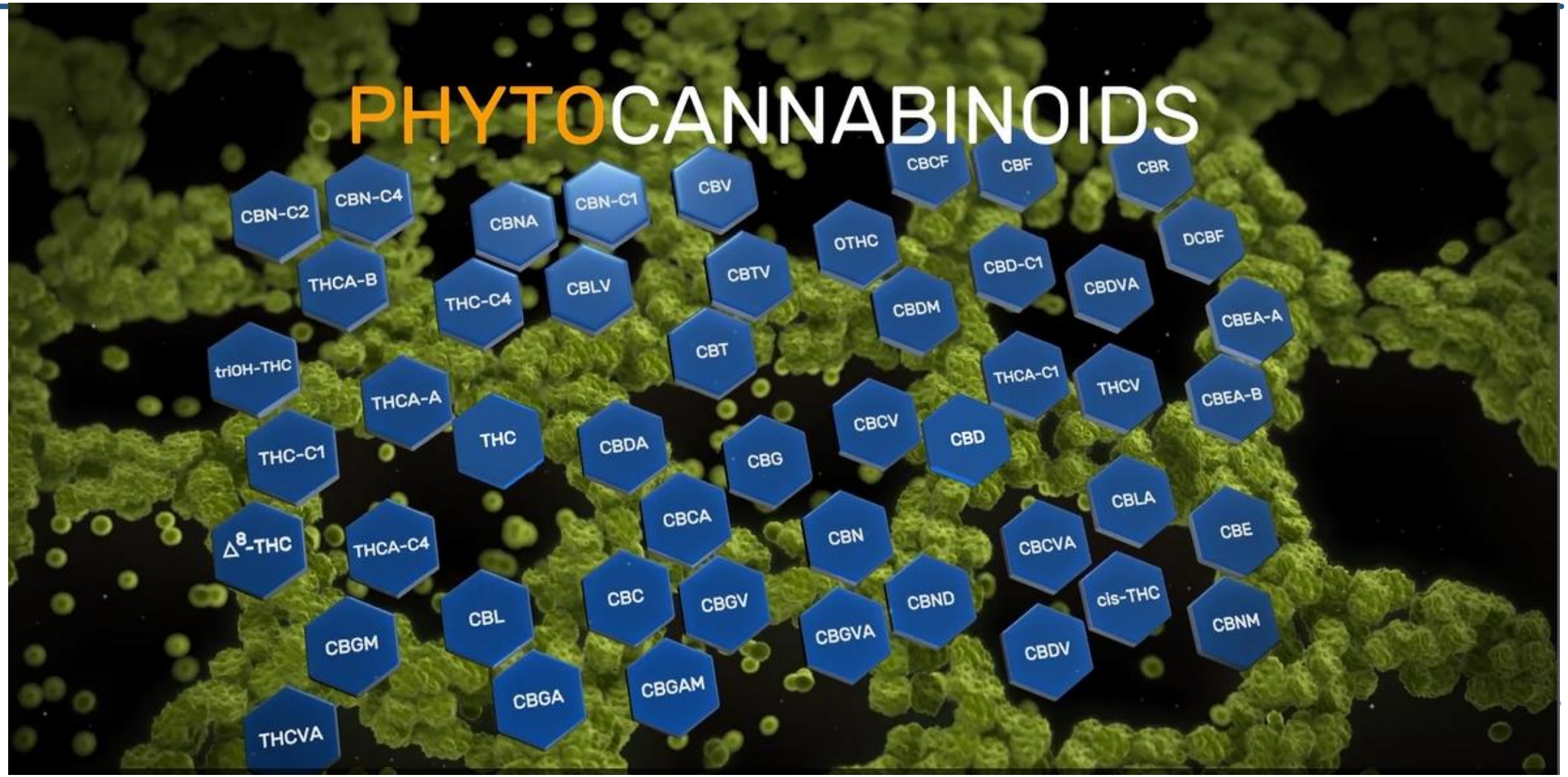
Does the drug work?

- What disease does it work for?
- How well does it compare?
- How long does it take to work?
- Will the efficacy continues?
- How much should I take?
- How long should I take it for?
- Should I take it with food?

Is the drug safe?

- What are the side effects?
- Is monitoring needed?
- Can I take it if I'm pregnant ?
- Can a child and elderly take it?
- Does it contain contaminants?
- Will it conflict with other drugs?
- How is it manufactured?
- Is every batch the same?

Over 100 identified cannabinoids in Cannabis *sativa L*



Work toward innovative cannabis medicines has just begun

CANNABINOID POTENTIAL

Autism | Rett | MS | TSC | NHIE | Glioblastoma | Schizophrenia | Neuropathic pain

GW studying cannabinoids for serious illnesses in neurology with unmet need

Research needed in cancer, glaucoma, HIV/AIDS, neurodegenerative disease, many others

Lack of federal regulatory standards coupled with aggressive commercialization in some states may be compounding public health risks

Unapproved Drugs Place Patients in Jeopardy: One Example

To the Editor,
Cannabidiol (CBD) is approved by the Food and Drug Administration under the name Epidiolex (GW Pharmaceuticals) for the treatment of refractory seizures in Dravet and Lennox–Gastaut syndromes [1]. **Non-pharmaceu… being used… control sei… have eithe…**

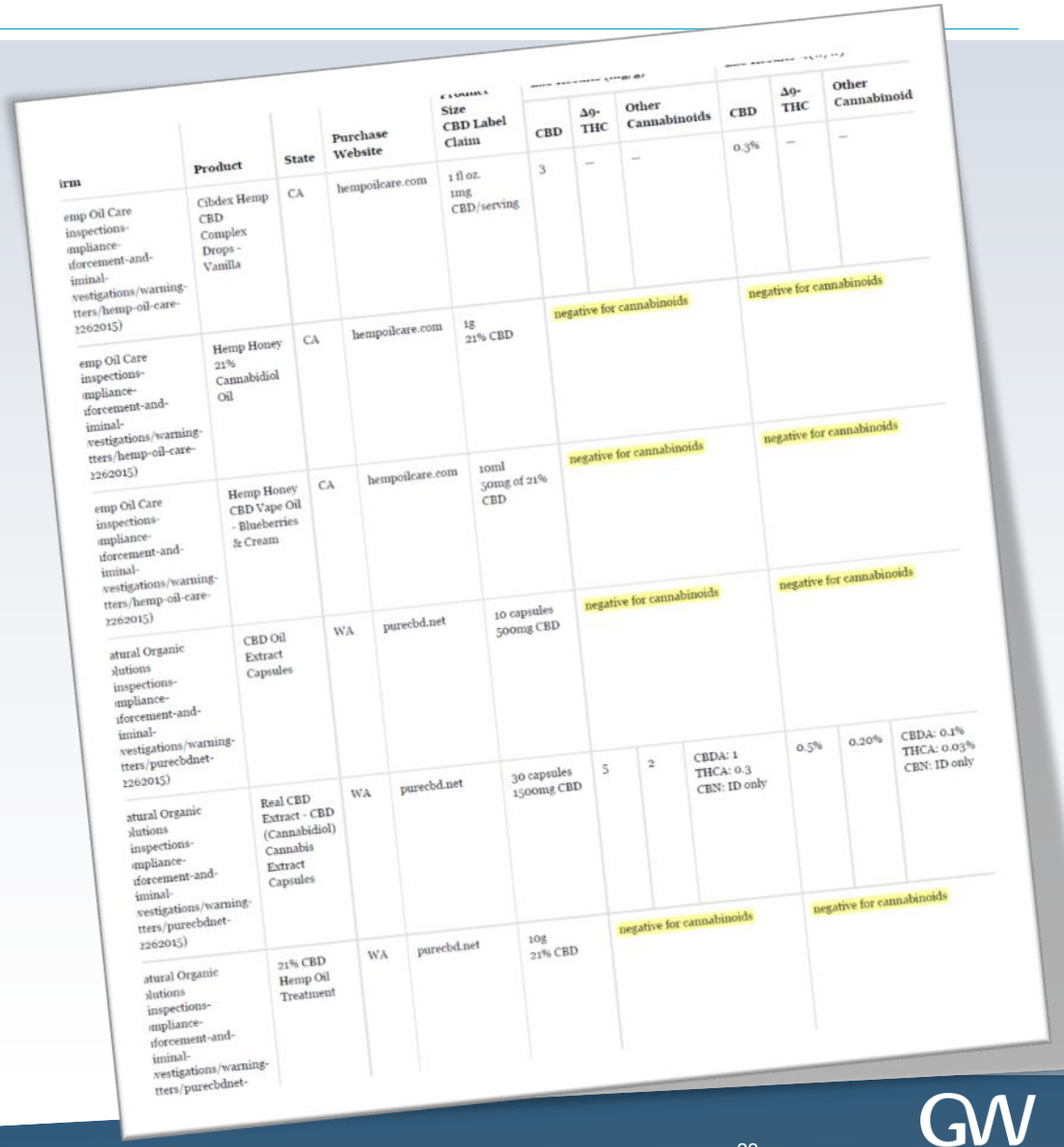
After a 9-day period of seizure-free activity on the CBD oil, the patient was brought to the emergency department for evaluation of **a 24-hour period in which he had >14 tonic-clonic episodes**. He was noted to have intermittent agitation, delirium, de… my…

Analysis confirmed presence of

AB-FUBINACA

a dangerous synthetic cannabinoid associated with multiple illness outbreaks and deaths

The boy survived after treatment in the ICU



irm	Product	State	Purchase Website	Size CBD Label Claim	CBD	Δ9-THC	Other Cannabinoids	CBD	Δ9-THC	Other Cannabinoid
emp Oil Care inspections- mpliance- iforcement-and- iminal- vestigations/warning- tters/hemp-oil-care- 2262015)	Cibdex Hemp CBD Complex Drops - Vanilla	CA	hempoilcare.com	1 fl oz. 1mg CBD/serving	3	—	—	0.3%	—	—
emp Oil Care inspections- mpliance- iforcement-and- iminal- vestigations/warning- tters/hemp-oil-care- 2262015)	Hemp Honey 21% Cannabidiol Oil	CA	hempoilcare.com	1g 21% CBD	negative for cannabinoids			negative for cannabinoids		
emp Oil Care inspections- mpliance- iforcement-and- iminal- vestigations/warning- tters/hemp-oil-care- 2262015)	Hemp Honey CBD Vape Oil - Blueberries & Cream	CA	hempoilcare.com	10ml 50mg of 21% CBD	negative for cannabinoids			negative for cannabinoids		
atural Organic olutions inspections- mpliance- iforcement-and- iminal- vestigations/warning- tters/purecbdnet- 2262015)	CBD Oil Extract Capsules	WA	purecbd.net	10 capsules 500mg CBD	negative for cannabinoids			negative for cannabinoids		
atural Organic olutions inspections- mpliance- iforcement-and- iminal- vestigations/warning- tters/purecbdnet- 2262015)	Real CBD Extract - CBD (Cannabidiol) Cannabis Extract Capsules	WA	purecbd.net	30 capsules 1500mg CBD	5	2	CBDA: 1 THCA: 0.3 CBN: ID only	0.5%	0.20%	CBDA: 0.1% THCA: 0.03% CBN: ID only
atural Organic olutions inspections- mpliance- iforcement-and- iminal- vestigations/warning- tters/purecbdnet-	21% CBD Hemp Oil Treatment	WA	purecbd.net	10g 21% CBD	negative for cannabinoids			negative for cannabinoids		

Accelerating development of FDA-approved cannabis medicines

The Problem

- Potential to treat many serious illnesses with unmet need
- Only one FDA-approved drug
- Widespread use of unapproved cannabis negating perception of need for FDA-approved options
- GW one of few companies investing in FDA-caliber research
- Patients with serious illnesses self-medicate with unproven and ill-regulated marijuana

Consumer protection concerns

- Mislabeling: THC & CBD
- Stability
- Dosing
- Variability
- Adverse Event Reporting
- Contamination

The Solution

- ✓ **Encourage rigorous research** and **accelerate development** of proven medicines from the plant
- ✓ More FDA-approved therapies might be the only viable approach for mitigating public health risks associated with unapproved drugs
- ✓ A framework that accelerates development of more FDA-approved therapies will, over time, displace unapproved products with FDA-approved options

GW pharmaceuticals

GW supports consideration of a comprehensive federal framework: Proven medicines for patients in need & safe consumer goods

Cannabis - Derived

MEDICINES for PATIENTS
FDA-approved | Rx drugs

- Research into medicinal potential just getting started
- FDA's decision could make or break the future of cannabis Rx medicine
- Strengthen incentives
- Clear and wide differentiation between consumer products and medicines

CONSUMER PRODUCTS
Supplements | Conventional foods

- Safety concerns with CBD
- FDA should identify safe concentration and daily intake levels
- Safety margin to account for:
  (1) Known and unknown safety issues
  (2) Vulnerable populations
  (3) High consumer demand and the likelihood of cumulative exposure

Comprehensive regulatory framework must:

1. **Encourage** development of FDA-approved **cannabis-derived medicines** for serious and life-threatening diseases
2. Ensure that consumer CBD products are **safe** for use in a mass-market setting without physician oversight
3. Establish **clear differentiation** between FDA-approved medicines and consumer-focused foods and supplements

Thank you!

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What is the Current Status of Cannabis Research?

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