

Cannabis Theraputics USC Keck School of Medicine

——March 9th 2005——

CANNABIS THERAPEUTICS PERSPECTIVES ON THE CLINICAL APPLICATION OF CANNABIS SATIVA AND CANNABIS INDICA

March 9, 2005

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CANNABIS THERAPEUTICS

PERSPECTIVES ON THE CLINICAL APPLICATION OF CANNABIS SATIVA AND CANNABIS INDICA

USC Keck School of Medicine March 9, 2005

12:00	Lunch
1:00	Introduction and Opening Comments Rich Partida, MS II Claudia Jensen, M.D.
1:15	Practicing Good Medicine Joan Jerzak
2:00	The Pharmacology of Cannabinoids Joseph Miller, Ph.D.
2:30	Cannabis Drug Safety Mitch Earleywine, Ph.D.
3:00	Break
3:15	Clinical Uses of Cannabis: Lessons from a CA Practice Philip a. Denney, M.D.
3:45	Marijuana as Medicine: The Law and Patient's Rights William R. McPike, J.D.
4:15	Conclusions and Pediatric Case Presentation Claudia Jensen, M.D.
5:00	Panel Discussion and Questions
6:00	Adjournment

CANNABIS THERAPEUTICS SYMPOSIUM SPEAKERS

JOAN JERZAK

Chief Enforcement Officer Medical Board of California

JOSEPH MILLER, PH.D.

Associate Professor of Cell and Neurobiology USC Keck School of Medicine

MITCH EARLEYWINE, PH.D.

Associate Professor of Clinical Psychology University of Southern California

PHILIP A. DENNEY, M.D.

Private Practice Family Medicine; Cannabis Consultant

WILLIAM MCPIKE, J.D.

Private Practice Medical Marijuana Defense

CLAUDIA JENSEN, M.D.

Private Practice
Pediatrics; Cannabis Consultant

FINANCIAL DISCLOSURE

Dr. Earleywine receives funding for research from the National Institute on Alcohol Abuse and Alcoholism, the Alcoholic Beverage Medical Research Foundation, and the Marijuana Policy Project.

Dr. Denney receives no compensation from any outside source. He owns stock in G.W. Pharmaceuticals, maker of SATIVEX.

MS. JOAN JERZAK is the Chief Enforcement Officer of the Medical Board of California, the State agency that licenses medical doctors, investigates complaints, disciplines those who violate the law, conducts physician evaluations, and facilitates rehabilitation where appropriate. She testified in Washington, D.C., at the House of Representatives Subcommittee on Criminal Justice, Drug Policy and Human Resources in April, 2004; about the Medical Board's approach to physicians who recommend cannabis as a medication.

DR. JOSEPH D. MILLER is Associate Professor of Cell and Neurobiology at the University of Southern California Keck School of Medicine. He is the Director of Pharmacology for the Keck School of Medicine at USC. For the last several years he has been part of a NIDA-supported consortium of scientists and educators who have endeavored to present the neurobiology of drugs and addiction in layman terms to a wide variety of audiences, including nurses, social workers, chemical dependency counselors, physicians and members of the criminal justice community. Dr. Miller's research interests revolve around the neuropharmacology of sleep and circadian rhythms. He is also involved in the new USC stem cell initiative.

DR. MITCH EARLEYWINE is Associate Professor of Clinical Psychology at the University of Southern California, where he teaches drugs and human behavior, substance abuse treatment and clinical research methods. He has received ten teaching commendations. He serves on the editorial boards of four psychology journals, reviews for over a dozen, and has more than seventy publications on drug use and abuse, including Understanding Marijuana (Oxford University Press, 2002). He is also Resident Faculty in Parkside International Residential College. He serves on the advisory board for the National Organization for the Reform of Marijuana Laws, and is a member of the Research Society on Alcoholism, the Association for the Advancement of Behavior Therapy, and the Drug Policy Alliance.

DR. PHILIP A. DENNEY is a Family Medicine Physician with a special interest in Cannabis Consultation. He earned his medical degree at the University of Southern California School of Medicine in 1976, having completed a tour of duty with the U.S. Navy (1966-1972). After medical school, he completed his medical training at USC in a rotating internship. Dr. Denney has an extensive career, including practices in General and Family Medicine, Urgent Care, Occupational Medicine and Cannabis Consultancy. He served as the Medical Director in many of his positions. He has testified as an expert in Medical Cannabis in seventeen counties in California.

DR. WILLIAM R. MCPIKE is an attorney practicing in California since 1980. He has handled thousands of court cases involving matters such as: international banking, real estate, contracts, landlord-tenant disputes, insurance and injury claims, family law, labor law, workman's compensation, collections, bankruptcy and medical marijuana defense. He specializes in defense of patients who have the legal right to use cannabis in the State of California and has been involved in several significant and strategic cases. In 2003, Dr. McPike obtained the State Bar of California approval for a continuing education program devoted to Marijuana Medicine Defense. He writes a legal column for the Fresno Bee and conducts a radio talk show on the law. He lectures on cannabis and the law.

DR. CLAUDIA JENSEN is a physician in private practice in Ventura and San Clemente. She completed her Residency in Pediatrics at the University of California at Irvine School of Medicine in 1984; then practiced as a staff physician until 1996 when she opened her private practice in Ventura. In 1997, she joined as a teacher in the ICM Program at USC. Dr. Jensen has an interest in human cognitive development, particularly in children and adults with Attention Related Disorders. In April, 2004, she testified in Congress in Washington, D.C. on the use of cannabinoids in children with ADD/ ADHD. Her written testimony is enclosed in this syllabus.



May 13, 2004

Medical Board Reaffirms its Commitment to Physicians Who Recommend Medical Marijuana

Board adopts statement clarifying implementation of California's Compassionate Use Act to insure California's physicians and consumers receive appropriate guidance under the law

SACRAMENTO — The Medical Board of California marked a milestone for California consumers and physicians by adopting a statement clarifying that the recommendation of medical marijuana by physicians in their medical practice will not have any effect against their physician's license if they follow good medical practice.

"The intent of the statement is to clearly and succinctly reassure physicians that if they use the same proper care in recommending medical marijuana to their patients as they would any other medication or treatment, their activity will be viewed by the Medical Board just as any other appropriate medical intervention," said Hazem Chehabi, M.D., immediate past president of the board. "This is consistent with the board's mission to protect and advance the interests of California patients."

In November 1996, the voters of California passed Proposition 215, the "Compassionate Use Act of 1996." The purposes of the act were "to ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where the medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana....and to ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction."

In January 1997 the Medical Board published standards for physicians when recommending medical marijuana. According to the board's new statement, consultation should include:

- History and good faith examination of the patient
- Development of a treatment plan with objectives
- Provision of informed consent including discussion of side effects
- Periodic review of the treatment's efficacy
- Consultation, as necessary
- Proper record keeping that supports the decision to recommend the use of medical marijuana

"The clarification of the guidelines regarding the recommendation for the use of medical marijuana assists both physicians and patients," said Dr. Chehabi. "Establishing clearly defined guidelines will allow the medical community to concentrate on the important medical needs of the patient and end the confusion about when recommendation of medical marijuana is appropriate."

According to testimony received by the board at its hearing on this issue last week, the author of the Act, Dennis Peron, supported the board's efforts to implement the law and assist California's physicians and their patients who receive a recommendation for the use of medical marijuana. "The Medical Board is in a unique position to guide physicians and patients on the proper standards for medical intervention for those who can benefit from treatment

using medical marijuana," stated Mr. Peron. "I applaud the board's efforts and hope their action puts an end to the controversy that has surrounded this issue since California citizens voted to support the Compassionate Use Act."

For a copy of the Medical Board's statement, please contact the board's information officer, Candis Cohen, at (916) 263-2394.

The mission of the Medical Board is to protect healthcare consumers through the proper licensing and regulation of physicians and surgeons and certain allied healthcare professions and through the vigorous, objective enforcement of the Medical Practice Act.

If you have a question or complaint about the healthcare you are receiving, the Board encourages you to visit its Web site at www.caldocinfo.ca.gov or for questions call the Consumer Information Line at (916) 263-2382, or with complaints call (800) 633-2322.

###

1 🔲	The Pharmacology of Marijuana Dr. Joseph Miller BMT408
2 🔲	phone 442-1629 e-meil jdm @ usc.edu
	Marijuana
	 Marijuana is not only one of the oldest (5000 yr) but also one of the most widely used of mind-altering drugs.
	 30-40 million persons in the USA have used this drug and substantial numbers are regular users.
	 The flowers and small leaves of Cannabis sativa supply most of the drug. Marijuana is a mixture of ground-up plant materials. Extraction of the resin from the plant provides a more potent product: hashish.
3 🔲	
	 Three major cannabinoids have been found in cannabis; cannabidiol (CBD), Δ9- tetrahydrocannabinoi (THC), and cannabinol (CBN).
	 The biosynthetic pathway begins with CBD, proceeds to THC, and ends with CBN.
	 Thus, one can deduce from the proportions of these cannabinoids in plant material the age of the plant. Only THC has psychoactivity.
4 🗆	
5 🔲	Pharmacokinetics
	 The preferred route of administration in western countries is by smoking. Peak effects occur about 20 minutes after smoking and continue for up to 3 hr. Bioevailability is about 45% by this route compared to 15% for oral ingestion.
	 The high lipid solubility of THC causes it to be readily trapped on the surfactant lining of the lungs.
	One metabolite, 11-hydroxy-THC, is actually more active than the parent compound.
6	Mechanism • A high degree of enantiomer selectivity suggests a

Cannabinoid receptors, CB1 and CB2 have indeed been identified and sequenced.

 CB1 is present in the CNS in such areas as the hippocampus, ventral tegmentum, nucleus accumbens, hypothalamus, dorsal motor nucleus of the vagus and dorsal horn.

highly selective receptor.

7 🔲	 At least two endogenous ligands, <u>anandamide</u>, and <u>2-arachidonovlgtycerol</u> (2-AG) have been described.
	 The cannabinoid receptors are G-protein coupled and serve to inhibit cAMP, in turn closing calcium channels and opening potassium channels, leading to neuronal inhibition.
	 One physiological action is to facilitate release of dopamine in the nucleus accumbens, but to a much smaller degree than amphetamine.
	 In contrast, presynaptic CB1 may act to inhibit transmitter release in many systems.
8 🗆	Endogenous cannabinoids
10	Anti-emetic use
	 CB1 receptors are in the area postrema, dorsal nucleus of the vagus, solitary nucleus (all components of the emesis circuit) and in the myenteric plexus of the stomach and duodenum. Cannabinoids (dronabinoi, nabilione) acting through this circuit prevent nausea and vomiting associated with anti-cancer drugs. Such agents are at least as effective as the traditional anti-emetics (phenothiazines, metoclopramide, domperidone).
	The difficulty with oral administration is low bioavailability and long latency to action (one hr or more).
	 Oral or nasal administration is now possible (Sativex, THC and CBD in an ethanol-based spray). Since the emetic centers lie largely beyond the blood-brain barrier, it may prove possible to target them selectively, eliminating the various cognitive side effects of cannabinoid treatment.
11 🔲	CB1 in the chemoreceptive trigger zone
12	Appetite stimulation
لسب	 Probably the most potent action of cannabinoids is on appetite (dronabinoi is effective at 50 microgram/kg; anandamide is about 10X more potent). At low therapeutic doses, psychotropic side effects are minimal. Smoked marijuana is better tolerated then oral administration, suggesting that probuodal administration (Sativex spray) may be a preferable route.
	 Cannabinoid treatment is very useful against the anorexia seen with opioids, some antiviral and chemotherapeutic drugs, AIDS and terminal cancer.
	 All of these effects appear to be mediated by CB1 in the hypothalamus, possibly by amplifying the orosensory stimuli associated with food through co-activation of limbic neurons with CB, endogenous opiate and dopamine receptors.
	 CB1 antagonists (e.g., Rimonabant) are currently in Phase III trials for human obesity and results so far are positive (4 kg average weight loss in a 16 wk double blind trial).
13 🔲	CB1 in hypothalamus
14	Glaucoma
	 The leading cause of irreversible blindness is glaucoma. All current treatments for glaucoma decrease intraocular pressure (IOP).
	 Cannabinoids reduce IOP through a poorly understood mechanism presumably dependent on CB1 receptor in the cornea, ciliary body, blood vessels and trabecular meshwork.

CB2 is present on various cells of the immune system (e.g., macrophages).

- Opthalmic administration of cannabinoids is the route of choice and new formulations based on water-soluble cannabinoids or cyclodextrin vehicles should prove effective, with few side effects.
- Cannabinoids may also have a neuroprotective effect by reducing the glutamate and NO that occurs in the glaucoma- ischemic eye.

15 Analgesia

- CB1 receptors are abundant in VPL of thalamus, periaqueductal grey and dorsal horn. Administration of cannabinoids in these areas prevents processing of pain information at spinal and suprespinal levels.
- Since CB1 is present on large and small myelinated fibers, cannabinoids would seem capable of inhibiting both acute and neuropathic pain, whereas morphine is more effective against acute pain. In general, there is considerable oploid/cannabinoid synergism in pain relief.

16 CB1 in the dorsal horn

17 Analgesia cont.

- Double and single-blind studies indicate usefullness of THC and other cannabinoids in treating cancer pain and post-operative pain, but not the pain of wisdom tooth extraction, or, surprisingly, in one study of neuropathic pain.
- · When cannabinoids are useful, their efficacy is comparable to codeine.

18 MS/Spasticity

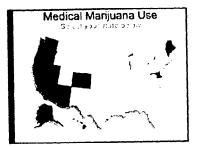
- There is some evidence from animal studies that relatively high does of cannabinoids impair cell-mediated and humoral immune responses.
- . Since MS is an autoimmune disease, cannabinoid-induced down regulation of the immune system may be therapeutic.
- Anti-specialty effects are more difficult to understand since high doses of cannebinoids may actually induce specialty.
- Clinical results have been mixed, with the targest double-blind trial reporting no objective improvement in spesticity, but considerable improvement in mobility and subjective estimates of eleep quality, analgesia and spesticity reduction.
- Many of these subjective effects may reflect the analgesic and sedative properties of cannabinoids.

19 Conclusions

- There is little doubt that cannabinoids are effective in the treatment of glaucoma, appetite and emetic disorders.
- Data supporting the therapeutic use of cannabinoids for pain management and spasticity is weaker, but suggestive.
- New pharmaceuticals, such as local opthalmic preparations for glaucoma, low dose orobuccal sprays for improving appetite and possible peripherally-selective cannabinoids for treating emesis will avoid many of the CNS side effects of inhalation or oral ingestion of

CANNABIS
DRUG SAFETY

MITCH EARLEYWINE, PH.D. UNIVERSITY OF SOUTHERN CALIFORNIA



REMEMBER

COSTS/BENEFITS
IDEOGRAPHIC REACTIONS
MARINOL?
ADJUNCT/COMBO
DRUG SAFETY

LITTLE EVIDENCE HUNTINGTON'S PARKINSON'S POTENTIAL EVIDENCE
ANXIETY (CBT)
ARTHIRITIS
DYSTONIA
INSOMNIA (CBT)
SEIZURE

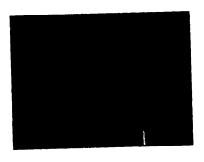
EFFECTIVE
APPETITE LOSS
GLAUCOMA (CANASOL)
NAUSEAU
VOMITING
PAIN
HEADACHE
SPASTICITY
WEIGHT LOSS

WHAT HARM?
Gateway
Brain troubles?
Driving troubles?
Fertility
Dependence
Lung troubles?
Legal troubles!!!!!

GATEWAY

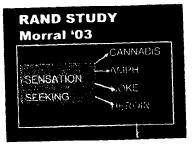
CAFF- ALC.-NIC CANNABIS--HALLUCINOGENS--AMPHETAMINE-COCAINE--CRACK--HEROIN Lynsky JAMA study

311 twins discordant for cannabis
Early involvement – more problems
NOT NEWS



GATEWAY

USED HARD DRUGS 1st 15% (Golub & Johnson '94) 29% (Blaze-Temple & Lo '92) 39% (Mackesy-Amiti '97)



YOU ARE THE CHOOSER

LEGAL SOURCE 3 MINIMIZE EXPOSURE TO HARD FOURS

ger aman & Cohen 2004

Brain structure and function

Original reports flawed Lots of media attention Disproved No media attention NO STRUCTURAL CHANGES
IN ADULTS
Teen data are scaly!

Wilson et al 2004

ERI Feller % GREY MATTER Higher % WHITE MATTER In Facts who started < 17



Brain structure and function?

Daily users for 2 years or more
Deviant evoked potentials
Some recovery with abstinence (Solowij)

Brain structure and function?
RECREATIONAL USERS
SMOKE LESS
Choose a time
Focus on effects
Enjoy yourself
Combat automaticity

Brain structure and function?
MEDICAL USERS
SMOKE LESS
Focus on alleviation of symptoms
Combat automaticity
SELF-MONITOR



Driving?
CANNABIS USERS
SLIGHTLY LESS
LIKELY TO CAUSE
ACCIDENTS (Bates &
Blakely, 1999; Terhune
et al., 1992; Williams et
al. 1985)
NO ONE BELIEVES IT!

Driving?
RECOMMENDATIONS
FOR MARINOL?
OPIATES?
ANTIHISTAMINES?

Driving?

lateral movement
NO CHANGE
Handling
Turning
Maneuvering
(Robbe, 1998)

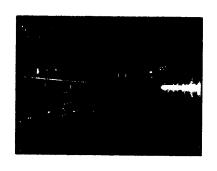
Driving?

HOW?

speed, passing

stopping distance,
space between cars

ADD ALCOHOL AND
DIE!



Driving?

DON'T DRINK AND

DRIVE

DON'T DRIVE HIGH

FERTILITY?

ANIMAL WORK
NAHAS STUDY
BUFFALO STUDY
DATA ON WOMEN?



Dependence?

SYMPTOMS PRESENT CORRELATE WITH: EARLIER ONSET GREATER FREQUENCY

Dependence Risk

Tobacco 31.9%
Heroin 23.1%
Cocaine 16.7%
Alcohol 15.4%
Stimulants11.2%
Marijuana 9.1%

Dependence Risk

ESD 3.26 (1.93)
MDMA 4.21 (1.91)
Cannabis 4.46 (1.78) +++
Caffeine 4.64 (1.74)
Amph 5.71 (1.45)
Alcohol 5.84 (1.46)
Cocaine 5.86 (1.37)

Dependence Risk

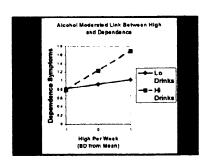
Meth 6.05 (1.44)
Oky 6.25 (1.40)
Crack 6.48 (1.15)
Nicotine 6.54 (1.05)
Heroin 6.62 (1.05)

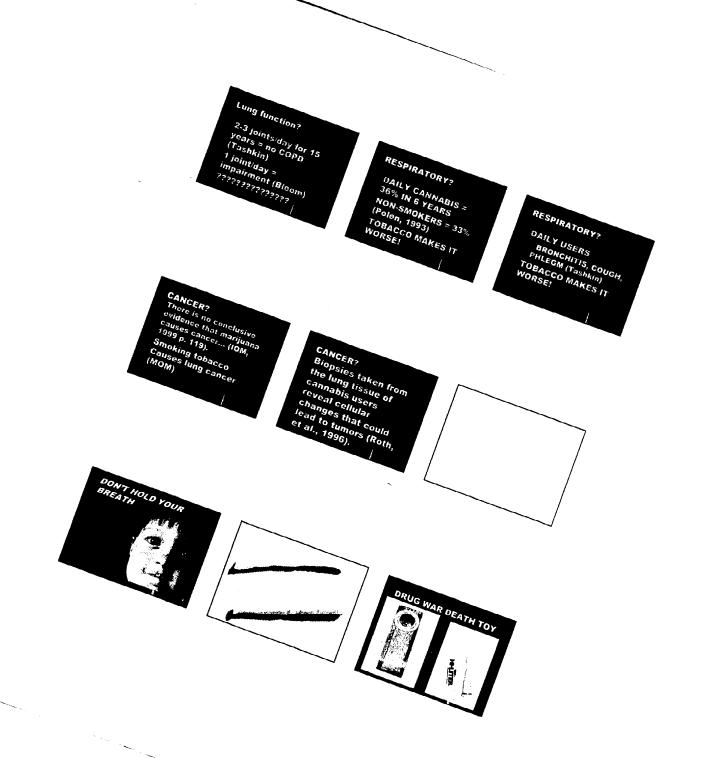
'ADDICTIVENESS' CANNABIS

WOMEN > MEN
TERMINAL DEGREE < NOT '
PUBLICATIONS (14)
HOURS (20)
SUBSTANCE USE HOURS (27)

MOST COMMON SYMPTOMS

TOLERANCE TIME LOSS (obtain, use, recover) MORE OFTEN/GREATER AMOUNTS



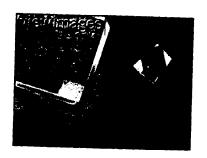


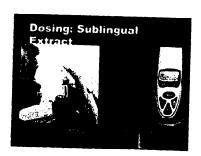
who gets more tars? 4% THC < 2% THC (Matthias et al., 1997) STRONGER CANNABIS

HELPS HARM REDUCTION!









Pulmonary harm reduction

Don't smoke cigarettes

Don't hold hits

Vaporize

Use quality cannabis

Consider oral ingestion





Know the law Buy < 1 oz. Buy in a safe place Having a friend 'pay you back' = dealing Multiple baggies = intention to distribute Work for reform Work for peace

CLINICAL USES OF CANNABIS LESSONS FROM A CALIFORNIA PRACTICE Philip A. Denney, M.D.

A. Introduction

- 1. Cannabis has been used for millennia by most cultures
- 2. Very safe
 - a. No potential for overdose
 - b. No addiction
 - c. Dependence similar to caffeine
- 3. Non-toxic
 - a. No end organ damage
 - b. Risk of smoking
- 4. Primarily adjunctive
- 5. Smoking, oral use, vaporization
- 6. How Does Cannabis Work?
 - a. Endocannabinoids-ancient system found in most species (hydra, starfish, leeches) preserved in evolution ~5 million years
 - b. "Depolarization suppression of inhibition"
- 7. Dosage
- B. Clinical Uses (9700 evaluations)
 - 1. Primary use is for chronic pain ~1/2 of patients
 - a. Very useful for patients on opiates
 - 1. Improves quality of life
 - 2. Allows less narcotics (≤½)
 - b. Especially good for neuropathic pain
 - 1. Neuropathy
 - 2. Radiculopathy
 - 3. Phantom Limb Syndrome
 - 4. Brachial Plexus injuries
 - 2. Conditions with Muscle spasm
 - a. Multiple Sclerosis
 - b. Paraplegia/Quadriplegia
 - c. Periodic Movement Disorder of sleep (Restless Legs Syndrome)
 - d. Works as well as or better than Baclofen
 - 3. Gastrointestinal Disorders
 - a. Nausca/Vomiting/Hepatitis C
 - b. Appetite problems
 - c. Wasting Syndrome
 - d. Inflammatory Bowel Disease
 - e. Eating Disorders
 - 4. Psychiatric Conditions
 - a. Chronic Anxiety
 - b. Depression elevates mood
 - c. Bipolar Affective Disorder

- d. PTSD promotes restful sleep
- e. ADHD
- 5. Glaucoma
 - a. Useful in situation with poorly controlled pressures despite optimum standard TX
- 6. Migraine
 - a. Dramatic success in patients with aura if used early
 - b. ? Prevention/Prophylaxis
- 7. Seizure Disorders
 - a. Decreases seizure threshold
 - b. Seizure meds more effective
 - c. ? Neuro Protective
- 8. Other Conditions
 - a. Tourette's Syndrome
 - b. Premenstrual Dysphoric Disorder
 - c. Hyperemesis Gravidarum
 - d. Harm Reduction substitute
- 9. How it works in California
 - a. Current law: State vs. Federal
 - b. Medical Board Policy
 - c. Politics
 - d. Risks
 - 1. Physician
 - 2. Patient
- C. Summary
 - 1. Cannabis is very useful in a variety of conditions
 - 2. Safe/Non-toxic
 - 3. Use is primarily adjunctive
 - 4. Biggest risk remains political
 - 5. Future uses Sativex

MARIJUANA AS MEDICINE

THE LAW AND PATIENT'S RIGHTS

By William R. McPike - 2005

Marijuana [cannabis] and Hemp are the same plant. This adaptable plant grows in all parts of the world.

The only difference between marijuana and hemp is that hemp has almost NO THC which is the drug found in cannabis. Hemp is industrially farmed for profit. After the WWII invasion of the Philippine Islands, the U.S. War Department and Agricultural Departments paid mid-western farmers to grow Hemp. This hemp is naturally growing today, is known as farrell hemp or wild hemp.

Why would the U.S. Government pay farmers to grow Hemp?

Well at that time, ropes and other products were for the most part made from hemp. Today paper, cloth, cooking oils, facial cremes, shampoos, and other products are made from Hemp. Most of these products are legally imported from Canada and China. This is not any modern day use of cannabis. Ancient China has records of the use of hemp for medical, clothing, paper and other uses. This is historically documented over thousands of years followed by records of similar medical and spiritual uses from India.

Cannabis [both marijuana and hemp] were legal until the U.S. Tax Act of 1937

There are papers showing that both George Washington and Thomas Jefferson cultivated cannabis. However, we must remember that into the early 1800s, bleeding was considered the best cure and was medically accepted. Washington died from a bleeding cure. There is a study, Ohio Medical Society 1860 which positively showed that the medical use of cannabis helped many types of illnesses. Cannabis was sold in stores as medicine, tinctures, oils, teas, etc. Drug manufacturers regulated under the first U.S. Food and Drug Act of 1906 sold derivatives from cannabis into the late 1930s.

U.S. history of Marijuana Prohibition:

In 1937 congress passed the Marijuana Tax Act of 1937, which didn't outlaw cannabis. This Act taxed the activity of importers, cultivators and doctors who prescribed cannabis. The IRS was responsible for issuing applications to these persons and for collecting the marijuana tax. The penalty for not applying for the tax stamp was, during the depression, \$2,000.00 and 5 years in prison. So for less than \$100.00 a person would be TAX-legal for cannabis activities. Thus, it was not the alleged health risk or any other issue that prohibited marijuana, it was strictly a revenue measure. If one paid the tax the activity was legal. So there was no prohibition or any excuse of cannabis having no medical properties. This was a tax/revenue prohibition that provided for medical and other distribution.

Prohibitions by tax are rare and have been overturned [U.S. v. Rock Island Armory] where the court determines that the applications for the tax stamp and paying the tax are intentionally delayed by the U.S. government or the applications are simply no longer accepted by the U.S. government. This becomes an unconstitutional prohibition. In the late 1960s in U.S. v. Leary, Timothy Leary proved that he applied for the marijuana tax and his application was denied, as no applications were *then* being processed. Leary prevailed and the U.S. Marijuana Tax Act of 1937 scheme was exposed in the U.S. v. Leary court decision.

Next the Schaffer Commission advised President Nixon that less than 1 ounce of marijuana should be legalized. Nixon sent the recommendation back to his Commission for a different conclusion. Nixon set up the DEA under the FDA. In 1906 as early version of the FDA was established to standardize the labels and contents of foods and drugs among the states. The problem with controlling marijuana was that it grew wild and did not have to be processed for any standard or label. It was grand fathered in. Generic botanical cannabis cannot be patented. Therefore no drug company can profit from a natural plant and they must develop some synthetic chemical in order to patent and make any profit.

Congress complemented Nixon by passing the Controlled Substances Act [CSA] of 1971. The CSA classified marijuana [remember it was a legal medical remedy under the Act of 1937 until the CSA of 1971] the botanical plant, with processed heroin and processed cocaine. These substances were determined by congress as having no medicinal value within the U.S. So from one day in 1971 [legal cannabis if the tax were paid] until the following day in 1971, our Congress made the decision that marijuana had no medical value.

This one day conclusion made no sense, and it is clear that both the tax and the CSA were excuses for 100% prohibition of this botanical plant. The CSA created a legal fiction that by planting a cannabis seed and watering it, was the "manufacturing" of a drug. While heroin is manufactured from the opium plant and powdered cocaine is manufactured from the natural coco plant, there is no manufacturing or extraction from natural marijuana. [The exception is manufacturing the concentrate hashish which is not distinguished from the generic definition of marijuana under California law. See Attorney General Opinion 03 - 411, on legal hashish concentrate for medical marijuana users.]

MODERN MEDICAL MARIJUANA LAWS - 1996

Next came California's initiative measure "The Compassionate Use Act of 1996" which excepted a class of person [qualified patients and their caregivers] from the application of two criminal Health and Safety statutes. Both B&S 11357 and 11358 do not apply to this class of person. These criminalizing statutes are possession and cultivation of marijuana. Thus, for the qualifying person, there is no illegal activity in the area of medical use and cultivation of marijuana. The only qualification for this class of person is that a licensed physician approve or recommend the medical use of marijuana. Thus, it is the physician who sanctions the use and who grants the medical status, the immunity from criminal laws to this class of person.

In law there is a hierarchy or importance in how law must be viewed by our courts. First level law is the constitution. 2^{nd} level law is initiatives enacted by the People. The lowest level law is a Legislative enactment. The importance of understanding this hierarchy of law is due to the continued problem with the Legislature attempting to clarify or modify both the constitution and the People's initiatives. The State Constitution [Art. 2., sect $10 \, \mathbb{C}$] prohibits the Legislature from amending the first 2 level laws.

Therefore, the People can override legislative inactivity and also modify their constitution and legislative enactments, while the Legislature is helpless to stop the sovereign People from directly making their own laws.

CONTINUING LAW ENFORCEMENT PROBLEM

The problem since 1996, is that law enforcement has failed to implement and enforce the ensured rights granted by the Compassionate Use Act of 1996.

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SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

HEARING ON

"Marijuana and Medicine: The Need For a Science-Based Approach"

Thursday, April 1, 2004

WITNESS LIST

Panel I

Honorable Nora D. Volkow, Director, National Institute on Drug Abuse, National Institutes of Health Dr. Robert J. Meyer, M.D., Director, Office of Drug Evaluation II, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Ms. Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration

Panel II

Dr. James D. Scott, M.D., Board Member, Oregon Board of Medical Examiners
Ms. Joan Jerzak, Chief of Enforcement, Medical Board of California
Dr. Claudia Jensen, M.D., Ventura, California
Mr. Robert Kampia, Executive Director, Marijuana Policy Project
Dr. Phillip E. Leveque, D.O., Ph.D., Portland, Oregon
Dr. Robert DuPont, M.D., Institute for Behavior and Health, Inc., Rockville, Maryland

Testimony of Claudia Jensen, M.D. for the House Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources

Marijuana and Medicine: The Need for a Science Based Approach

April 1, 2004

I am very grateful for the opportunity to submit my written testimony to the Members of the Subcommittee of the Committee on Government Reform. Thank-you. I am also thankful for the opportunity to have five minutes of oral presentation time. I apologize for the summarized nature of this report as I was invited to speak on March 16, 2004 and have had minimal time to prepare. I pray Members of the Subcommittee as well as the Committee on Government Reform will read the enclosed information with the intention of considering actual social reform.

I am a 49 year old mother of two teenage daughters, and a Physician educated at the University of Arkansas for both undergraduate and medical schools. I studied Pediatrics at the University of California at Irvine, completing my Internship and Residency training in 1981. I have a total of 23 years working as a Pediatrician, first as an HMO physician with Cigna HealthPlans, then in private practice in Ventura, CA.¹

I currently work two days a week in a small community clinic servicing a poor patient population, three days a week in my own private office and I teach first year medical students one day a week at the University of Southern California Keck School of Medicine. I have always had a reputation for being a patient advocate since the very beginning of my training.

Congressman Souder has asked me to discuss my "practice" of recommending "marijuana" for use by "dozens of patients, including children with ADD.²" This "practice" is a direct consequence of California's passing of the Compassionate Use Act of 1996³ (Health and Safety Code 11362.5, also known as Proposition 215) and my compliance with the law as determined by State of California⁴ and the United States Supreme Court.⁵ The people of the State of California, as well as a majority of Americans⁶ believe marijuana should be available to patients who are ill or in pain. Contrary to popular opinion and scientific fact, it is the position of the Government of the

¹ Jensen, Claudia, M.D., Curriculum Vitae, 2004.

² Invitation to speak to the Subcommittee on Criminal Justice, Drug Policy and Human Resources, March 16, 2004.

³ Health and Safety Code 11362.5, entire text.

⁴ State of California, Senate Bill 420.

⁵ Conant v. McCaffrey, No. C97-00139 WHA, subsequent Ninth Circuit Court of Appeals Decision and Supreme Court refusal to hear the appeal.

⁶ Stein, Joel, "The Politics of Pot", <u>Time</u>, November 4, 2002, page 57.

United States of America that there are no known medicinal uses for marijuana⁷. Consequently, marijuana has been classified as a drug as dangerous as heroin and LSD. This is clearly contrary to the truth. At this time, while Americans are dying overseas and at home in the service of protecting democracy, it is even more critical for the American people to have faith in the information being disseminated by government. Enclosed in this testimony are references to corroborating documents refuting the position of the Drug Enforcement Administration, the official watchdog of American Physicians and the medications they prescribe, and an agency under the guardianship of this committee. (A full copy of all of the references will be provided to Chairman Souder upon my arrival at the Hearing.)

AN ABBREVIATED HISTORY OF CANNABIS

"Marijuana" is a term used to describe the plants Cannabis sativa and Cannabis indica. Cannabis has been used as a medication for over five thousand years. "The first evidence of the medicinal use of cannabis is an herbal published during the reign of the Chinese Emperor Chen Nung five thousand years ago. It was recommended for malaria. constipation, rheumatic pains, 'absentmindedness,' and 'female disorders.'" Marijuana was also recommended for "senile insomnia", analgesia, as a sleep inducer (hypnotic), in the treatment of gastric ulcers, morphine addiction, migraine headaches, tic douloureux, depression, and epilepsy. The first Western physician to take an interest in cannabis as a medicine was W. B. O'Shaughnessy, a young professor at the Medical College of Calcutta, who had observed its use in India." 10 Dr. O'Shaughnessy studied cannabis in India, then introduced the medication to European and American physicians. It was listed in the "United States Dispensatory" in 1854. By 1860, American doctors used cannabis to treat a multitude of medical problems "including tetanus, neuralgia, dysmenorrhea (painful menstruation), convulsions, the pain of rheumatism and childbirth. asthma, post-partum psychosis, gonorrhea, and chronic bronchitis. As a hypnotic (sleepinducing drug) he compared it to opium"..."The whole effect of hemp being less violent, and producing a more natural sleep."11

Cannabis was readily dispensed by U.S. pharmacies until after passage of the Marihuana Tax Act of 1937, a strictly political shuffle motivated by Harry Anslinger under the Federal Bureau of Narcotics. Anslinger's campaign was orchestrated through an aggressive, but largely hysterical media campaign. During Congressional hearings to decide the fate of cannabis as a medication, a spokesman from the American Medical Association, W. C. Woodward, M.D., J.D. noted, "It has surprised me, however, that the

⁷US.GOV website, House of Representatives, Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources, News, "Chairman Souder wants you to know that Marijuana is not Medicine" plus related links.

⁸ Grinspoon, Lester, M.D., Bakalar, James B., <u>Marihuana</u>, the Forbidden Medicine, Yale University Press, New Haven and London, 1997, page 3.

⁹ <u>Ibid.</u>, page 6.

¹⁰ Ibid., page 4.

¹¹ Ibid., page 5.

¹² Ibid., pages 7-8.

facts on which these statements have been based have not been brought before this committee by competent primary evidence." From the very beginning, the choice to ignore the medical therapeutics of cannabis was politically motivated, not based on truth.

In 1970, during a period of great upheaval in America, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (also called the Controlled Substances Act), which placed cannabis in a category called "Schedule I." Schedule I drugs "have no known medicinal use" by definition. ¹⁴ Clearly, this was not scientifically based as evidenced by 5000 years of a longitudinal outcome-based folk medicine "study" (i.e. people from all over the world have been using cannabis for medicine after 5000 years of observation of how it works.) Nonetheless, cannabis became illegal with the passage of both these Acts, neither of which was based on scientific facts.

Subsequent to the Controlled Substances Act, several patients applied for special permission to use cannabis to relieve pain and suffering. As there was, indeed, evidence to support the use of cannabis as a medication, Federal drug agencies granted "Investigational New Drug" permits to patients to use marijuana medicinally. The Federal Government took over the dispensing, ¹⁵ of marijuana to several sick people and established a cannabis farm in Mississippi. Today there are seven Americans who continue to receive prescriptions of marijuana from the U.S. Government sent to them in the U.S. Mail.

In 1988, Francis L. Young, J.D., and Administrative Law Judge for the Drug Enforcement Administration reviewed the medical literature on Cannabis. "Based upon the foregoing facts and reasoning, the administrative law judge concludes that the provisions of the Act permit and require the transfer of marijuana from Schedule I to Schedule II. The Judge realizes that strong emotions are aroused on both sides of any discussion concerning the use of marijuana. Nonetheless it is essential for this Agency, and its Administrator, calmly and dispassionately to review the evidence of record, correctly apply the law, and act accordingly." He ordered the DEA to change the classification of Cannabis such that patients could gain legal access through their physicians. The DEA disobeyed Judge Young and ignored his order. There were no enforcement measures available to force the DEA to comply.

The Compassionate Use Act of California ("Proposition 215") was passed in 1996. In it, patients who are "seriously ill Californians" are given the right to seek their physician's approval to use cannabis to aid in the treatment of their illnesses. Since passage of the act, much legislation has ensued. California lawmakers subsequently put into law a corollary to the Compassionate Use Act. Senate Bill 420 provides for systems to aid Law Enforcement in the compliance with California Law H&S Code Section 11362.5. Additional litigation resulted in a decision protecting patients and physicians from

^{13 &}lt;u>Ibid.</u>, page 9.

¹⁴ On cit.

^{15 &}quot;Medical Pot Users Win Key Ruling",

¹⁶ United States Department of Justice Drug Enforcement Administration, Docket No. 86-22, September 6, 1988

interference in their relationships. The Supreme Court of the United States of America has upheld the right of autonomy in this matter for both patients¹⁷ and physicians¹⁸.

Although it is the Law, and although the Law has been supported by the Supreme Court, many enforcement measures have been meted out on both patients and physicians to try to prevent them from complying with California State Law. Many patients have lost their medicine and been subjected to criminal prosecution. William Eidelman, M.D. lost his license to practice medicine. Miriam ("Molly") Fry, M.D. lost her right to write prescriptions for antibiotics and everything else. The grandfather of the Medical Marijuana movement, Tod Mikuriya, M.D., was investigated at great length by the Medical Board of California and subsequently fined \$75,000 for his care of medical marijuana patients. Although no patient has complained to the Medical Board about my medical care, I am also under investigation for my care of three patients.

Many physicians who have medical marijuana patients in their practices are currently under investigation although the Medical Board of California's policy clearly states physicians are not to be unduly harassed: "The Board seeks to provide greater guidance to physicians to enable them to participate appropriately in the implementation of Proposition 215, while meeting their professional and ethical obligations under the relevant standard of care. Adherence to such guidance by both physicians and Medical Board enforcement staff will ensure that physicians are not investigated merely because they have issued recommendations for marijuana use to patients. Investigations must be based on information received by the Board which provides a reasonable basis to believe that the physician is not adhering to acceptable medical practice standards when making the recommendation."²⁰

In fact, the Medical Board of California has not lived up to its own standards. Not only are the doctors being investigated, frequently without just cause, but physicians have benefited from no guidance from the Medical Board, whatsoever. Physicians evaluate whether a patient is ill and determine if the risk/ benefit ratio of using any medication warrants condoning the patient's use of the drug or not. Examining risk/ benefit ratios in the care of patients is exactly what physicians have been trained to do. It's our job.

Instead of trusting licensed physicians to make educated decisions regarding patient care, the Medical Board depends on its enforcement branch to attend to the physicians who care for medical marijuana patients. No physicians with the Medical Board of California have any experience or training in the management of this highly complex patient population. The care of Medical Marijuana patients is a specialty and requires much greater skills in many areas than does the traditional practice of medicine. The physicians of the California Cannabis Research Medical Group²¹ have carved out

¹⁷ "Court Accepts Medical Pot Use", Los Angeles Times, July 19, 2002.

¹⁸ "Medical Pot Use Given a Boost", Los Angeles Times, December 17, 2003.

¹⁹ Ventura County Star, "Doctor could lose license over marijuana", July 14, 2003.

²⁰ Medical Board of California, Action Report, www.medbd.ca.gov, July, 2003.

²¹ Gardner, Fred, O'Shaughnessy's, Journal of the California Cannabis Research Medical Group, "Cannabis Specialists Agree on Health History Questionnaire," Spring, 2004, page 2.

accepted Practice Guidelines, but they would greatly benefit from a cooperative relationship with the Medical Board rather than the current adversarial relationship. Doctors in the State of California are afraid to learn about how to use cannabis. In the eight years since passage of the Compassionate Use Act, only two educational programs for physicians have been presented.^{22,23}

Books have been written on the details of the history of cannabis. They are filled with facts, data, mystery, descriptions of maltreatment and calls for governmental reform. More and more literature is being published annually. Scientific studies documenting the safety and efficacy of "cannabinoids" (cannabis compounds) are being published (mostly in extra-American journals) with increasing frequency. The "medical marijuana movement" has evolved from a "grass roots" endeavor to become a progressively better organized demand for social reform. In the absence of a totalitarian government, the Medical Marijuana Movement will continue to flourish because its premise is exposing the misrepresentations about cannabis in the pursuit of compassion for sick people.

THE SCIENCE OF CANNABIS AS A MEDICATION

Even the government of the United States of America has documented the safety and efficacy of cannabis compounds in the treatment of chronic pain, neurological and movement disorders, nausea and vomiting, Glaucoma, appetite stimulation/cachexia, ²⁴ Wasting Syndrome, spasticity, Multiple Sclerosis, Tourette's Syndrome, Epilepsy, and Alzheimer's Disease. ²⁵ A thorough review of the Institute of Medicine Report (a partial text is included in references) and the National Institutes of Health Report (included in references) clearly identify medicinal uses for marijuana sprinkled among the disclaimers about how it would be nice to do more research.

"Since oral delta-9 THC has some analgesic activity, it is highly likely that smoked marijuana has some analgesic activity in some kinds of clinical pain," is a direct quote from the NIH report. That's it. There is the science in review by a group of analysts who are clearly not part of the Medical Marijuana Movement. That statement alone warrants an order to the Drug Enforcement Administration to correct the mistake of labeling cannabis "without medical benefit". But, in fact, the entire report documents repeatedly that cannabis compounds in all formulations have medicinal benefit.

²² "Cannabis Therapy: Science, Medicine and the Law", University of California at San Francisco, San Francisco, CA, June 10, 2000.

²³ "Perspectives on the Clinical Application of *Cannabis Sativa* and *Cannabis Indica*", University of Southern California Keck School of Medicine, Los Angeles, CA, February 13, 2004.

²⁴ Ad Hoc Group of Experts, NIH.GOV, "Workshop on the Medical Utility of Marijuana. Report to the Director, National Institutes of Health", February 19-20, 1997, pages 1-30.

²⁵ Joy, Janet E., Watson, Stanley J., Jr. Benson, John A., Jr., Editors, <u>Marijuana and Medicine Assessing the Science Base</u>, Institute of Medicine, National Academy Press, Washington, D.C., 2003, http:books.nap.edu/catalog/6376.html, pages 137-191.

²⁶ Ibid., page 19 ("Analgesia: 2. What are the major unanswered scientific questions?")

"In conclusion, the available evidence from animal and human studies indicates that cannabinoids can have a substantial analgesic effect."²⁷ The IOM Report clearly refutes the position of the DEA in classifying Cannabis as a Schedule I drug. At the very worst, Cannabis should be included in the Schedule II classification (known medicinal uses with high abuse potential) along with cocaine and amphetamines.

In addition to the U.S. Government funded reports, a panoply of books have been written on the medical efficacy of cannabinoids. Of the many, I use Dr. Grinspoon's, Dr. Earleywine's and Dr. Russo's the most. 28,29,30. (Dr. Earleywine has provided a copy of his book for the Committee.) Lynn Zimmer, Ph.D. and John P. Morgan, M.D.have published an excellent evaluation of the myths about marijuana.³¹ Even the most cursory perusal of these texts reveals the great depth of science behind the use of cannabinoids in medicine.

Also available to review to discover the details about pharmacology, biochemistry, clinical uses and safety/ efficacy profiles of cannabinoids are hundreds of published scientific articles. I ran a literature search through the library at the University of Southern California Keck School of Medicine and printed hundreds of pages of recent studies documenting many therapeutic trials documenting the effectiveness of cannabis. I have attached a few as addenda to this testimony.

One article from the German literature, describes the "endogenous cannabis receptors" in the human body.³² That is, human nerve cells and immune cells have pockets of tissue, like keyholes to a lock, whose sole responsibility is to bind to cannabis compounds. This discovery resulted in a search for an "endogenous" key-like compound produced by the body to plug in to those little locks. The discovery of the "endocannabinoid" (cannabislike compounds produced in the body naturally), Anandamide has led researchers on a further quest to develop synthetic cannabinoids for use in medicine. There are over 483 natural compounds in the cannabis plant, with more than 66 "cannabinoids" (a distinctive class of compounds found only in the cannabis plant). Many cannabinoids function like delta-9 THC (tetrahydrocannabinol) to some degree. Many do not.

Perhaps the most important reason to value the use of cannabis as a medication is because of the testimonials from American citizens who have personally witnessed relief from suffering because of the ability to use cannabis as a medication.³³ We tend to undermine

²⁹ Earleywine, Mitch, Ph.D., <u>Understanding Marijuana A New Look at the Scientific Evidence</u>, Oxford University Press, Oxford, New York, 2002, pages 1-317.

³¹ Zimmer, Lynn, Ph.D., Morgan, John P., M.D., Marijuana Myths Marijuana Facts, The Lindesmith

33 CBS News, "Recipe for Trouble", CBSNEWS.com, March 7, 2002 12:21:49, pages 1-2.

²⁷ Op. cit., Joy, Janet E., page 145.

Op. cit., Grinspoon.

³⁰ Russo, Ethan, M.D., Grotenhermen, Franjo, M.D., Editors, Cannabis and Cannabinoids Pharmacology, Toxicology, and Therapeutic Potential, The Haworth Integrative Healing Press, New York, London, Oxford, 2002, pages 1-427.

Center, New York, San Francisco, 1997, pages 1-233.

Pertwee, R. G., Forsch Komplementarmed, "Cannabis and Cannabinoids: Pharmacology and Rationale for Clinical Use", 1999;6 (suppl 3):12-15.

these stories as "anecdotal", suggesting that a single patient's experiences are not that critical to care about. Many prefer to pretend these patients are merely lying, or manufacturing statements so that they can "get high." As a physician with twenty-three years experience caring for the sick and suffering, I find this attitude disrespectful and un-Christian (I beg forgiveness from those who are offended by my religious orientation.) If there is just one person who is truly benefited from the use of cannabis, it should not be denied to them. It is clearly inhumane and a violation of that poor soul's "right to life, liberty and the pursuit of happiness" to be forbidden access to any medication that can relieve his/her torment.

CANNABIS AND ATTENTION DEFICIT DISORDER (ADD)

Attention Deficit Disorder is a neuropsychiatric disorder which affects 3-7% of American children and 3-4% of adults.³⁴ ADD has three subtypes: Inattentive, Hyperactive and Combined. Patients with ADD or its partner ADHD (Attention Deficit Hyperactivity Disorder) have difficulty with the executive management of their ability to attend to tasks. They frequently and inappropriately have difficulty focusing, listening attentively, completing homework and projects, organizing tasks and activities. Many are forgetful ("absentminded" in archaic terminology), impatient, fidgety, overly active, talkative, intrusional and have difficulty in engaging in quiet play.

There are multiple variations on the syndrome, but approximately 70% of people who suffer from ADD also experience other neuropsychiatric problems, including mood disorders (15-75%) especially depression, antisocial disorders (23-64%) including oppositional-defiant behavior disorder, anxiety (8-30%), and learning disabilities (6-92%.)³⁵ ADD/ ADHD can be an extremely debilitating problem and generates untold cost to society. Studies suggest incarcerated criminals have a disproportionate incidence of ADD/ ADHD, up to 40% in some studies.³⁶

From my experience, it is the adolescents who seem to be having the greatest difficulty in coping with ADD. A teenager with difficulty focusing, listening attentively, completing homework and projects, organizing tasks and activities who is also forgetful ("absentminded"), impatient, fidgety, overly active, talkative, intrusional and has difficulty in engaging in quiet play is likely to have social and academic problems. This is particularly true if the adolescent also experienced life events resulting in him/ her having a poor self image. Adolescents with mood disorders (15-75%) especially depression, antisocial disorders (23-64%) including oppositional-defiant behavior

 ³⁴ Brown, Thomas E., Ph.D., "Recognizing ADHD: Neurobiology, Symptoms, and Treatment, New Approaches to ADHD: Addressing Patient Needs From a Whole-life Perspective, Pragmaton Office of Medical Education supported by an unrestricted education grant from Eli Lilly and Company, 2001, page 3.
 ³⁵ Spencer, Thomas J., M.D., "ADHD in Children and Adults: Diagnosis and Comorbidity Issues", New Approaches to ADHD: Addressing Patient Needs From a Whole-life Perspective, Pragmaton Office of Medical Education supported by an unrestricted education grant from Eli Lilly and Company, 2001, page 13.

³⁶ McCallon, M.D., T. Dwaine, "If He Outgrew It, What Is He Doing in My Prison?", http://add.org/images2/prison.htm, March 25, 2004, pages 1-3.

disorder, anxiety (8-30%), and learning disabilities (6-92%.)³⁷ can be dangerous. ADD/ADHD can be an extremely debilitating problem and generates untold cost to society.

Patients with ADD/ ADHD frequently need medication to be able to function normally in society. Unfortunately, amphetamines are the most commonly used drugs to treat ADD in the United States today. Amphetamines can have very undesirable side effects. They can contribute to increased seizure activity, mental illness, cachexia and malnutrition, insomnia and severe behavior disorders. Only 70% of children with ADD respond well to amphetamines, anyway. The use of amphetamines in already emotionally impaired and academically challenged adolescents is not the best idea. Yet, Americans spend more than a billion of dollars every year buying legal amphetamines for their children who have ADD.

The more amphetamines we sell in the U.S., the more amphetamines we need to manufacture. The more amphetamines we manufacture, the more amphetamines can leak into the black market. Amphetamines in the black market fund crime. And they are addictive. Amphetamine users crave more and more drug. Amphetamine abuse is a serious problem in America, and we should limit amphetamine manufacture and distribution, especially for use in children and adolescents.

The other legal drugs used to treat ADD are helpful in many patients, but they all have side effects in some people. Actually, the other five of the nine drugs used to treat ADD in this country haven't even been scientifically tested to find out if they are effective treatments for ADD in children. These are drugs for depression and high blood pressure, and they all have bad side effects in some people. Yet, doctors all over America write prescriptions for depression and high blood pressure medications to treat ADD in children. Even though those drugs have not been tested scientifically, if they do help the child, it is not uncommon to use a drug "off label" I support the physician's right to be able to try them.

Although not all adolescents with ADD become violent while taking amphetamines, enough are emotionally impaired to warrant having a medication available, like cannabis, whose specific side effect is to make adolescents more peaceful. We really don't need another Columbine. With the help of knowledgeable physicians, adolescents who are suffering with ADD can have access to a medication that can help them function more normally in society while at the same time helping them to be more tranquil rather than more agitated, sleepless, irritable and anorexic. Because all medicines used to treat ADD have side effects, even cannabis, it is better to use any medication only if it is truly necessary; and only under the guidance of an *experienced* physician. Of all the drugs used to treat ADD, cannabis has the least number of serious side effects. 41, 38

³⁷ Op. cit., Spencer, Thomas J., M.D., page 13.

³⁸ Op. cit., Brown, Thomas E., page 14.

³⁹ Thomson's Physician's Desk Reference, Fifty-eighth Editions, 2004, multiple pages.

⁴⁰ Thomson's <u>Physician's Desk Reference</u>, Fifty-eighth Editions, 2004, Page 3295 under "General Information."

⁴¹ <u>Physician's Desk Reference for Herbal Medicines</u>, First Edition, Medical Economics Company, New Jersey, 1998, pages 712-714.

There are hundreds of case reports of patients who report improvement of their ADHD with Cannabis. There is evidence in the laboratory to show cannabinoids are effective in treating rats with ADHD. We need more research to define which routes of administration (oral seems preferable clinically), dosing, strain types to use, etc. Unfortunately, no pharmaceutical companies are motivated to spend the money on research and the United States Government has a monopoly on the available (poor quality) marijuana and research permits.

THE PROBLEM DEFINED

The problem of using Cannabis as a medication is not an issue of morality. It is immoral to deprive sick people of any medication that can help them.⁴⁴

The real problem with allowing patients to use Cannabis as a medication is economics.

If Cannabis were approved for use in just the ADD/ ADHD market alone, it could significantly impact the \$1 Billion a year sales⁴⁵ for traditional ADD/ ADHD pharmaceuticals. Why would anyone want to give their child an expensive pill (averages about \$100 a month)⁴⁶ with unacceptable side effects if s/he could just go into the backyard, pick a few leaves off a plant and make a tea for him/ her instead? Multiply those numbers by the tens of medical diagnoses that are effectively treated by Cannabis (for example chronic pain, which is a much bigger business than the treatment of ADD; or Glaucoma, or Multiple Sclerosis, etc) and it is easy to see the pharmaceutical industry would suffer beyond calculation.

We currently have the most expensive pharmaceuticals in the world, largely because American citizens are funding the research and development of new drugs. What company would want to invest the money in R & D if the expected revenues could be diminished by a plant able to be grown in the backyard? It's a serious and real problem. Of course, some companies would adapt. For example, Eli Lilly Pharmaceuticals manufactured a Tincture of Cannabis in the 1920's. Perhaps Lilly would be wise to begin R & D in Cannabinoids to try to beat the foreign markets (e.g. GW Pharmaceuticals in Great Britain.) Perhaps Lilly's \$575 million profit in the fourth

³⁸ See 38 above.

⁴² Gardner, Fred, "Which Conditions are Californians Actually Treating With Cannabis?",

O'Shaughnessy's, Journal of the California Cannabis Research Medical Group, Summer, 2003.

Adriani, Walter, et.al., "The spontaneously hypertensive-rat as an animal model of ADHD: evidence for impulsive and non-impulsive subpopulations," Neuroscience and Biobehavioral Reviews, 27 (2003) pages 639-651

⁴⁴ Clark, Peter A., "The Ethics of Medical Marijuana: Government Restrictions vs. Medical Necessity", <u>Journal of Public Health Policy</u>, (2001?), Volume 21, Number 1, pages 40-60.

⁴⁵ Attention Deficit Disorder Help Center, "Drug Concerta, Atomoxetine, Metadate CD, Ritalin LA, Focalin; The New Meds.", http://www.add-adhd-help-center.com/newsletters/newsletter_31dec02.htm. ⁴⁶ Jensen, Claudia, M.D., Telephone survey of local pharmacies, 2004.

⁴⁷ See photograph of Tincture of Cannabis and letter from Parke-Davis dated June 19, 1968.

quarter, 2001⁴⁸ and other annual profits could be invested in less risky business (although pharmaceuticals don't appear to be too risky at this time. If Cannabis stays off the market, pharmaceuticals are more secure.)

Two other American traditions would suffer if Cannabis were reclassified as (at worst) a Schedule II drug. It is highly likely Americans who could use Cannabis more would use alcohol and tobacco less. Most Cannabis users I have interviewed are not daily alcohol or tobacco consumers; and this seems to be a consensus among the Physicians who actually manage Medical Marijuana patients. Rarely do patients use other illicit drugs, although most of them have a history of having tried other drugs in their lifetimes.

But the real economic catastrophe to be expected if Cannabis is reclassified would be to the Law Enforcement and Judicial branches of government. "According to ONDCP, the \$18.822 Billion spent by the federal government on the drug war in 2002 breaks down as follows:..."

"...Domestic Law Enforcement: \$9.513 Billion (50.5% of total)

Interdiction: \$2.074 Billion (11.0% of total) International: \$1.098 Billion (5.8% of total)

In other words, \$12.686 Billion in 2002 was directed to supply reduction, i.e. law enforcement (67.4% of total.)"⁴⁹

"Nearly eight cents of every dollar spent by State and local governments in 1999 was for justice activities." And, as long as Cannabis is classified Schedule I, the Federal Government will be forced to continue to spend money on investigating, arresting, prosecuting, incarcerating, and "rehabilitating" medical marijuana users. The marijuana smokers of America (some 4.2% of the population, and the numbers actually rose since the "War on Drugs" has begun) will continue to funnel \$10.6 billion annually into the black market to buy marijuana. That is, 10.6 Billion Dollars are spent funding criminals selling marijuana in this country, and the American people are paying it.

CONCLUSION: What Should We Do?

Tell the truth. Cannabis does not fit into the category "no known medicinal use."

Enforcement procedures should be implemented to carry out Judge Young's 1988 orders to the Drug Enforcement Administration. Marijuana should actually be rescheduled as

 ^{48 &}quot;Prozac's slippage cuts Lilly's earnings", <u>The Indianapolis Star</u>, January 25, 2002, http://www.indystar.com/library/factfiles/business/companies/lilly/stories/2002_0125.html, page 1.
 49 Office of National Drug Control Policy, "National Drug Control Strategy: FY 2003 Budget Summary" (Washington, DC: Office of the President, February 2002), Table 2, page 6 as reported by Drug War Facts at http://www.drugwarfacts.org/marijuan.htm.

Gifford, Sidra Lea, US Department of Justice, Bureau of Justice Statistics, Justice Expenditure and Employment in the United States, 1999 (Washington, DC: US Department of Justice, February, 2002), page 4 as reported by <u>Drug War Facts</u> at http://www.drugwarfacts.org/marijuan.htm.
 "Changing the Way Americans Think About Marijuana Talking Points",

http://reform.house.gov/CJDPHR/News/DocumentSingle.aspx?DocumentID=1692 plus attachments.

Schedule III because of its safety profile, but Schedule II would be more honest than what it is now.

Research grants should be awarded to investigators with the intention of producing studies to define how to use cannabis effectively.

Systems should be developed to divert the \$10.6 billion Americans spend on marijuana annually into Public Health, Law Enforcement (to guard the crops and distribution), American farmers (to grow the medicine), to Pharmaceutical Industries to promote research and development on smoke-less delivery forms, and to the tobacco giants to manage the smoked products. The American farmers employed should preferably have previous experience in the cultivation and processing of Cannabis as the "medicine" being produced at the Mississippi farm reportedly is embarrassingly low quality. All of the funds could be administered through a "Tax Stamp" system which could feasibly generate \$0.50 per gram of Cannabis sold.

We as a nation should value the truth about marijuana. It is the only compassionate thing to do. When law enforcement is freed from mercilessly targeting sick people, it can focus on hard drugs, like methamphetamine and cocaine.

The truth is: Americans should never have to be afraid of the law if they need a medication to relieve pain and suffering.

Thank God in California the law protects patients from being punished for using a medication that helps them. Thank God that the Supreme Court Justices of the United States of America have their eyes open to the truth. I pray that the Committee on Government Reform will take action. Please ask them to do so.

California Health & Safety Code §11362.5 Compassionate Use Act of 1996

- (a) This section shall be known and may be cited as the Compassionate Use Act of 1996.
- (b) (1) The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:
 - (A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.
 - (B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.
 - (C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana.
 - (2) Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for nonmedical purposes.
- (c) Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes.
- (d) Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.
- (e) For the purposes of this section, "primary caregiver" means the individual designated by the person exempted under this section who has consistently assumed responsibility for the housing, health, or safety of that person.

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THE DRAMATIC STORY

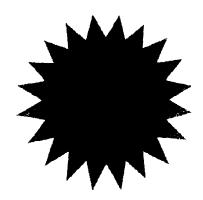
of one family's refusal to give up on a deeply troubled child

What People Are Saying About Jeffrey's Journey

"This is a remarkable account of one mother's love for her son and her courage to question conventional thinking in medicine and politics. Readers will take strength and hope from the Jeffries' story. I certainly did." – MONTEL WILLIAMS

"A compelling first-hand account of the successful use of medical marijuana to treat a serious behavioral disorder in a child. This engaging case report offers an honest look at conventional psychiatric medications, and sheds new light on the untapped possibilities of cannabis as an alternative." – ANDREW WEIL, MD

"This is a book that should be read by parents, healthcare practitioners and policy makers—all of whom will find something captivating and persuasive in this family's story." – JOYCELYN ELDERS, Former U.S. Surgeon General

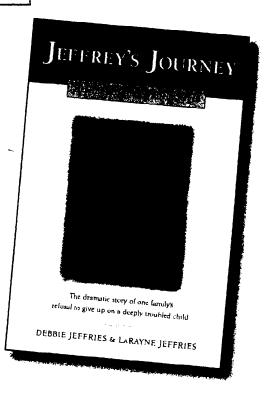


By age seven, Jeffrey had already been prescribed more than a dozen drugs to control his violent rages. Nothing had helped. Then state officials gave Jeffrey's mother an ultimatum: Find something to manage your son or lose him to institutional lock-down. Extensive research convinced this conservative, Christian mother that medical marijuana could be her son's last hope.

Jeffrey's Journey chronicles the success of Jeffrey's treatment, as well as the family's court battle defending their son's right to unconventional medicine. This family's story makes clear that, for parents, the need to relieve a child's suffering must transcend politics.

"We feel strongly that this could help many other children in the same situation as Jeffrey, even if it is just buying time until the child is old enough to respond to psychotherapy. There is proof positive that marijuana was effective on Jeffrey's out-of-control behavior. It proved to be a valuable bridge in this long journey."

— Jeffrey's grandmother and co-author of Jeffrey's Journey



Jeffrey's Journey \$12.95, 128 pp.

Available at bookstores everywhere or online at www.jeffreysjourney.com

For additional information or to inquire about quantity prices contact: jane@quickamerican.com



Philip A. Denney, M.D. Robert E. Sullivan, M.D. 5500 Hollow Lane Greenwood, CA 95635

Phone 530-333-2162

Facsimile 530-333-2165

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