MMP-040

#### New Jersey Department of Health Medicinal Marijuana Program PO 360 Trenton, NJ 08625-0360

#### MEDICINAL MARIJUANA PETITION (N.J.A.C. 8:64-5.1 et sea.)

#### INSTRUCTIONS

This petition form is to be used <u>only</u> for requesting approval of an additional medical condition or treatment thereof as a "debilitating medical condition" pursuant to the New Jersey Compassionate Use Medical Marijuana Act, N.J.S.A. 24:6I-3. Only one condition or treatment may be identified per petition form. For additional conditions or treatments, a separate petition form must be submitted.

NOTE: This Petition form tracks the requirements of N.J.A.C. 8:64-5.3. Note that if a petition does not contain all information required by N.J.A.C. 8:64-5.3, the Department will deny the petition and return it to petitioner without further review. For that reason the Department strongly encourages use of the Petition form.

This completed petition must be postmarked August 1 through August 31, 2016 and sent by certified mail to:

New Jersey Department of Health Office of Commissioner - Medicinal Marijuana Program Attention: Michele Stark 369 South Warren Street Trenton, NJ 08608

Please complete <u>each</u> section of this petition. If there are any supportive documents attached to this petition, you should reference those documents in the text of the petition. If you need additional space for any item, please use a separate piece of paper, number the item accordingly, and attach it to the petition.

1.	Petitioner Information
	Name:
	Street Address:
	City, State, Zip Cod
	Telephone Number
	Email Address:
2.	Identify the medical condition or treatment thereof proposed. Please be specific. Do not submit broad categories (such as "mental illness").
X,Lo	wer Back, Neck, Lea spossing Chronic Pain, Gusion L5-SI Gradures L3-44,
بجذاو	spentant, Neck, Lea spossors Chronic Pain, fusion L5-SI fractures L3-44, Spentant Concussion, Multiple Munes + Surgeries after Being Struck By Pi
3.	Do you wish to address the Medical Marijuana Review Panel regarding your petition?
	☐ Yes, in Person
	¥ Yes, by Telephone
	□ No
4.	Do you request that your personally identifiable information or health information remain confidential?
-1.	Yes
	∑ No
	If you answer "Yes" to Question 4, your name, address, phone number, and email, as well as any medical or health information
	specific to you, will be redacted from the petition before forwarding to the panel for review.

# MEDICINAL MARIJUANA PETITION (Continued)

5.	Describe the extent to which the condition is generally accepted by the medical community and other experts as a valid
	existing medical condition.
	existing medical condition.  Severe Chronic Pain, Muscular Spasticity Back
	•
6.	If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, describe the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition.
	resistant to convention medical Therapy
	· ·
_	
7.	and/or chronic pain severe nauses and/or vomiting or otherwise severely impair the nation's shilly to carry on
6	activities of daily living. Chronic pain due to multiple injuries, multiple Surgence Pack, Pain Neck, Buck Leas Fusion L.5 - S.1 Mesh net put in Blacon custion Fenus Frictor Short Term memory Loss After Being Hit
	Concussion Fenur fractor Shottern memory was After Being Hit
	Pickup Truck.
8.	Describe the availability of conventional medical therapies other than those that cause suffering to alleviate suffering
	caused by the condition and/or the treatment thereof.
	More percription drugs that will make me a Addict
	Mor percurption drugs that will make me a Addict with Being Able To function in This world. T
0	Describe the extent to which evidence that is generally accepted among the medical community and other experts
9.	supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof.
	[Note: You may attach articles published in peer-reviewed scientific journals reporting the results of research on the effects of marijuana on the medical condition or treatment of the condition and supporting why the medical condition should be added to
	the list of debilitating medical conditions.]

# MEDICINAL MARIJUANA PETITION (Continued)

10. Attach letters of support from physicians or other licensed health care professionals knowledgeable about the condition. List below the number of letters attached and identify the authors. (2) വരുന്നു സംവര്ദ്ദേശി						
D. Gno Chrapettia 4813 Belmar Blud-	My Orthopedic Doctor. Has Been My doctor. Jan 2011 To present					
	Jan 2011 To prevent					
Coall, NJ 07753	*					
732-938-6090						
I certify, under penalty of perjury, that I am 18 years of age or older; that the information provided in this petition is true and accurate to the best of my knowledge; and that the attached documents are authentic.						
	Date 8-31-16					

I am a 54 yo, relatively fit female, I have lived with severe Chronic Back pain, since 2010 when I was hit while out walking by a pick up truck.

I had a fractured femur, L3 and L4 fractures, head injury stitches, concussion.

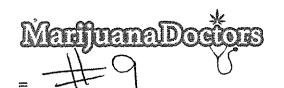
If pain where to be given a number 0-10 with 10 being horrendous, I would be at a 5 or 6 on a good day. I have to receive 2 hours of week in massage therapy, per my own cost, just so I can move my body to walk and keep body in motion. I have severe PAIN, spasms

In legs and back, I had other surgeries. L5 and S-1 fusions, bladder mesh, and breast reduction, to try and help alleviate the pain to no avail. Doctors have prescribed medication that only make me not in touch with the world, and can not function. I would like to be able to be a person that can live a life that does not make me addicted to prescription drugs, and be an addict.

I truly know that medical marijuana is right for my case, and I only hope that you will be able to see that it will save my life, and help me live the best life possible for my condition. Please consider adding chronic pain to the list to help me. Thank you

8-31-10

#7



Enter City, State or Zip







ABOUT

FIND A DOCTOR

LEGAL STATES

PENDING STATES

RESOURCES

NEWS/BLOG

PRODUCERS

CAREGIVERS

FACTS

SEE DOCTOR NOW

## Resources

Appointment Info

General

Media

Research & Studies

Telemedicine

Tools

Uses of Medical Marijuana

#### Request An Appointment Today

Complete this form to have a patient support specialist find and book an appointment with a certified physician near you.

#### First Name\*

**Enter First Name** 

#### Last Name\*

Enter Last Name

#### Phone Number\*

**Enter Phone Number** 

#### Your Email\*

**Enter Email Address** 

#### City/State/Zip\*

FRESNO, CALIFORNIA

# Medical Marijuana and Skeletal Muscular Spasticity

#### What Is Skeletal Muscular Spasticity?

Muscle spasticity is a neurological condition/symptom that presents as increased muscle tone, muscle stiffness and inability to stretch the affected muscles. It primarily inhibits skeletal muscle. It is most commonly seen in disorders like multiple sclerosis, which causes lesions that affect the nervous system. Medical marijuana is fast becoming a breakthrough medicine in treating muscle spasticity. There are a limited number of treatments and none of them provides complete relief for all sufferers.

Muscle spasticity is a neurological condition/symptom that presents as increased muscle tone, muscle stiffness and inability to stretch the affected muscles. It primarily inhibits skeletal muscle. It is most commonly seen in disorders like multiple sclerosis, which causes lesions that affect the nervous system. Medical marijuana is fast becoming a breakthrough medicine in treating muscle spasticity. There are a limited number of treatments and none of them provides complete relief for all sufferers.

While the mechanisms behind skeletal muscular spasticity are not completely understood, we do know that it can occur with spinal injury, head injury, multiple sclerosis, cerebral palsy and other conditions that damage the brain and/or other parts of the nervous system. It can cause muscle spasms, pain, difficulty moving, loss of bodily functions and severe disability. Research is showing that it changes the muscle itself. Once this is well understood, we may understand treatment with medical marijuana and how it works to fight skeletal muscular spasticity better.

#### Medical Marijuana and Skeletal Muscular Spasticity

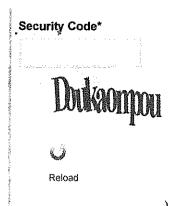
#### MEDICAL MARIJUANA AND SKELETAL MUSCLE SPASTICITY RESEARCH

A 2004 paper on a double-blind, placebo-controlled study of 57 individuals with multiple sclerosis induced skeletal muscle spasticity concluded that medical marijuana can provide spasm relief and increased mobility in MS patients who are not responding well to other treatments. They further noted that medical marijuana had "tolerable" side effects in these patients. The patients were given both cannabidiol and tetrahydrocannibinol. Some were given 14 days worth of treatment while others were given fewer days of treatment broken up by placebo. They were given a number of tests to show changes in muscle spasticity. Those who were given steady treatment for two weeks showed the greatest improvement in both their perception of spasms and observable spasms, though side effects were also more likely in this group.

Another study, conducted at Oxford, showed similar results. They found that medical marijuana could indeed decrease muscle spasticity as well as other effects of multiple sclerosis, such as pain. One particularly noteworthy finding is that side effects of THC, CME (a whole plant extract as opposed to a single component) and CBD were predictable and tolerable in the study's subjects. The study included 24 individuals with skeletal muscle spasticity brought on by multiple sclerosis, neurofibromatosis, brachial plexus injury or spinal cord injury. Some of the most uncomfortable effects of these conditions, such as loss of bladder control, were alleviated by these cannabis extracts.

A much larger study was conducted on 667 multiple sclerosis patients in the UK. The findings of this study differed from those above. However, it still found that medical marijuana was useful in treating muscle spasticity. The paper's authors stated that they found no decrease in spasticity, according to the Ashworth scale. (Note: The study conducted in 2004 used several parameters to test spasticity and came to a different conclusion.) They did see a difference in patients' perception of spasticity and other discomforts. Thus, the authors concluded that even if there is no observable difference, medical marijuana could be used to treat skeletal muscle spasticity nonetheless.

MEDICAL MARIJUANA AND SKELETAL MUSCLE SPASTICITY ANECDOTAL RESEARCH AND



Submit Request

EVIDENCE

Anecdotal evidence collected on the topic of muscle spasticity and marijuana use has shown that some skeletal muscular spasticity sufferers experience significant relief from their symptoms when using marijuana. The research in this area goes back at least 30 years. In 1982, 43 individuals were given a survey to see how medical marijuana affected their muscle spasticity. Each of these individuals suffered muscle spasticity as a result of spinal cord injuries. Twenty-one of them said that medical marijuana reduced their muscle spasticity.

A study conducted 15 years later contained 112 participants. The information given by the participants pertained to skeletal muscle spasticity and the pain that often comes with it. Nearly every one of them reported a reduction in skeletal muscular spasticity and related pain. This type of anecdotal research is helpful in uncovering the patient experience of medical marijuana and skeletal muscular spasticity. The sheer number of respondents experiencing relief shows that there is either something in the psychoactive components of the drug that gives them comfort or that medical marijuana affects the cause of spasticity itself. However, only observed reactions in clinical studies can prove medical marijuana's efficacy enough to introduce it to a wider patient base.

Book Appointment | Back to Glossary | Back to List

Sign Up To Get Our FREE Newsletter!

Featuring

 Discounts, Coupons, and Giveaways ' Medical Marijuana Updates Trusted Information And Much More!

MarijuanaDoctor's Medical Marijuana Updates

©2013 MD MCN Co, Inc. All Rights Reserved





As Seen On





Bloomberg

**O**CBS



About Medical Warfluaria Doctors

Contact Us Legal Resources **Privacy Policy** Site Map

Terms of Use

Our Medical Marijuana Pariners

Medical Marijuana Dispensaries Marijuana Legalization Petition

Srowse Marilliana Doctors

Alaska Minnesota Arizona Montana California New Hampshire

Colorado New Jersey Connecticut **New Mexico** Nevada

Washington D.C. Delaware

Florida

Georgia

Hawaii

Illinois Massachusetts

Maryland Maine

Michigan

New York

Ohio

Oregon Pennsylvania

Rhode Island

Vermont

Washington

Privacy Policy

- Terms of Use
- Legal Resources
- Contact Us
- Site Map

©2013 MD MCN Co, Inc. All Rights Reserved

#9

Question.

# CHRONIC PAIN AND MEDICAL CANNABIS



Advancing Legal Medical Marijuana Therapeutics and Research

#### A Note from Americans for Safe Access

We are committed to ensuring safe, legal availability of marijuana for medical uses. This brochure is intended to help doctors, patients and policymakers better understand how marijuana—or "cannabis" as it is more properly called—may be used as a treatment for people with serious medical conditions. This booklet contains information about using cannabis as medicine. In it you'll find information on:

Why Cannabis is Legal to Recommend	3
Overview of the Scientific Research on Medical Cannabis	4
Research on Cannabis and Chronic Pain	6
Comparison of Medications: Efficacy and Side-Effects	9
Why Cannabis is Safe to Recommend	11
Testimonials of Patients and Doctors	13
History of Cannabis as Medicine	19
Scientific and Legal References	22

We recognize that information about using cannabis as medicine has been difficult to obtain. The federal prohibition on cannabis has meant that modern clinical research has been limited, to the detriment of medical science and the wellness of patients. But the documented history of the safe, medical use of cannabis dates to 2700 B.C. Cannabis was part of the American pharmacopoeia until 1942 and is currently available by prescription in the Netherlands and Canada.

Testimonials from both doctors and patients reveal valuable information on the use of cannabis therapies, and supporting statements from professional health organizations and leading medical journals support its legitimacy as a medicine. In the last few years, clinical trials in Great Britain, Canada, Spain, Israel, and elsewhere have shown great promise for new medical applications.

This brochure is intended to be a starting point for the consideration of applying cannabis therapies to specific conditions; it is not intended to replace the training and expertise of physicians with regard to medicine, or attorneys with regard to the law. But as patients, doctors and advocates who have been working intimately with these issues for many years, Americans for Safe Access has seen firsthand how helpful cannabis can be for a wide variety of indications. We know doctors want the freedom to practice medicine and patients the freedom to make decisions about their healthcare.

For more information about ASA and the work we do, please see our website at AmericansForSafeAccess.org or call 1-888-929-4367.

# Is Cannabis Legal to Recommend?

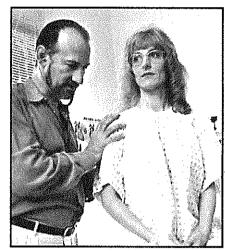
In 2004, the United States Supreme Court upheld earlier federal court decisions that doctors have a fundamental Constitutional right to recommend cannabis to their patients.

**The history.** Within weeks of California voters legalizing medical cannabis in 1996, federal officials had threatened to revoke the prescribing privileges of any physicians who recommended cannabis to their patients for medical use. In response, a group of doctors and patients led by AIDS specialist Dr. Marcus Conant filed suit against the government, contending that such a policy violates the First Amendment. The federal courts agreed at first the district level, then all the way through appeals to the Ninth Circuit and then the Supreme Court.

What doctors may and may not do. In Conant v. Walters,4 the Ninth Circuit Court of Appeals held that the federal government could nei-

ther punish nor threaten a doctor merely for recommending the use of cannabis to a patient.<sup>5</sup> But it remains illegal for a doctor to "aid and abet" a patient in obtaining cannabis.<sup>6</sup> This means a physician may discuss the pros and cons of medical cannabis with any patient, and issue a written or oral recommendation to use cannabis without fear of legal reprisal.<sup>7</sup> This is true regardless of whether the physician anticipates that the patient will, in turn, use this recommendation to obtain cannabis.<sup>8</sup>

What physicians may not do is actually prescribe or dispense cannabis to a patient or



Angel Raich & Dr. Frank Lucido

tell patients how to use a written recommendation to procure it from a cannabis club or dispensary. Doctors can tell patients they may be helped by cannabis. They can put that in writing. They just can't help patients obtain the cannabis itself.

Patients protected under state, not federal, law. In June 2005, the U.S. Supreme Court overturned the Raich v. Ashcroft Ninth Circuit Court of Appeals decision. In reversing the lower court's ruling, Gonzales v. Raich established that it is legal under federal law to prosecute patients who possess, grow, or consume medical cannabis in medical cannabis states. However, this Supreme Court decision does not overturn or supersede the laws in states with medical cannabis programs.

For assistance with determining how best to write a legal recommendation for cannabis, please contact ASA at 1-888-929-4367.

# **Scientific Research Supports Medical Cannabis**

Between 1840 and 1900, European and American medical journals published more than 100 articles on the therapeutic use of the drug known then as Cannabis Indica (or Indian hemp) and now simply as cannabis. Today, studies published in peer-reviewed journals demonstrate cannabis has medical value in treating patients with serious illnesses such as AIDS, glaucoma, cancer, multiple sclerosis, epilepsy, arthritis, and chronic pain.

The safety of the drug has been attested to by numerous studies and reports, including the LaGuardia Report of 1944, the Schafer Commission Report of 1972, a 1997 study conducted by the British House of Lords, the Institutes of Medicine report of 1999, research sponsored by Health Canada, and numerous studies conducted in the Netherlands, where cannabis has

#### INSTITUTE OF MEDICINE

"Nausea, appetite loss, pain and anxiety . . all can be mitigated by marijuana.... For patients, such as those with AIDS or undergoing chemotherapy, who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad spectrum relief not found in any other single medication."

Marijuana and Medicine: Assessing the Science Base, 1999 been quasi-legal since 1976 and is currently available from pharmacies by prescription.

Recent published research on CD4 immunity in AIDS patients found no compromise to the immune systems of patients undergoing cannabis therapy in clinical trials.<sup>11</sup>

The use of medical cannabis has been endorsed by numerous professional organizations, including the American Academy of Family Physicians, the American Public Health Association, and the

American Nurses Association. Its use is supported by such leading medical publications as The New England Journal of Medicine and The Lancet.

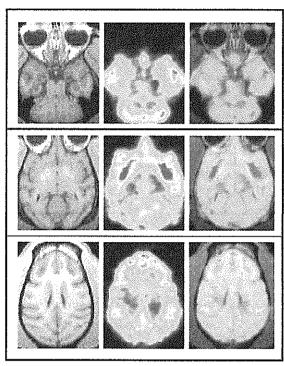
#### **Recent Research Advances**

While research has until recently been sharply limited by federal prohibition, the last few years have seen rapid change. More than 15,000 modern peer-reviewed scientific articles on the chemistry and pharmacology of cannabis and cannabinoids have been published, as well as more than 2,000 articles on the body's natural endocannabinoids. The International Cannabinoid Research Society was formally incorporated as a scientific research organization in 1991. Membership in the Society has more than tripled from about 50 members in the first year to over 500 in 2010. The International Association for Cannabis as Medicine (IACM) was founded in March 2000. It publishes a bi-weekly newsletter and the IACM-Bulletin, and holds a bi-annual symposium to highlight emerging research in cannabis therapeutics.

In 2001, the State of California established the Center for Medicinal Cannabis Research to coordinate an \$8.7-million research effort at University of California campuses. As of 2010, the CMCR had completed six of 14 approved studies. Of those, five published double-blind, placebo-controlled studies studied pain relief; each showed cannabis to be effective. A 2009 review of controlled clinical studies conducted over a 38-year period, found

that "nearly all of the 33 published controlled clinical trials conducted in the United States have shown significant and measurable benefits in subjects receiving the treatment." The review's authors note that the more than 100 different cannabinoids in cannabis have the capacity for analgesia through neuromodulation in ascending and descending pain pathways, neuroprotection, and anti-inflammatory mechanisms.

In the United Kingdom, GW
Pharmaceuticals has been conducting
clinical trials with its cannabis-based
medicine, Sativex®, for the past
decade. GW's Phase II and Phase III trials of cannabis-based medicine show
positive results for the relief of neurological pain related to: multiple sclero-



Cannabinoid receptors in the brain

sis (MS), spinal cord injury, peripheral nerve injury (including peripheral neuropathy secondary to diabetes mellitus or AIDS), central nervous system damage, neuroinvasive cancer, dystonias, cerebral vascular accident, and spina bifida. They have also shown cannabinoids to be effective in clinical trials for the relief of pain and inflammation in rheumatoid arthritis and also pain relief in brachial plexus injury.<sup>13-16</sup>

As of December 2010, the company has obtained regulatory approval in Spain, New Zealand, and the UK for Sativex® Oromucosal Spray, a controlled-dose whole-plant extract. Sativex® was approved in Canada for symptomatic relief of neuropathic pain in 2005, in 2007 for patients with advanced cancer whose pain is not fully alleviated by opiods, and in 2010 for spasticity related to multiple sclerosis. Sativex® has been made available either for named patient prescription use or for clinical trials purposes in a total of 22 countries. In the US, GW was granted an import license for Sativex® by the DEA following meetings in 2005 with the FDA, DEA, the Office for National Drug Control Policy, and the National Institute for Drug Abuse. Sativex® is currently an investigational drug in FDA-approved clinical trials as an adjunctive analgesic treatment for patients with advanced cancer whose pain is not relieved by strong opioids.

allows the active compounds in cannabis to be absorbed into the blood stream with greater speed and efficiency. It is for this reason that inhalation is an increasingly common, and often preferable, route of administration for many medications. Cannabis may also be more effective than Marinol because it contains many more cannabinoids than just the THC that is Marinol's active ingredient. The additional cannabinoids may well have additional and complementary antiemetic qualities. They have been conclusively shown to have better pain-control properties when taken in combination than THC alone, and mitigate anxiety and other side-effects of THC.

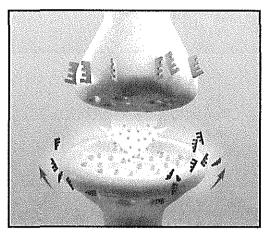
# Research on cannabis and pain management

Cannabis has been used as an analgesic for thousands of years<sup>18-20</sup> and patients often report significant pain relief from cannabis, even in cases where conventional pain therapies have failed.<sup>21-26</sup>

After reviewing a series of trials in 1997, the U.S. Society for Neuroscience concluded that "substances similar to or derived from marijuana could ben-

efit the more than 97 million Americans who experience some form of pain each year."<sup>27</sup> A 1999 study commissioned by the White House and conducted by the Institute of Medicine recognized the role that cannabis can play in treating chronic pain.<sup>28</sup> "After nausea and vomiting, chronic pain was the condition cited most often to the IOM study team as a medicinal use for marijuana."

From 1975 to February 2011, there have been nearly 300 studies showing that cannabinoids and cannabis can help patients experiencing chronic pain.<sup>29,30</sup>

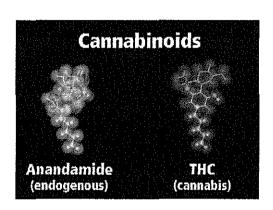


**CB1** receptor

Some of the most encouraging clinical data on effects of cannabinoids on chronic pain are from studies of intractable cancer pain and hard-to-treat neuropathic pain.<sup>31</sup> The effectiveness of cannabis and cannabinoids in relieving neuropathic pain has been demonstrated in more than three dozen preclinical and clinical trials.<sup>32</sup> A trial of cannabis cigarettes to treat HIV-associated daily neuropathic pain in 50 patients showed an average reduction of pain by 30% over a treatment course of only 5 days.<sup>33</sup> In 2001, researchers reported that cannabis extract sprayed under the tongue (Sativex®) was effective in reducing pain in patients suffering intractable neuropathic pain.<sup>34</sup> A review of over 20 clinical trials on cannabis and cannabinoids found that whole plant cannabis and extracts are superior to oral THC for the treatment of pain. Health Canada approved Sativex® for prescription in the treatment of HIV-associated neuropathic pain in 2005 and cancer pain in 2007.

#### **CANNABIS AND CHRONIC PAIN**

Persistent and disabling pain can have numerous and sometimes multiple causes. Among them are cancer; AIDS; sickle cell anemia; multiple sclerosis; defects or injuries to the back, neck and spinal cord; arthritis and other rheumatic and degenerative hip, joint and connective tissue disorders; and severe burns. Pain is not a primary condition or injury, but rather a severe, frequently intolerable symptom that varies in frequency, duration, and



severity according to the individual. The underlying condition determines the appropriate curative approach, but does not determine the proper symptom management. It is the character, severity, location and duration of the pain that determines the range of appropriate therapies.

Chronic pain is a public health issue that is widespread across the aging populations of industrialized nations. Epidemiological statistics are alarming: In Europe, it is estimat-

ed that one in four adults has a chronic pain condition.<sup>17</sup> In the US, it is estimated that at least 38 million adults suffer from chronic pain, and at least 12 million have used cannabis as a treatment.

For patients in pain, the goal is to function as fully as possible by reducing their pain as much as possible, while minimizing the often-debilitating side effects of the pain therapies. Failure to adequately treat severe and/or chronic pain can have tragic consequences. Not infrequently, people in unrelieved pain want to die. Despair can also cause patients to discontinue potentially life-saving procedures (e.g., chemotherapy or surgery), which themselves cause severe suffering. In such dire cases, anything that helps to alleviate the pain will prolong these patients' lives.

Cannabis can serve at least two important roles in safe, effective pain management. It can provide relief from the pain itself (either alone or in combination with other analgesics), and it can control the nausea associated with taking opioid drugs, as well as the nausea, vomiting and dizziness that often accompany severe, prolonged pain.

Opioid therapy is often an effective treatment for severe pain, but all opiates have the potential to induce nausea. The intensity and duration of this nausea can cause enormous discomfort and additional suffering and lead to malnourishment, anorexia, wasting, and a severe decline in a patient's health. Some patients find the nausea so intolerable that they are inclined to discontinue the primary pain treatment, rather than endure the nausea.

Inhaled cannabis provides almost immediate relief for nausea with significantly fewer adverse side effects than orally ingested Marinol. Inhalation

The activity of the more than 100 cannabinoids and other components on the plant may explain its superiority in reducing pain when comparing whole plant cannabis and extracts to THC alone. For instance, the cannabinoid cannabichromene (CBC), the third most common ingredient on the

#### FEDERATION OF AMERICAN SCIENTISTS

"Based on much evidence, from patients and doctors alike, on the superior effectiveness and safety of whole cannabis compared to other medications,... the President should instruct the NIH and the FDA to make efforts to enroll seriously ill patients whose physicians believe that whole cannabis would be helpful to their conditions in clinical trials"

FAS Petition on Medical Marijuana, 1994

plant, exhibits anti-inflammatory and analgesic actions, although weaker than THC.<sup>35</sup> Similarly, beta-sitosterol, a non-cannabinoid ingredient found in cannabis, was able to decrease inflammation and edema in skin treatment.<sup>36</sup> And a unique flavanoid found only in cannabis, cannaflavin A, inhibits the inflammatory molecule PGE-2, thirty times more potently than aspirin.<sup>37</sup> Lastly beta-caryophyllene, a

cannabinoid found in many plants besides cannabis, has strong anti-inflammatory properties but no noticeable side effects.<sup>38</sup> Beta-caryophyllen is the most commonly consumed FDA-approved cannabinoid in food.

The IOM report found that "basic biology indicates a role for cannabinoids in pain and control of movement, which is consistent with a possible therapeutic role in these areas. The evidence is relatively strong for the treatment of pain and intriguingly, although less well established, for movement disorder." According to the IOM Report and numerous independent research articles, a number of areas in the brain that have an established role in sensing and processing pain respond to the analgesic effect of cannabis, adding that cannabinoids have been used successfully to treat cancer pain, which is often resistant to treatment with opiates. The effectiveness of cannabinoids in treating intractable cancer pain has been demonstrated in several subsequent clinical trials of a dosage-controlled sublingual spray.

Several studies have found that cannabinoids have analgesic effects in animal models, sometimes equivalent to codeine.<sup>39-43</sup> Cannabinoids also seem to synergize with opioids, which often lose their effectiveness as patients build up tolerance. One study found morphine was 15 times more active in rats with the addition of a small dose of THC. Codeine was enhanced on the order of 900 fold.<sup>44</sup> In 1990, researchers conducted a double-blind study comparing the antispasmodic and analgesic effects of THC, oral Codeine, and a placebo on a single patient suffering from a spinal cord injury.<sup>45</sup> Their findings confirmed the analgesic effects of THC being "equivalent to codeine." A 1997 study made similar findings related to morphine.<sup>46</sup>

A 1999 article reviewing the body of scientific animal research concerning the analgesic effects of marijuana concludes that "[t]here is now unequivo-

cal evidence that cannabinoids are antinociceptive [capable of blocking the appreciation or transmission of pain] in animal models of acute pain."<sup>47</sup>

The report further notes that multiple cannabinoids and noncannabinoid components can serve as anti-inflammatory agents, and so have potential in preventing and reducing pain caused by swelling (such as arthritis).

In short, the research community recognizes the potential benefits of cannabis for certain patients, including:

- Chemotherapy patients, especially those being treated for mucositis, nausea, and anorexia.
- Postoperative pain patients (using cannabinoids as an opioid adjunct to reduce the nausea and vomiting).
- Patients with spinal cord injury, peripheral neuropathic pain, or central post-stroke pain.
- Patients with chronic pain and insomnia.
- AIDS patients with cachexia, AIDS neuropathy, or any significant pain.

Britain's House of Lords reached similar conclusions and called for making cannabis available by prescription.<sup>48</sup>

# How cannabis compares to other medications

According to the Institute of Medicine, "All of the currently available analgesic (pain-relieving) drugs have limited efficacy for some types of pain. Some are limited by dose-related side effects and some by the development of tolerance or dependence."

The opioid analgesics commonly used to combat pain include **codeine** (Dolacet, Hydrocet, Lorcet, Lortab, Vicodin); **morphine** (Avinza, Oramorph); **oxycodone** (Oxycontin, Roxicodone, Percocet, Roxicet); **propoxyphene** (Darvon, Darvocet) and **tramadol** (Ultram, Ultracet). These medicines can cause psychological and physical dependence, as well as constipation, dizziness, lightheadedness, mood changes, nausea, sedation, shortness of breath and vomiting. Taking high doses or mixing with alcohol can slow down breathing, a potentially fatal condition.

In addition, patients in pain are often prescribed muscle relaxants such as Robaxin and Flexeril; anti-anxiety agents like Valium, Sinequan, Vistaril, Ativan and Xanax; hypnotics such as Halcion, Restoril, Chloralhydrate, Dalmane and Doral and antiemetics like Zofran, Compazine, Phenergan, Tigan and Marinol.

**Robaxin's** side effects include abnormal taste, amnesia, blurred vision, confusion, dizziness, drop in blood pressure and fainting, drowsiness, fever, flushing, headache, hives, indigestion, insomnia, itching, light-headedness, nasal congestion, nausea, pinkeye, poor coordination, rash, seizures, slowed heartbeat, uncontrolled eye movement, vertigo, vomiting and yellow eyes and skin.

Flexeril can cause abnormal heartbeats, aggressive behavior, agitation, anxiety, bloated feeling, blurred vision, confusion, constipation, convulsions, decreased appetite, depressed mood, diarrhea, difficulty falling or staying asleep, difficulty speaking, disorientation, double vision, excitement, fainting, fatigue, fluid retention, gas, hallucinations, headache, heartburn, hepatitis, hives, increased heart rate, indigestion, inflammation of the stomach, itching, lack of coordination, liver diseases, loss of sense of taste, low blood pressure, muscle twitching, nausea, nervousness, palpitations, paranoia, rash, ringing in the ears, severe allergic reaction, stomach and intestinal pain, sweating, swelling of the tongue or face, thirst, tingling in hands or feet, tremors, unpleasant taste in the mouth, urinating more or less than usual, vague feeling of bodily discomfort, vertigo, vomiting, weakness, and yellow eyes and skin.

The newer antiemetics, **Anzamet**, **Kytril** and **Zofran**, are serotonin antagonists, blocking the neurotransmitter that sends a vomiting signal to the brain. Rare side effects of these drugs include fever, fatigue, bone pain, muscle aches, constipation, loss of appetite, inflammation of the pancreas, changes in electrical activity of heart, vivid dreams, sleep problems, confusion, anxiety and facial swelling.

**Regian**, a substituted benzamide, increases emptying of the stomach, thus decreasing the chance of developing nausea and vomiting due to food remaining in the stomach. When given at high doses, it blocks the messages to the part of the brain responsible for nausea and vomiting. Side effects include sleepiness, restlessness, diarrhea and dry mouth. Rarer side effects are rash, hives and decreased blood pressure

**Haldol** and **Inapsine** are tranquilizers that block messages to the part of the brain responsible for nausea and vomiting. Possible side effects include decreased breathing rate, increased heart rate, decrease in blood pressure when changing position and, rarely, change in electrical activity of the heart.

**Compazine** and **Torecan** are phenothiazines, the first major anti-nausea drugs. Both have tranquilizing effects. Common side effects include dry mouth and constipation. Less common effects are blurred vision, restlessness, involuntary muscle movements, tremors, increased appetite, weight gain, increased heart rate and changes in electrical activity of heart. Rare side effects include jaundice, rash, hives and increased sensitivity to sunlight.

**Benadryl**, an antihistamine, is given along with Reglan, Haldol, Inapsine, Compazine and Torecan to counter side effects of restlessness, tongue protrusion, and involuntary movements. Its side effects include sedation, drowsiness, dry mouth, dizziness, confusion, excitability and decreased blood pressure.

Benzodiazepine drugs Ativan and Xanax are prescribed to combat the anxi-

ety associated with chronic pain. Ativan causes amnesia. Abruptly stopping the drug can cause anxiety, dizziness, nausea and vomiting, and tiredness. It can cause drowsiness, confusion, weakness, and headache when first start-

ing the drug. Nausea, vomiting, dry mouth, changes in heart rate and blood pressure, and palpitations are possible side effects.

**Cannabis:** By comparison, the side effects associated with cannabis are typically mild and are classified as "low risk." Euphoric mood

#### AMERICAN ACADEMY OF FAMILY PHYSICIANS

"The American Academy of Family Physicians [supports] the use of marijuana ... under medical supervision and control for specific medical indications."

1996-1997 AAFP Reference Manual

changes are among the most frequent side effects. Cannabinoids can exacerbate schizophrenic psychosis in predisposed persons. Cannabinoids impede cognitive and psychomotor performance, resulting in temporary impairment. Chronic use can lead to the development of tolerance. Tachycardia and hypotension are frequently documented as adverse events in the cardiovascular system. A few cases of myocardial ischemia have been reported in young and previously healthy patients. Inhaling the smoke of cannabis cigarettes induces side effects on the respiratory system. Cannabinoids are contraindicated for patients with a history of cardiac ischemias. In summary, a low risk profile is evident from the literature available. Serious complications are very rare and are not usually reported during the use of cannabinoids for medical indications.

#### Is cannabis safe to recommend?

"The smoking of cannabis, even long term, is not harmful to health...." So began a 1995 editorial statement of Great Britain's leading medical journal, The Lancet. The long history of human use of cannabis also attests to its safety—nearly 5,000 years of documented use without a single death. In the same year as the Lancet editorial, Dr. Lester Grinspoon, a professor emeritus at Harvard Medical School who has published many influential books and articles on medical use of cannabis, had this to say in an article in the Journal of the American Medical Association (1995):

"One of marihuana's greatest advantages as a medicine is its remarkable safety. It has little effect on major physiological functions. There is no known case of a lethal overdose; on the basis of animal models, the ratio of lethal to effective dose is estimated as 40,000 to 1. By comparison, the ratio is between 3 and 50 to 1 for secobarbital and between 4 and 10 to 1 for ethanol. Marihuana is also far less addictive and far less subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics. The chief legitimate concern is the effect of smoking on the lungs. Cannabis smoke carries even more tars and

other particulate matter than tobacco smoke. But the amount smoked is much less, especially in medical use, and once marihuana is an openly recognized medicine, solutions may be found; ultimately a technology for the inhalation of cannabinoid vapors could be developed."49

The technology Dr. Grinspoon imagined in 1995 now exists in the form of "vaporizers," (which are widely available through stores and by mail-order) and recent research attests to their efficacy and safety. Additionally, pharmaceutical companies have developed sublingual sprays and tablet forms of the drug. Patients and doctors have found other ways to avoid the potential



Angel Raich using a vaporizer

problems associated with smoking, though long-term studies of even the heaviest users in Jamaica, Turkey and the U.S. have not found increased incidence of lung disease or other respiratory problems.

A decade-long study of 65,000 Kaiser-Permanente patients comparing cancer rates among nonsmokers, tobacco smokers, and cannabis smokers found that those who used only cannabis had a slightly lower risk of lung and other cancers as compared

to non-smokers.<sup>51</sup> Similarly, a study comparing 1,200 patients with lung, head and neck cancers to a matched group with no cancer found that even those cannabis smokers who had consumed in excess of 20,000 joints had no increased risk of cancer.<sup>52</sup>

As Dr. Grinspoon notes, "the greatest danger in medical use of marihuana is its illegality, which imposes much anxiety and expense on suffering people, forces them to bargain with illicit drug dealers, and exposes them to the threat of criminal prosecution." This was the same conclusion reached by the House of Lords report, which recommended rescheduling and decriminalization.

#### **Cannabis or Marinol?**

Those committed to the prohibition on cannabis frequently cite Marinol, a Schedule III drug, as the legal means to obtain the benefits of cannabis. However, Marinol, which is a synthetic form of THC, does not deliver the same therapeutic benefits as the natural herb, which contains at least 100 cannabinoids in addition to THC. Recent research conducted by GW Pharmaceuticals in Great Britain has shown that Marinol is simply not as effective for pain management as the whole plant; a balance of cannabinoids, specifically CBC and CBD with THC, is what helps patients most. In

fact, Marinol is not labeled for pain, only appetite stimulation and nausea control. But studies have found that many severely nauseated patients experience difficulty in getting and keeping a pill down, a problem avoided with inhaled cannabis.

Clinical research on Marinol vs. cannabis has been limited by federal restrictions, but a 2001 review of clinical trials conducted in the 70's and 80's reports that "...the inhalation of THC appears to be more effective than the oral route." Additionally, patients frequently have difficulty getting the right dose with Marinol, while inhaled cannabis allows for easier titration and avoids the negative side effects many report with Marinol. As the House of Lords observed, "Some users of both find cannabis itself more effective."

#### THE EXPERIENCE OF PATIENTS

# **Angel McClary Raich**

I have been permanently disabled since September 1995. I am a mother of two teenage children. My children know more than anyone how medical cannabis brought their mommy back to them. The hardest part of being disabled is watching the suffering in your children's eyes as they watch you endure such suffering with no end in sight.

In late 1997, my doctor felt cannabis would be an effective medication to treat my many complicated and complex medical conditions. I was in a wheelchair from January 1996 to August 1999. Cannabis was responsible for getting me out of my wheelchair and restoring mobility on the whole right side of my body. For years I felt as if I was suffering in Hell. What I had to endure was unbelievable and indescribable torture.

I suffer greatly from severe chronic pain every single day. The prolonged pain and suffering from my medical conditions significantly interferes with my quality of life. My treatment is complicated by the fact that I am violently allergic and have severe multiple chemical sensitivities to almost all pharmaceutical medicines. This interferes with the treatment of all of my medical conditions, and it means my suffering cannot be controlled by synthetic medications. This makes it extremely difficult for doctors to effectively help me combat my diseases. Without cannabis my life would be a death sentence.<sup>54</sup>

# **Dorothy Gibbs**

In 1911, at the age of one, I contracted the polio virus. . . The early onset of polio caused permanent damage in my legs, spine, and back, resulting in significant weakness and atrophy in my legs. As a result, I have never been able to walk without the assistance of crutches and braces or a wheelchair. Approximately 30 years ago, my condition began to deteriorate. I began to

suffer from increasing levels Angel Raich using a vaporizer in the hospital of pain and weakness in my legs and back as well as severe osteoarthritis in my hands, arms, and joints. Over time, my deteriorating medical condition has been exacerbated by my pain, leaving me increasingly immobilized....

By May, 1996, my physician [Dr. Arnold Leff, M.D.] had tried various prescription medications to relieve my pain, including: Tylenol #3, Ultram, Daypro, Tegretol, Soma, Valium, steroid injections into the trigger point, Dilantin, Duragesic, Zofran and Comapazine for the nausea caused by the opioid

#### AMERICAN NURSES ASSOCIATION

In 2003 the American Nurses Association passed a resolution that supports those health care providers who recommend medicinal use, recognizes "the right of patients to have safe access to therapeutic marijuana/cannabis," and calls for more research and education, as well as a rescheduling of marijuana for medical use.

pain relievers, and Doloboid and Lodine as nonsteroids. Nothing seemed to work, and the pain persisted. I was growing increasingly depressed by the inability of anything to relieve my pain....

During this period it was clear to me, my caretaker, and my physician that nothing was working to combat my pain. My caretaker, Pat, had heard of the success some people experience with the

medicinal use of marijuana for pain management. Sometime during the end of 1997, she obtained a sample for me. Although I had never used marijuana in my previous eighty-seven years of life, I was willing to try anything that could alleviate even part of the pain.

The relief I experienced from medical marijuana was almost immediate. I was so pleased with the result that I wrote to Dr. Leff about my use of medical marijuana and we talked about the benefits of the medicine. Dr. Leff examined me and noted that medical marijuana helped me experience less chronic pain and nausea, leading him to recommended medical marijuana as part of my daily pain care regimen....

I strongly feel that I should have the right to use anything that may relieve any or some of my pain, and my last days should not be spent suffering. In 1998, around the time that I had to stop using the Duragesic patch, Dr. Leff prescribed 5 milligram tablets of Marinol, to be taken as needed, for pain management. He explained that Marinol was like marijuana, which I was already using on occasion. Although Marinol provided me with some minor relief from muscle spasms and bodily pains, its effect was slow and unpredictable.... At times, however, I am stricken with severe spasms of pain, and medical marijuana is the only medication that provides quick and effective relief.... Medical marijuana also combats the nausea that accompanies many of the oral medications I am prescribed, including anti-inflammatory medications such as Motrin.

Ever since trying medical marijuana, my life has drastically improved. Although chronic pain, related to my post-polio syndrome will always

be a part of my life, medical marijuana had helped me manage this pain by providing fast and effective relief for my muscle spasms, acute pains, and arthritis....

Since I began using medical marijuana, my pain is no longer persistent or debilitating. When I do suffer from pain, I am usually able to "get ahead of it" by using medical marijuana and make it manageable....<sup>55</sup>

## **James Daniel Baehr**

In 1994, I was diagnosed with inoperable prostate cancer.... the cancer had metastasized to my spine, hips, and ribcage. The neuropathic back pain was excruciating, emanating from my spine to my hips and ribcage. I also experienced an overall loss of strength that substantially limited my ability to work. Employment in the transportation industry involves a considerable amount of carrying, lifting, and other manual labor that requires flexibility and mobility. The performance of these requirements exacerbated the magnitude and amount of pain I experienced on a daily basis and depleted any energy that had not already been beaten down by the disease itself.

I began taking numerous medications to treat the cancer, the excruciating pain that it caused, and the depression I felt as a result of my prognosis and the profound restrictions on my life. My medications included a daily dosage of 7.5 mg of Lortab (a painkiller), .25 mg of Xanax (which combats depression and anxiety), 40 mg of Paxil (an anti-depressant), and 250 mg of Eulexin (which treats the cancer by reducing the testosterone emitted from adrenal glands), and monthly shots of 7.5 mg of Lupron Depot (a testosterone blocker/hormonal therapy). I suffered various side effects from these medications, including persistent exhaustion, general pain, a lack of mental focus, and overall body tenderness. In combination, these side effects were quite debilitating....

From September through December of 1995, I endured nine weeks of radiation. The treatment left me with continued back pain, intense nausea, loss of appetite, diverticulitis, sleep abnormalities, and digestive and intestinal complications. It also left me increasingly depressed.

In late 1994 or 1995, a physician at the Radiology Department at Stanford University Hospital prescribed Marinol to alleviate my pain and nausea from the radiation. I tried the Marinol but did not respond well to it. Not only did Marinol make me feel drugged and not in control of my thoughts or body, but it failed to relieve my painful symptoms. In fact, Marinol just made me feel sicker, upsetting my stomach, disrupting my mental acuity, and causing me to hallucinate. During this period, I was also taking 7.5 mg of Lortab, an opioid analgesic, several times a day and Ambien to help me sleep. These drugs alleviated the pain somewhat, but also made me disoriented, constipated, and caused me to lose my short-term memory and fine motor skills.

Perhaps sensing that my hope was receding as my misery was increasing, a nurse at Stanford Hospital suggested that medical marijuana could alleviate my nausea, restore my appetite, and even help me manage my pain - all potentially without the negative side effects I experienced with Marinol and other medications..

I decided to try a small amount of medical marijuana, and when I did I found that it provided significant relief from the side effects of the cancer medications and the radiation treatment. In addition, it helped reduce the pain I was experiencing from the cancer itself. This new combination of therapies, which included medical marijuana, turned my health around. Where before I had been doubled over with nausea, couldn't eat, or sleep, I was now not only able to handle my medications, but could sleep, eat and manage my pain. I found that a small amount of medical marijuana taken in the evening enabled me to sleep through the entire night so that I no longer needed to take Ambien.

Over time, the pain got progressively worse. In February 1997 I began to take morphine to help with the pain. The amount of morphine that I need to take to adequately control my pain leaves me utterly incapacitated, mentally and physically. Medical marijuana helps me manage my pain, while limiting my dependence on more powerful narcotics.

When I smoke medical marijuana, I can achieve the same degree of pain relief with a much smaller amount of morphine and with far fewer and less harsh side effects. The coupling of medical marijuana with my prescription analgesics has been one of the most significant and successful aspects of my medical treatment.<sup>56</sup>

#### THE EXPERIENCE OF DOCTORS

# Dr. Harvey L. Rose

Both my research and my many years as a clinician have convinced me that marijuana can serve at least two important roles in safe and effective pain management. Ample anecdotal evidence and clinical observations, as well as significant research findings, strongly indicate that marijuana, for whatever reason, is often effective in relieving pain. This is true across a range of patient populations, including the elderly, the terminally ill seeking comfort in their final days, young adults stricken with life-threatening conditions, and cancer patients unable to tolerate the devastating effects of potentially life-saving therapies. Marijuana is also widely recognized as an antiemetic that reduces the nausea and vomiting often induced by powerful opioid analgesics prescribed for chronic, severe pain, as well as the nausea, vomiting and dizziness which often accompany severe and/or prolonged pain. I have had the benefit of consultations on this subject over many years with a range of treatment providers, including physicians, oncologists, pharmacolo-

gists, family practitioners, hospice workers, and pain specialists....

Specifically, I have found that cannabis can have an important opioid-sparing effect for pain patients. That is to say that patients who are prescribed high doses of opioid analgesics can significantly reduce their reliance on

these medications and improve their daily functioning by incorporating cannabis into their pain care regimen.

Marijuana not only has important analgesic properties but it also is an effective and important adjuvant therapy for patients suffering acute and/or chronic pain. No experienced and respected physician will deny that for such patients opioid therapy is central to palliative care. By the same token, the same experienced physicians will readily acknowledge that opioids often induce nausea and vom-

#### **NEW ENGLAND JOURNAL OF MEDICINE**

"A federal policy that prohibits physicians from alleviating suffering by prescribing marijuana to seriously ill patients is misguided, heavy-handed, and inhumane.... It is also hypocritical to forbid physicians to prescribe marijuana while permitting them to prescribe morphine and meperidine to relieve extreme dyspnea and pain...there is no risk of death from smoking marijuana.... To demand evidence of therapeutic efficacy is equally hypocritical"

Jerome P. Kassirer, MD, editor N Engl J Med 336:366-367, 1997

iting. For a number of pain patients, standard prescription antiemetics (e.g., Compazine, Zofran and Reglan) simply do not substantially reduce their nausea. For many, those medications are substantially less effective, or produce more debilitating side effects, than marijuana....

Quite simply, marijuana can serve much the same function for pain patients undergoing opiate therapy that it does for cancer patients undergoing chemotherapy: it suppresses the nausea and vomiting associated with treatment, and reduces the pain associated with prolonged nausea and retching, thereby increasing the chances that the patient will remain compliant with the primary treatment. With both chemotherapy and long-term pain management, failure to obtain and continue proper palliative and adjutant care can have dire, even fatal, consequences....

Finally, it is important to note that in my clinical experience observing patients who ingest cannabis for relief from pain and nausea and/or to stimulate appetite, I have witnessed no adverse complications. By contrast, many of the first-line pharmaceuticals used to combat cancer, HIV/AIDS, and pain associated with these and other illnesses can induce a variety of iatrogenic effects, including, in some instances, death. While patients may face serious legal implications related to their use of medical marijuana, as a physician I have yet to encounter a medical downside to their cannabinoid therapy....

[A]gainst the backdrop of a growing body of scientific research, the reports

of myriad pain patients, and the burgeoning clinical experience of physicians like myself, it is my considered opinion that cannabis can constitute an acceptable and sometimes necessary medicine to alleviate the immediate suffering of certain patients.<sup>57</sup>

—Dr. Rose served as a medical officer in the Air Force before entering private practice as a specialist on chronic pain. During his 40-year career, he has taught at the UC Davis School of Medicine and consulted with state legislative bodies in California, Idaho, Nevada, Washington and Oregon on pain management and the appropriate role of regulatory agencies.

#### Richard I. Gracer, M.D.

For a small number of patients, even aggressive opiate therapies are not sufficient. Unless alternative pain treatments are found for such patients, they will continue to suffer. For those individuals, their daily lives are often tortuous. As a physician, I am acutely aware of the disturbing connection between intractable pain, overwhelming despair, and suicide.

I can state confidently, as a physician with an extensive practice and specialized expertise in pain management, that marijuana can prove (and has proven) medically useful to at least some chronic pain patients. Accordingly, I believe that physicians should be able to recommend and/or prescribe marijuana to patients for whom it is medically appropriate. Absent that authority, my ability to treat my patients and provide relief from horrific pain is undermined, as is the trust essential to therapeutic relationship.

—Dr. Gracer is Director of Orthopedic Medicine for ChiroView. He is a Fellow of the American Academy of Family Physicians and a Diplomate of the American Academy of Pain Management.

# Robert V. Brody, M.D.

As a physician responsible for the care and treatment of those who live in horrible pain, I believe that these patients need, above all else, the broadest possible range of therapeutic options and as full and accurate information as possible regarding those options as they relate to the individual patient. In recent years, I have noted that the public and the government have become increasingly aware of these needs, and one hopes that measures have been taken to promote adequate pain care for the seriously ill and injured. Several states, including California, have adopted laws and/or guidelines for the prescribing of controlled substances, which seem to permit physicians to treat pain patients without fear of sanction or interference from state authorities.

Insofar as The Compassionate Use Act passed in 1996 expressly provides that chronic pain is a condition for which physicians are authorized to recommend marijuana without threat or fear of punishment, the Act appears to be an additional assurance for physicians like myself that we can rely upon a

full range of treatment modalities to care for patients in pain. The IOM Report provides still further support for doctors insofar as it recognizes the potential medical benefits of marijuana.... Marijuana has a place in any pain physician's armamentarium.<sup>58</sup>

—Dr. Brody is Chief of the Pain Consultation Clinic at San Francisco General Hospital. He is a peer reviewer for the Western Journal of Medicine, Journal of General Internal Medicine, Annals of Internal Medicine, and the Journal of Law, Medicine and Ethics.

#### THE HISTORY OF CANNABIS AS MEDICINE

The history of the medical use of cannabis dates back to 2700 B.C. in the pharmacopoeia of Shen Nung, one of the fathers of Chinese medicine. In the west, it has been recognized as a valued, therapeutic herb for centuries. In 1823, Queen Victoria's personal physician, Sir Russell Reynolds, not only prescribed it to her for menstrual cramps but wrote in the first issue of The Lancet, "When pure and administered carefully, [it is] one of the of the most valuable medicines we possess." <sup>59</sup>

The American Medical Association opposed the first federal law against cannabis with an article in its leading journal. Their representative, Dr. William C. Woodward, testified to Congress that "The American Medical Association knows of no evidence that marihuana is a dangerous drug," and that any prohibition "loses sight of the fact that future investigation may show that there are substantial medical uses for Cannabis." Cannabis remained part of the American pharmacopoeia until 1942 and is now available by prescription in the Netherlands and Canada.

# **Federal Policy is Contradictory**

Federal policy on medical cannabis is filled with contradictions. Cannabis was widely prescribed until the turn of the century. Now cannabis is a Schedule I drug, classified as having no medicinal value and a high potential for abuse, yet its most psychoactive component, THC, is legally available as Marinol and is classified as Schedule III. But the U.S. federal government also grows and provides cannabis for a small number of patients today.

In 1976 the federal government created the Investigational New Drug (IND) compassionate access research program to allow patients to receive medical cannabis from the government. The application process was extremely complicated, and few physicians became involved. In the first twelve years the government accepted about a half dozen patients. The federal government approved the distribution of up to nine pounds of cannabis a year to these patients, all of whom report being substantially helped by it.

In 1989 the FDA was deluged with new applications from people with AIDS, and 34 patients were approved within a year. In June 1991, the Public Health Service announced that the program would be suspended because it undercut the administration's opposition to the use of illegal drugs. The program was discontinued in March 1992 and the remaining patients had to sue the federal government on the basis of "medical necessity" to retain access to their medicine. Today, a few surviving patients still receive medical cannabis from the federal government, grown under a doctor's supervision at the University of Mississippi and paid for by federal tax dollars.

Despite this successful medical program and centuries of documented safe use, cannabis is still classified in America as a Schedule I substance. Healthcare advocates have tried to resolve this contradiction through legal and administrative channels. In 1972, a petition was submitted to reschedule cannabis so that it could be prescribed to patients. The DEA stalled hearings for 16 years, but in 1988 their chief administrative law judge, Francis L. Young, ruled that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known... It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance."

The DEA refused to implement this ruling based on a procedural technicality and continues to classify cannabis as a substance with no medical use.

# Widespread public support; state laws passed

Public opinion is clearly in favor of ending the prohibition of medical cannabis and has been for some time. A CNN/Time poll in November 2002 found that 80% of Americans support medical cannabis. The AARP, the national association whose 35 million members are over the age of fifty, released a national poll in December 2004 showing that nearly two-thirds of older Americans support legal access to medical marijuana. Support in the West, where most states that allow legal access are located, was strongest, at 82%, but at least 2 out of 3 everywhere agreed that "adults should be allowed to legally use marijuana for medical purposes if a physician recommends it."

The refusal of the federal government to act on this support has meant that patients have had to turn to the states for action. Since 1996, 15 states have removed criminal penalties for their citizens who use cannabis on the advice of a physcian. Voters have passed medical cannabis ballot initiatives in 10 states plus the District of Columbia, while the legislatures in Hawaii, Maryland, New Jersey, New Mexico, Rhode Island, and Vermont and have enacted similar bills. Approximately one third of the U.S. population resides in a state that permits medical use, and medical cannabis legislation is introduced in more states every year.

Currently, laws that effectively remove state-level criminal penalties for growing and/or possessing medical cannabis are in place in Alaska, Arizona, California, Colorado, Hawaii, Maine, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, Washington, and the District of Columbia. Maryland has reduced the criminal penalty for medical use to a maximum \$100 fine. Thirty-six states have symbolic medical cannabis laws (laws that support medical cannabis but do not provide patients with legal protection under state law).

# 2005 U.S. Supreme Court ruling

In June 2005, the U.S. Supreme Court overturned a decision by a U.S. appeals court (Raich v. Ashcroft) that had exempted medical marijuana from federal prohibition. The 2005 decision, now called Gonzales v. Raich, ruled that federal officials may prosecute medical marijuana patients for possessing, consuming, and cultivating medical cannabis. But courts have found that ruling does not affect individual states' medical marijuana programs, and only applies to prosecution in federal, not state, court.

# **Petitions for legal prescriptions pending**

The federal Department of Health and Human Services (HHS) and the FDA are currently reviewing two legal petitions with broad implications for medical marijuana. The first, brought by ASA under the Data Quality Act, says HHS must correct its statements that there is no medical use for marijuana to reflect the many studies which have found it helpful for many conditions. Acknowledging legitimate medical use would then force the agency to consider allowing the prescribing of marijuana as they do other drugs, based on its relative safety. A separate petition, of which ASA is a co-signer, asks the Drug Enforcement Administration for a full, formal re-evaluation of marijuana's medical benefits, based on hundreds of recent medical research studies and two thousand years of documented human use.

# **Legal Citations**

- 1. See "The Administration's Response to the Passage of California Proposition 215 and Arizona Proposition 200" (Dec. 30, 1996).
- 2. See Conant v. McCaffrey, 172 F.R.D. 681 (N.D. Cal. 1997).
- 3. See id.; Conant v. McCaffrey, 2000 WL 1281174 (N.D. Cal. 2000); Conant v. Walters, 309 F.3d 629 (9th Cir. 2002).
- 4. 309 F.3d 629 (9th Cir. 2002).
- 5. Id. at 634-36.
- 6. Criminal liability for aiding and abetting requires proof that the defendant "insome sort associate[d] himself with the venture, that he participate[d] in it as something that he wishe[d] to bring about, that he [sought] by his action to make it succeed." Conant v. McCaffrey, 172 F.R.D. 681, 700 (N.D. Cal. 1997) (quotation omitted). A conspiracy to obtain cannabis requires an agreement between two or more persons to do this, with both persons knowing this illegal objective and intending to help accomplish it. Id. at 700-01.
- 7. 309 F.3d at 634 & 636.

- 8. Conant v. McCaffrey, 2000 WL 1281174, at \*16 (N.D. Cal. 2000).
- 9. 309 F.3d at 634.
- 10. See id., at 635; Conant v. McCaffrey, 172 F.R.D. 681, 700-01 (N.D. Cal. 1997).

#### **Research Citations**

- 11. Abrams DI et al (2003). Short-Term Effects of Cannabinoids in Patients with HIV-1 Infection: A Randomized, Placebo-Controlled Clinical Trial. Ann Intern Med. Aug 19;139(4):258-66.5.
- 12. Aggrawal S et al. 2009. Medicinal use of cannabis in the United States: historical perspectives, current trends, and future directions. J Opioid Manag. May-Jun;5(3):153-68.
- 13. Russo EB. (2008) Cannabinoids in the management of difficult to treat pain. Therap and Clincial Risk Manag 4(1) 245-259.
- 14.Barnes MP (2006). Sativex: clinical efficacy and tolerability in the treatment of symptoms of multiple sclerosis and neuropathic pain. Expert Opin Pharmacother, 7:607-15.
- 15. Perez J (2006) Combined cannabinoid therapy via an oral mucosal spray. Drugs Today (Barc.), 42:495-501.
- Selvarajah D et al (2010). Randomized placebo-controlled double-blind clinical trial of cannabis-based medicinal product (Sativex) in painful diabetic neuropathy. Diabetes Care. 33(1):128-30.
- 17. Russo 2008. Op cit.
- 18.Dixon WE (1899). The pharmacology of Cannabis indica. BMJ, ii: 1354-1357.
- 19.O'Shaughnessy WB (1838). On the preparations of the Indian hemp, or gunjah (Cannabis indica); their effects on the animal system in health, and their utility in the treatment of tetanus and other convulsive diseases. Transactions of the Medical and Physical Society of Bengal 18; 40: 71-102, 421-61.
- 20.Reynolds JR (1890) Therapeutical uses and toxic effects of Cannabis indica. Lancet, i: 637-638.
- 21. Noyes R et al (1975). The analgesic properties of delta-9-tetrahydrocannabinol and codeine. Clinical Pharmacology and Therapeutics, 18: 84-89.
- 22. Noyes R, Baram D (1974). Cannabis analgesia. Compr. Psychiatry 15: 531.
- 23.Petro D (1980). Marihuana as a therapeutic agent for muscle spasm and spasticity. Psychosomatics 21 81-85.
- 24.El-Mallakh R (1987). Marijuana and migraine. Headache, 27 442-443.
- 25. Holdcroft A et al (1997). Pain relief with oral cannabinoids in familial Mediterranean fever. Anaesthesia, 5 483-486.
- 26.Hall W et al (1994). The Health and Psychological Consequences of Cannabis Use. Canberra, Australian Government Publishing Service.
- 27. Society for Neuroscience Press Conference, October 26, 1997. www.calyx.com/%7Eolsen/MEDICAL/POT/analgesia.html.
- 28. Joy J et al (1999). Marijuana and Medicine: Assessing the Science Base. Washington D.C. National Academy Press.
- 29. Martin-Sanchez E, Toshiaki A., et al (2009) Systematic Review and Meta-analysis of Cannabis Treatment for Chronic Pain. Pain Medicine.
- 30. Ware M, Wang W, Shapiro S, et al (2007). Smoked cannabis for chronic neuropathic pain: results of a pilot study. 17th Annual Symposium on the Cannabinoids. Saint-Sauveur, Quebec, Canada: International Cannabinoid research Society p31.
- 31. Growing L et al (1998). Therapeutic use of cannabis: clarifying the debate. Drug and Alcohol Review. 17 445-452.
- 32. Rahn EJ Hohmann AG. 2009. Cannabinoids as pharmacotherapies for neuropathic pain: from the bench to the bedside. Neurotherapeutics. Oct;6(4):713-37.
- 33. Abrams DI, Jay CA, Shade SB et al (2007). Cannabis in painful HIV-associated senseory neuropathy: a randomized placebo-controlled trial. Neurology, 68:515-21.
- 34. Cookson C (2001). High Hopes for Cannabis to Relieve Pain. British Association

- Science Festival in Glasgow, Financial Times, September 4, at National News pg. 4. 35. Ibid. Russo 2008.
- 36. Gomez MA, Saenz MT et al (1999). Study of the topical anti-inflammaotry activity of achillea ageratum on chronic and acute inflammation models. Z Naturforsch , 54:937-41.
- 37. Barrett ML, Scutt AM et al (1988) Cannaflavin A and B, prenylated flavones from Cannabis Sativa L. Expermentia, 42:452-3.
- 38. Gertsch J. (2008) Anti-inflammatory Xannabinoids in Diet. Communicative & Intergrative Biology 2008 vol.1 issue 1.
- 39.Karst M et al (2003). Analgesic Effect of the Synthetic Cannabinoid CT-3 on Chronic Neuropathic Pain A Randomized Controlled Trial. JAMA. 290:1757-1762.
- 40.Richardson J et al (1998). Cannabinoids Reduce Hyperalgesia and Inflammation via Interaction with Peripheral CB1 Receptors. Pain. 75(1): 111-119.
- 41. Meng I et al (1998). An analgesic circuit activated by cannabinoids. Nature 395 381-383. www.nature.com/cgitaf/DynaPage.taf?file=/nature/journal/v395/n670.../395381a0\_r.htm
- 42. Klarreich E (2001). Cannabis spray blunts pain: Early trials suggest cannabis spritz may give relief to chronic pain sufferers. British Association for the Advancement of Science.
- 43. Callahan R (1998). "How Does Marijuana Kill Pain?" Associated Press, October 4. http://www.mapinc.org/drugnews/v98/n868/a07.html
- 44. Welch SP, Eads M (1999). Synergistic interactions of endogenous opioids and cannabinoid systems. Brain Res. Nov. 27;848 (1-2):183-90.
- 45. Maurer et al. (1990). Delta-9-tetrahydrocannabinol Shows Antispastic and Analgesic Effects in a Single Case Double-Blind Trial. European Archives of Psychiatry and Clinical Neuroscience 240:1-4
- 46. Holdcroft, A., op cit.
- 47. Martin WJ (1999). Basic Mechanisms of Cannabinoid-Induced Analgesia. International Association for the Study of Pain Newsletter, Summer. p. 89.
- 48. House of Lords Select Committee on Science and Technology, "Ninth Report" (1998). London: United Kingdom. Section 5.26.
- 49. Grinspoon L et al. (1995). Marihuana as medicine. A plea for reconsideration. JAMA. 273(23):1875-6.
- 50. Hazekamp A et al (2006). Evaluation of a vaporizing device (Volcano(R)) for the pulmonary administration of tetrahydrocannabinol. J Pharm Sci 95 (6) Apr 24: 1308-1317.
- 51. Sidney S et al (1997). Marijuana Use and Cancer Incidence. Cancer Causes and Control; 8: 722-728.
- 52. Tashkin D (2006). Marijuana Use and Lung Cancer: Results of a Case-Control Study. American Thoracic Society International Conference. May 23, 2006.
- 53. Musty R, Rossi R (2001). Effects of smoked cannabis and oral delta-9-tetrahydrocannabinol on nausea and emesis after cancer chemotherapy: a review of state clinical trials. Journal of Cannabis Therapeutics. 1: 29-56.
- 54. Statement of Angel McClary Raich. From angeljustice.com, website for her suit, Angel McClary Raich, et. al. vs. John Ashcroft, et. al. United States District Court of the North District of California. No. C 02-4872. United States Court of Appeals for the Ninth District. No. 03-15481. Retrieved from http://angeljustice.com/article.php?list=type&type=6.
- 55.Declaration of Dorothy Gibbs. County of Santa Cruz et. al. vs. Ashcroft et. al. United States Court of Appeals for the Ninth District. Retrieved from http://www.santacruzvsashcroft.com/pleadings\_gibbs.htm.
- 56.Declaration of James Daniel Baehr. Ibid. Retrieved from http://www.san-tacruzvsashcroft.com/pleadings\_baehr.htm.
- 57. Declaration of Robert Brody, M.D. Ibid. Retrieved from http://www.santacruzvsashcroft.com/pleadings\_brody.htm.
- 58. Declaration of Harvey L. Rose, M.D. Ibid. Retrieved from http://www.san-tacruzvsashcroft.com/pleadings\_rose.htm.
- 59.Lancet 1; 1823.
- 60.108 J.A.M.A. 1543-44; 1937.

#### **DEA CHIEF ADMINISTRATIVE LAW JUDGE**

Marijuana, in its natural form, is one of the safest therapeutically active substances known... It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance.

The Honorable Francis L. Young, Ruling on DEA rescheduling hearings, 1988

# **ADDITIONAL RESOURCES**

Americans for Safe Access maintains a website with additional resources for doctors and patients. There you will find the latest information on legal and legislative developments, new medical research, and what you can do to help protect the rights of patients and doctors.

With more than 45,000 active members and chapters and affiliates in all 50 states, ASA is the largest national member-based organization of patients, medical professionals, scientists, and concerned citizens promoting safe and legal access to cannabis for therapeutic uses and research.



Advancing Legal Medical Marijuana Therapeutics and Research

**888-929-4367** www.AmericansForSafeAccess.org 1322 Webster Street, Suite 402, Oakland, California 94612

## State of New Jersey PRESCRIPTION BLANK

UNIVERSITY ORT  D. STEPHEN KAYIAROS, M.D.  J. GINO CHIAPPETTA, M.D.  DAVID R. POLONET, M.D.	HOPAEDIC NPI# NPI# NPI#	LIC#	, LLC
LICENSE#		3	
PATIENT ADDRESS		D.O.B.	<u>116</u>
Rofered Maryum	for 1	nedicil	
o clar	P	+	
slp multiple Surgenes	a Her Sh	inck	
SUBSTITUTION PERMISSIBLE	ATURE OF PRESCRIBER	DO NOT SUBSTITUTE	
REFILL TIMES	for each controlled a		ENSUABLE BY LAW

#10

#### State of New Jersey PRESCRIPTION BLANK

UNIVERSITY ORTHOPAEDIC ASSOCIATES, LLC

□ JOHN M. I GINO CHI □ DAVID R.	APPETTA, M	.D.	NPI# NPI# NPI#	LIC# LIC# LIG#		
	4810 B	ELMAR BLVD TEL: 732-9	5 6 1	07753		
	PRESCRIPTION IS NO PRINT ALTERNA					
PATIEI				er i	D.O.B	
ADDRESS					DATE .	(5
		eral				les L
. · · · · · · · · · · · · · · · · · · ·	redica	l more	yums	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		28 5
dhe	to a	hronic 1	lain			
Coll	olly r	nultiple	Injuri	Ls	485	
Form SUBSTITUTION F	heing s	truck by	1 CAR	DO NOT SUBST	TUTE	
DO NOT REFILL		SIGNATURE OF P	RESCRIBER			
	Use a separate i n possessou mom					BIE BY LEW

