MOVEMENT DISORDERS AND MEDICAL CANNABIS

AmericansFor SafeAccess

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:

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.

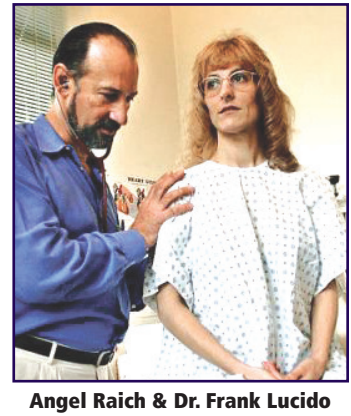
For more information about ASA and the work we do, please see our website at **AmericansForSafeAccess.org** or call **1-888-929-4367**.

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.[1] 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.[2] The federal courts agreed at first the district level,[3] 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 neither punish nor threaten a doctor merely for recommending the use of cannabis to a patient.[5] But it remains illegal for a doctor to "aid and abet" a patient in obtaining cannabis.[6] 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.[7] This is true regardless of whether the physician anticipates that the patient will, in turn, use this recommendation to obtain cannabis.[8] What physicians may not do is actually prescribe or dispense cannabis to a patient[9] or tell patients how to use a written recommendation to procure it from a cannabis club or dispensary.[10] 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.



Angel Raich & Dr. Frank Lucido

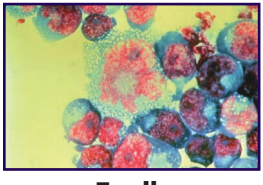
Patients protected under state, not federal, law. In June 2005, the U.S. Supreme Court overturned the Raich v. Ashcroft Ninth Circuit Court of Appeals decision. In reversing the lower court's ruling, Gonzales v. Raich established that it is legal under federal law to prosecute patients who possess, grow, 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, new studies are being published in peer-reviewed journals that demonstrate cannabis has medical value in treating patients with serious illnesses such as AIDS, glaucoma, cancer, multiple sclerosis, epilepsy, 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 been quasi-legal since 1976 and is currently available from pharmacies by prescription.



T cells

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

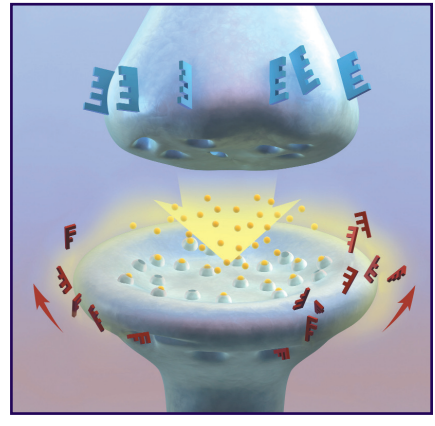
The use of medical cannabis has been endorsed by numerous professional organizations, including the American Academy of Family Physicians, the American Public Health Association, and the American Nurses Association. Its use is supported by such leading medical publications as The New England Journal 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. 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.

In the United Kingdom, GW Pharmaceuticals has been conducting clinical trials with its cannabis-based medicine 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 sclerosis (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.



CB1 receptor

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.

CANNABIS AND MOVEMENT DISORDERS

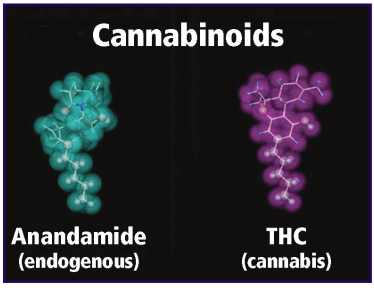
Movement disorders and neurodegenerative diseases, which are sometimes interlinked, are among the many conditions that cannabis and cannabinoids may be particularly well suited to treat.

The therapeutic use of cannabis for treating muscle problems and movement disorders has been known to western medicine for nearly two centuries. In reference to the plant's muscle relaxant and anti-convulsant properties, in 1839 Dr. William B. O'Shaughnessy wrote that doctors had "gained an anti-convulsive remedy of the greatest value."[12] In 1890 Dr. J. Russell Reynolds, physician to Queen Victoria, noted in an article in The Lancet that for "organic disease of a gross character in the nervous centers . . . India hemp (cannabis) is the most useful agent with which I am acquainted."[13]

Muscular spasticity is a common condition, affecting millions of people in the United States. It afflicts individuals who have suffered strokes, as well as those with multiple sclerosis, cerebral palsy, paraplegia, quadriplegia, and spinal cord injuries. Conventional medical therapy offers little to address

spasticity problems. Phenobarbital and diazepam (Valium) are commonly prescribed, but they rarely provide complete relief, and many patients develop a tolerance, become addicted, or complain of heavy sedation. These drugs also cause weakness, drowsiness, and other side effects that patients often find intolerable.

Extensive modern studies in both animals and humans have shown that cannabis can treat many movement disorders affecting older patients, such as tremors and spasticity, because cannabinoids have antispasticity, analgesic, antitremor, and antiataxia properties.[14-25]



In the federal court brief filed in support of physicians' right to recommend cannabis, the American Public Health Association states that "marijuana is effective in treating muscle spasticity." They point out that the government's own Institutes of Medicine report on medical use of cannabis found that "current treatments for painful muscle spasms . . . have only limited effectiveness and their use is complicated by various adverse side effects."

They go on to note that "a survey of British and American MS patients reports that after ingesting marijuana a significant majority experienced substantial improvements in controlling muscle spasticity and pain. An extensive neurological study found that herbal cannabis provided relief from both muscle spasms and ataxia (loss of coordination), a multiple benefit not achieved by any currently available medications" (amicus brief in Conant v. McCaffrey, 2001 filing).

Cannabis also has enormous potential for protecting the brain and central nervous system from the damage that leads to various movement disorders. Researchers have also found that cannabinoids can alleviate the damage caused by strokes, as well as brain trauma, spinal cord injury, and multiple sclerosis. More than 100 research articles have been published on how cannabinoids act as neuroprotective agents to slow the progression of such neurodegenerative diseases as Huntington's, Alzheimer's and particularly Parkinson's, which affects more than 52% of people over the age of 85.

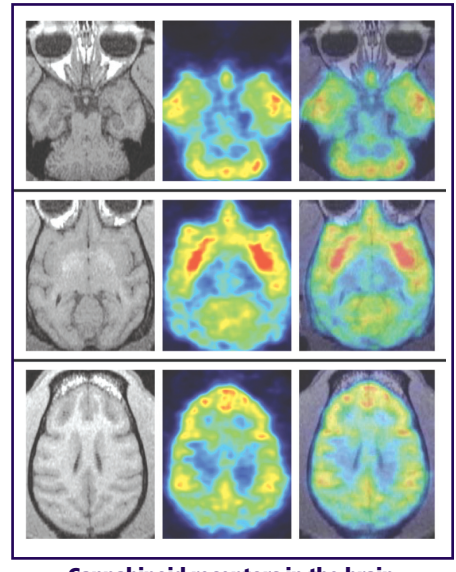
An understanding of the actions of cannabis was spurred by the discovery of an endogenous cannabinoid system in the human body. This system appears to be intricately involved in normal physiology, specifically in the control of movement.[26-30] Central cannabinoid receptors are densely located in the basal ganglia, the area of the brain that regulates body movement.

Endogenous cannabinoids (which are those cannabinoids produced by our

bodies) also appear to play a role in the manipulation of other transmitter systems within the basal ganglia - increasing transmission of certain chemicals, inhibiting the release of others, and affecting how others are absorbed. Research suggests that endogenous cannabinoids play a part in the body's control of movements.[31-35]

Endocannabinoids have paradoxical effects on the mammalian nervous system: sometimes they block neuronal excitability and other times they augment it. As scientists are developing a better understanding of the physiological role of the endocannabinoids, it is becoming clear that these chemicals may be involved in the pathology of several neurological diseases. Researchers are identifying an array of potential therapeutic targets within the human nervous system.

Movement disorders can be chronic disorders which arise from the loss or destruction of neurons and other structures in the brain. nterestingly, the activation of cannabinoid receptors was shown to trigger neuronal growth, suggesting that a role in neuronal regeneration.[36] Various cannabinoids found in the cannabis plant can modulate the synthesis, uptake or metabolism of the endocannabinoids that are involved in the progression of Huntington's disease, Parkinson's disease, multiple sclerosis, and Alzheimer's disease.[37-38]



Cannabinoid receptors in the brain

Parkinson's disease has been linked to dysfunction in the body's dopamine system, specifically the production of too much of the neurotransmitter glutamate and oxidative damage to dopaminergic neurons. Studies have found a tight association between cannabinoids and dopamine, and recent research has produced anatomical, biochemical and pharmacological evidence supporting a role for the endogenous cannabinoid system in the modulation of dopaminergic transmission. Furthermore, the CB1 receptor appears to be deregulated in the basal ganglia of mice with this disease. Specifically, the down regulation of the CB1 receptor may be an early event in the beginning of Parkinson's disease.[39-41] A profound up regulation of the CB1 receptor may occur after Parkinson's symptoms appear,

Oxidative stress in the brain is a major hallmark of motor and neurological diseases such as Parkinson's and Alzheimer's disease. Cannabinoids are able to protect neurons from oxidative damage.[42] The neuroprotective action

of cannabinoids appears to result from their ability to inhibit reactive oxygen species, glutamate, and tumour necrosis factor. THC, CBD, and synthetic AM404 all contain phenolic groups in their chemical structure and are thus able to reduce radical oxygen species. Notably CBD has extraordinary antioxidant properties and can effect Calcium homeostasis, both of which lead to positive effects against a wide range of neurodegenerative diseases.[43]

Few clinical trials have looked at Cannabinoids and Parkinson's disease. However, research has shown that 25% of Parkinson's patients smoke cannabis and 46% of these patients report improvement resulting from side effects of long term levodopa treatment.[44] A randomized placebo controlled study using extracts of cannabis produced significant improvements in patients' cognition. The authors note that they did not see improvements in pain or sleep disorders. They speculate that the oral route (versus inhaled) of cannabis ingestion leads to too much variability of cannabinoids in blood.[45]

Plant cannabinoids, such as CBD have been effective in experimental models of Alzheimer's, Parkinson's, and Huntington's disease. Hence, cannabinods represent an emerging therapeutic option that could be available in the near future. However, cannabinoids are still in an early phase of development but research suggest that they can be useful drugs for the treatment of many disease processes of the brain and central nervous system.

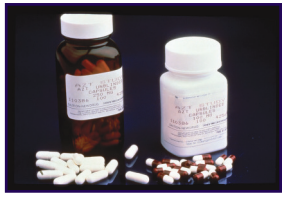
Spasticity and Movement Disorder Medications

Benzodiazepines, levedopa, baclofen, dantrolene sodium, and tizanidine are the most widely used agents for reduction of spasticity. At high dosages, oral medications can cause unwanted side effects that include sedation, as well as changes in mood and cognition.

Benzodiazepines, which include **Diazepam** (Valium) and **Clonazepam** (Klonopin, Rivotril), are centrally acting agents that increase the affinity of GABA to its receptor. Diazepam is the oldest and most frequently used oral agent for managing spasticity. Benzodiazepine side effects include sedation, weakness, hypotension, GI symptoms, memory impairment, incoordination, confusion, depression, and ataxia are possible side effects of. Tolerance and dependency may occur and withdrawal on cessation. Tolerance may also lead to unacceptable dosage escalation.

Levedopa is common long-term treatment option for Parkinson's disease. Long-term use can result in diskynesia and is often a reason for not taking the drug. Diskynesia can lead to less control of voluntary movements and can result in tics or chorea. Dikynesia can result in excessive tongue rolling and after years of use it can manifest as "jerky" movements of the head and arms.

Baclofen (Lioresal) has been widely used for spasticity since 1967. It is a GABA agonist. Tolerance to the medication may develop. Baclofen must be slowly weaned to prevent withdrawal effects such as seizures, hallucinations and increased spasticity. It must be used with care in patients with renal insufficiency as its clearance is primarily renal. Side effects are predominantly from central depressant properties including sedation, ataxia, weakness and fatigue. May cause depression when combined with tizanidine or benzodiazepines.



Dantrolene Sodium (Dantrium) acts peripherally at the level of the muscle fiber and works best for cerebral palsy and traumatic brain injury. Because the action of dantrolene sodium is not selective for spastic muscles, it may cause generalized weakness, including weakness of the respiratory muscles. Side effects include drowsiness, dizziness, weakness, fatigue and diarrhea. In addition, hepatotoxicity (liver damage) occurs in < 1% of patients who take dantrolene sodium.

Tizanidine (Zanaflex) facilitates short-term vibratory inhibition of the H-reflex. Tizanidine in conjunction with baclofen or benzodiazepines has potential additive effects, including sedation and the possibility of liver toxicity. Dry mouth, somnolence, asthenia and dizziness are the most common side effects. Liver function problems and hallucinations may also occur.

How Cannabis Compares

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

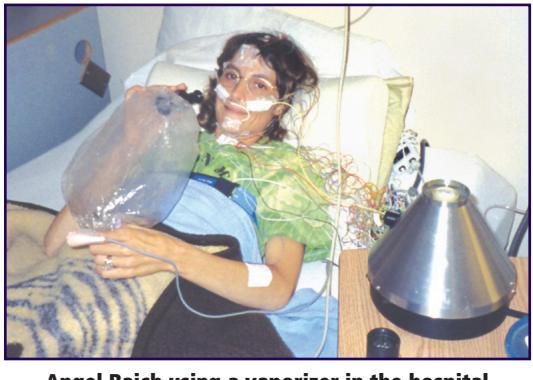
Is cannabis safe to recommend?

"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."

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. [46] Additionally, pharmaceutical companies have developed sublingual sprays and tablet forms of the drug. Patients and doctors have found other ways to avoid the potential 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 non-smokers, 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.[47] 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.[48]



Angel Raich using a vaporizer in the hospital

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 also the conclusion reached by the House of Lords, 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 another 60 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 by use of 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."[49] 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 oberves, "Some users of both find cannabis itself more effective."

THE EXPERIENCE OF PATIENTS

Vollie Rutledge, Jr.

In July of 1990 I was driving home from work and as I came around a corner doing 55 MPH I came into a herd of deer. I tried to miss them but one of them fell down and my right front tire went up on the deer's hip like a ramp. My car flipped over and went down an embankment. It landed on the roof smashing the driver's compartment down to the level of the top of the seat. I didn't have a seat-belt on so I was able to dive into the passenger's floorboard but even that didn't save me.

I woke up in the hospital a couple of days later with a broken vertebra. Medically it was called "an unstable fracture of the second vertebra" or C-2 fracture. Somehow it didn't kill me, but it did paralyze my left side for a couple of weeks. When the feeling came back all of the nerves reacted spastically. If I reached for something I couldn't control where my hand was going. If I sneezed my hand would fly uncontrollably.

Several times I bloodied my nose with my left hand just sneezing. I finally learned to grab my left arm when I sneezed. I couldn't walk without a cane

because I couldn't trust my left leg to go where I wanted it to. It was an extremely difficult time in my life. About two months after the accident my friends had come over to visit and as it happened, I sneezed. My arm came up and hit me in the face and bloodied my nose once again. I was embarrassed to say the least.

One of my friends rolled a joint and something happened... The muscles in my neck relaxed and when I reached for my coffee my arm went where it was supposed to. As long as I moved very slowly, I could move correctly. Within a week I was using my hand to shuffle a deck of cards. I can't explain how dramatic the difference was. I went from not being able to eat with a fork (previously too spastic to grab and hold a fork) to shuffling a deck of cards and dealing them in just one week. Within three weeks I could walk without a cane. Once again I could trust my legs to go where I wanted them. Marijuana is the only drug that any doctor has found, in eight years of trying different drugs, that works.

Anonymous

I work and lead a normal and productive life. I consume very little alcohol, I exercise and eat right. I do not smoke cigarettes. I am involved with my family, the community and participate in fund-raising events to benefit folks internationally. I have a happy, modest family. We gather weekly for activities, food and company. I have a college degree and several certifications in my field. I am a white collar professional. I am an executive for a large financial corporation and I use and grow medical marijuana for the relief of chronic neuro-muscular pain and spasms.

This plant reduces and even stops my chronic muscle spasms as a result of severe neuro-muscular damage from an industrial accident I suffered 12 years ago. In short, I nearly lost my right hand and upper arm in a terrible accident. Surgically my parts were re-attached, however my nerves are to this day temperamental and spastic. There are days my hand is locked in a fist and I am unable to release it. The pain from this literally brings me to my knees.

So called "legal" prescription drugs not only did not work for my condition, they made me very ill, prevented me from being able to do simple things in life like; work, drive, talk, cook, read and even wipe myself. My so called "legal prescriptions" all went into the garbage can where they belong. I no longer care what the propaganda machine says about marijuana anymore. This drug works without all of the undesired side effects.

Anonymous

For years I have suffered with chronic pain and severe muscle spasms due to a hunting accident and surgery on my back. I have taken more medicine than I can remember—over 50 different medicines that I know of—with still no relief for the pain. The only medicine that even came close to helping

the muscle spasms was Valium, but my doctor took me off it for fear I would get hooked. I have been smoking marijuana for many years, and it is the only other drug that has helped me with the spasms.

When a violent spasm in my leg starts coming on, my wife will roll me a joint and within minutes of smoking half of it, the spasms start to dissipate. Before, it could spasm for hours without relief. My question is, why will this drug do this when all of the prescription medicines I have taken will not? Also, I have a medicine pump in my stomach, which was put in this February by a pain clinic doctor. I receive a half a milligram of Dilaudid every fifteen minutes from this pump. The doctor started me out on low doses and is gradually building up, but it still does not in any way compare to the effect from smoking a joint.

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

THE EXPERIENCE OF DOCTORS

Denis Petro, M.D.

As a practicing neurologist, I saw many patients for whom uncontrollable spasticity was a major problem. Unfortunately, there are very few drugs specifically designed to treat spasticity. Moreover, these drugs often cause very serious side effects. …Dantrium or dantrolene sodium carries a boxed warning in the Physician's Desk Reference because of its very high toxicity. …The adverse effects associated with Lioresal Baclofen are somewhat less severe, but include possibly lethal consequences, even when the drug is properly prescribed and taken as directed…. Unfortunately, neither Dantrium or Lioresal are very effective spasm control drugs. Their marignal medical utility, high toxicity, and potential for serious adverse effects, make these drugs difficult to use in spasticity therapy.

[Dr. Petro discussed a patient who was smoking cannabis for his symptoms. Dr. Petro asked him to refrain from smoking for six weeks.]

After six weeks he returned for another examination. At this time, he reported an increase in his symptoms to the point where he had leg pains, increased clonic activity, and uncontrolled leg spasms every night. More disturbing to him was urinary incontinence, which occurred on two occasions during leg spasms. On objective examination….in layman's terms, this patient's spasticity had increased dramatically in six weeks. This spasticity made his legs extremely rigid, he was finding it increasingly difficult to walk or sleep, and he was losing bladder control.

Following our examination, and at the patient's request, he left the clinic then returned one hour later to be examined for a second time. This second examination was remarkable. The earlier findings of moderate to severe spasticity could not be elicited. Deep tendon reflexes were brisk, but without spread, ankle clonus was absent, and the plantar response was flexor on the left and equivocal on the right. In short, this patient had undergone a stunning transformation. Moreover, this unmistakable improvement had occurred in an incredibly brief period of time-less than an hour separated the two examinations. On questioning, the patient informed us he had smoked part of one marijuana cigarette in the interval between examinations.

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

Denis Petro, M.D., Former FDA Review Officer and principal investigator on spasticity and cannabis studies, in testimony submitted before the DEA.

Leo E. Hollister, M.D.

Patients with spinal cord injuries often self-treat their muscle spasticity by smoking cannabis. Cannabis seems to help relieve the involuntary muscle spasms that can be so painful and disabling in this condition. A muscle relaxant or antispastic action of THC was confirmed by an experiment in which p.o. doses of 5 or 10 of THC were compared with placebo in patients with multiple sclerosis. The 10 mg of THC reduced spasticity by clinical measurment. Such single small studies can only point to the need for more study of the potential use of THC or possibly some of its homologs. Diazepam, cyclobenzaprine, baclofen, and dantrolene, which are used as muscle relaxants, all have major limitations. A new skeletal muscle relaxant would be most welcome.

Leo E. Hollister, Veterans Administration Medical Center and Stanford University School of Medicine, Palo Alto, California

Lester Grinspoon, M.D.

There are many case reports of marihuana smokers using the drug to reduce pain: post-surgery pain, headache, migraine, menstrual cramps, and so on. Ironically, the best alternative analgesics are the potentially addictive and lethal opioids. In particular, marihuana is becoming increasingly recog-

nized as a drug of choice for the pain that accompanies muscle spasm, which is often chronic and debilitating, especially in paraplegics, quadriplegics, other victims of traumatic nerve injury, and people suffering from multiple sclerosis or cerebral palsy. Many of them have discovered that cannabis not only allows them to avoid the risks of other drugs, but also reduces muscle spasms and tremors; sometimes they can even leave their wheelchairs.

The years of effort devoted to showing that marihuana is exceedingly dangerous have proved the opposite. It is safer, with fewer serious side effects, than most prescription medicines, and far less addictive or subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics.

Thus cannabis should be made available even if only a few patients could get relief from it, because the risks would be so small. For example, as I mentioned, many patients with multiple sclerosis find that cannabis reduces their muscle spasms and pain. A physician may not be sure that such a patient will get more relief from marihuana than from the standard drugs baclofen, dantrolene, and diazepam—all of which are potentially dangerous or addictive—but it is almost certain that a serious toxic reaction to marihuana will not occur. Therefore the potential benefit is much greater than any potential risk.

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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." (Lancet 1; 1823).

The American Medical Association opposed the first federal law against cannabis with an article in its leading journal (108 J.A.M.A. 1543-44; 1937). 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 available by prescription in the Netherlands and Canada.

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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 helped by it substantially.

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.

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

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 according to numerous legal opinions, 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).

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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.

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rev. Feb 2011