MULTIPLE SCLEROSIS AND MEDICAL CANNABIS



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:

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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**.

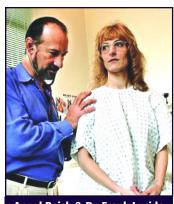
Is Cannabis Legal to Recommend?

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 nei-

ther 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 patient⁹



Angel Raich & Dr. Frank Lucido

or 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, 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 it has been quasi-legal since 1976 and is 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.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 with 50 members; as of 2010, there are nearly 500 around the world. The International Association for Cannabis as Medicine (IACM), founded in March 2000, publishes a bi-weekly bulletin and holds international symposia 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.

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

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

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 MULTIPLE SCLEROSIS

An estimated 350,000 people in the United States are living with multiple sclerosis (MS), a debilitating and sometimes fatal disorder of the central nervous system. MS is the most common debilitating neurological disease of young people, often appearing between the ages of 20 and 40, affecting more women than men. Current treatment of MS is primarily symptomatic, focusing on such problems as spasticity, pain, fatigue, bladder problems and depression.

MS is a disease of the central nervous system (CNS) that manifests due to the immune system attacking the myelin of neurons and dendrites. As the disease progresses, normal neurotransmission is inhibited and such additional symptoms develop as: pain, spasms, spasticity, limb tremor, fatigue, and incontinence. All of the disease symptoms have a large negative impact on the quality of life of MS patients. MS most frequently presents at onset as a relapsing and remitting disorder, where symptoms come and go.

MS exacerbations appear to be caused by abnormal immune activity that causes inflammation and the destruction of myelin (the protective covering

of nerve fibers) in the brain or spinal cord. After repeated attack from the immune system, nerves lose plasticity, which creates stress in nerve tissue. This stress leaves nerve tissue vulnerable to progressive damage and death.

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.

Although symptom-specific treatments exist, these are often associated with adverse side effects. This has prompted many people who suffer from MS to seek alternative therapies. Cannabinoids, the active ingredients in cannabis, have demonstrated the ability to control aspects of MS disease progression

Anecdotal reports on the self medication of cannabis to treat

MS are supported by recent advances in the understanding of the biology of cannabis and the cannabinoid receptors.¹²⁻¹³ Controlled studies have found that cannabis and cannabinoids can control such symptoms as pain, spasms, spasticity, and incontinence.

The leading effects of prolonged neurodegeneration in MS cause permanent disabilities. This neurodenergation has yet to be effectively treated. Initial neurodegeneration occurs with inflammation, cannabis and cannabinoids have been shown to have neuroprotective effects during immune attacks on the CNS.¹⁴⁻¹⁸

Surveys and Clincial Research on Cannabis Use for MS

Numerous case studies, surveys and double-blind studies have reported improvement in patients treated with cannabinoids for symptoms including spasticity, chronic pain, tremor, sexual dysfunction, bowel and bladder dysfunctions, vision dimness, dysfunctions of walking and balance (ataxia), and memory loss.¹⁹⁻²⁷

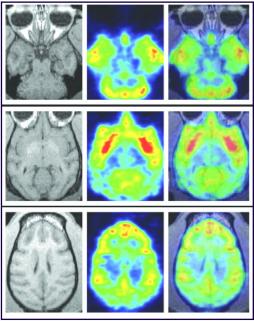
A House of Lords reports states that the British Multiple Sclerosis Society (consisting of some 35,000 MS-suffering patients) estimates that as many as 4% of their population already use cannabis for the relief of their symptoms despite the considerable legal risks associated with prohibition. The chairman of the committee concluded, "We have seen enough evidence to convince us that a doctor might legitimately want to prescribe cannabis to relieve...the symptoms of multiple sclerosis and that the criminal law ought not to stand in the way."

Many of the witnesses for that report shared the British Medical Association's view that "A high priority should be given to carefully controlled trials of cannabinoids in patients with chronic spastic disorders." The

BMA has requested that the synthetic cannabinoids Nabilone and Dronabinol be officially licensed for use in MS and other spastic disorders.

A recent British survey of MS patients found that 43 percent of respondents used cannabis therapeutically. Among them, nearly three quarters said that cannabis mitigated their spasms, and more than half said it alleviated their

pain. A survey published in August 2003 in the Canadian Journal of Neurological Sciences reported that 96 percent of Canadian MS patients believe that cannabis is therapeutically useful for treating the disease. Of those who admitted using cannabis medicinally, the majority found it to be beneficial, particularly in the treatment of chronic pain, spasticity, and depression.28 The accompanying editorial states, "This is an exciting time for cannabinoid research. There is a growing amount of data to suggest that cannabis (marijuana) can alleviate symptoms like muscle spasticity and pain in patients with MS "29



Cannabinoid receptors in the brain

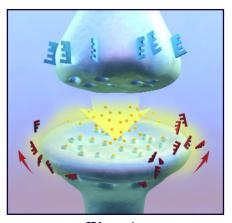
The published results of a number of GW Pharmaceuticals Phase

III studies show that pain relief was significantly superior to placebo and there were subjective improvements in spasm frequency, bladder control, spasticity and sleep. The authors of one such trial concluded that "the results of this study suggest that Sativex® is an effective treatment for spasticity associated with MS." In April 2005, GW announced that it had received approval to distribute Sativex in Canada for the symptomatic relief of neuropathic pain in adults with Multiple Sclerosis.³⁰

A U.K. study published in the journal Lancet looked at 630 multiple sclerosis patients after 15 weeks of orally delivered treatment. Fifty-seven percent of the patients taking a whole cannabis extract said their pain had eased, compared with 50% who took capsules containing THC and 37% who were given placebo capsules. Patients also reported improved sleep and fewer or less intense muscle spasms and stiffness. Those who could walk were significantly more mobile as measured by a walking test. The investigators also noted there were fewer relapses in the treatment groups; however, the study was not designed to investigate impact on relapses.³¹ An accompany-

ing editorial suggests that current data supporting the benefit of cannabinoid treatment of spasticity in MS is now as strong as for any available pharmaceutical agent.³²

Clinical studies on the efficacy of THC to treat MS spasticity demonstrate that tremors and spasms can be inhibited by cannabis through stimulating the CB1 receptor.³³⁻³⁴ Patients also benefit from long-term treatments with THC.³⁵ Pain is a common problem in MS and many patients who report



CB1 receptor

using cannabis say it helps. In clinical trials, an oral cannabis extract was not initially shown not to be effective; however, pain relief became evident after long-term treatment. This may be due to the neuroprotective effects of plant cannabinoids that promote the repair of damaged pathways.³⁶ A large-scale trial on the effects on long-term THC use on the progression of MS is underway and will be complete in 2012.³⁷

In addition to studying the potential role of marijuana and its derivatives in the treatment of MS-related symptoms, scientists are exploring the potential of

cannabinoids to inhibit neurodegeneration. A 2003 study that the American MS Society calls "interesting and potentially exciting" demonstrated that cannabinoids were able to slow the disease process in mice by offering neuroprotection against EAE.³⁸ After analyzing the findings, authors at London's Institute of Neurology concluded, "In addition to symptom management, cannabis may also slow down the neurodegenerative processes that ultimately lead to chronic disability in multiple sclerosis and probably other diseases."³⁹

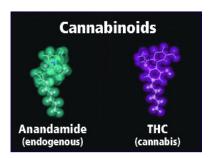
Basic research findings on cannabis and MS

Animal models of MS have greatly expanded our understanding of MS and Cannabinoid biology. A growing body if literature demonstrates that cannabinoids have the potential to measurably lessen MS symptoms and may also halt the progression of the disease.⁴⁰

The distribution of cannabinoid receptors in the brain suggests that they may play a role in movement control. Recently researchers found an animal model for MS, called experimental allergic encephalomyelitits (EAE), allowing testing for symptom suppression. Recent pre-clinical reports found that cannabinoids lessened both tremor and spasticity in mice suffering from EAE.⁴¹

Animal studies in transgenic mice without cannabinoid receptors has shown that the cannabinoid system play an important role in MS. Mice lacking the

cannabinoid type 1 receptor (CB1), experience rapid neurodegenration in a model of MS. FAAH deficient mice have improved recovery from immune attacks. FAAH is an enzyme that works by degrading endocannabinoids, i.e. Anandamide. Without this enzyme animals will have higher levels of endocannabinoids. This work on FAAH deficient mice indicates that Anadamide has neuroprotective functions.



The cannabinoid type 2 (CB2) receptor may control inflammatory events, according to animal models. Mice lacking the CB2 receptor exhibit increased severity of MS compared to normal mice. It is thought that the CB2 receptor may control the production of inflammatory signals and immune cell migration into tissue.⁴²⁻⁴³

Efficacy and side effects: how cannabis compares

A recent review of all available medications for MS concluded that "forth-coming information relating to the use of cannabinoids in MS may result in there being better evidence of the effectiveness of new treatments than of any of the currently used drugs."⁴⁴

Over 40 medicines are listed by the Multiple Sclerosis Society as commonly used by MS patients. Symptoms and medications prescribed include "acute exacerbations" (Decadron, Solu-Medrol); depression (Effexor, Paxil, Prozac, Wellbutrin, Zoloft); erectile dysfunction (Papaverine, Levitra, MUSE, Prostin VR, Viagra); fatigue (Amantadine, Cylert, Provigil, Prozac); itching (Atarax); nausea (Antivert); pain (Aventyl, Dilantin, Elvail, Neurontin, Gabapentin, Pamelor, Tegretol); urinary tract infections (Bacrtim, Cipro, Hiprex, Macrodantin, Nitrofurantoin, Pyridium); and urinary frequency or bladder dysfunction (DDAVP, Ditropan, Oxytrol, Pro-Banthine, Tofranil). Interferon-based medicines are also prescribed as "disease-modifying agents."

Drugs commonly prescribed for muscle spasticity and tremor include **Klonopin**, **Dantrium**, **Baclofen** (Medtronic), **Zanaflex** and **Valium**. Klonopin (Clonazepam) and Valium (diazepam) are both benzodiazepines, central nervous system (CNS) depressants maufactured by Roche. Overdoses of these medications, especially when taken with alcohol, may lead to unconsciousness and death. They frequently cause people to become drowsy, dizzy, lightheaded, clumsy, or unsteady. Other common side effects include slurred speech; abdominal cramps or pain; blurred vision or other changes in vision; changes in sexual drive or performance; gastrointestinal changes, including constipation or diarrhea; dryness of mouth; fast or pounding

heartbeat; muscle spasm; trouble with urination; trembling. Studies in animals have shown that clonazepam and diazepam can cause birth defects or other problems, including death of the animal fetus. Overuse of clonazepam during pregnancy may cause the baby to become dependent on it and it may pass into breast milk and cause drowsiness, slow heartbeat, shortness of breath, or troubled breathing in nursing babies.

Dantrium is a muscle relaxant manufactured by Proctor & Gamble. It has been shown to cause cancer and non-cancerous tumors in animals, can cause liver damage, and should not be taken with alcohol. Common side effects include diarrhea, dizziness, drowsiness, weakness, nausea, unusual tiredness, abdominal cramps, blurred or double vision, chills and fever; constipation, frequent urination, headache, loss of appetite, speech difficulties, sleep difficulties and nervousness.

Baclofen (Medtronic) may be administered orally or with a surgically implanted pump in the spine. Its side effects include high fever, altered mental status, spasticity that is worse than was experienced prior to starting ITB Therapy, and muscle rigidity. Symptoms of overdose include shortness of breath or troubled breathing, vomiting, seizures, loss of consciousness and coma. Abruptly stopping implanted baclofen has been fatal.

Cannabis: 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. 45 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 decadelong 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. 46 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. 47

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 another 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

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

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."48 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 report states, "Some users of both find cannabis itself more effective."

THE EXPERIENCE OF PATIENTS

Greg Paufler

Some days I would be semi-ambulatory. Most days I was completely bedridden. My eyesight became very blurred and I lost all ability to focus. Unable to walk, read, or be with my family, I became very depressed... One evening some old friends came to visit and we smoked several joints. When my friends got up to leave, I stood up to say goodbye. Everybody in the room suddenly stopped talking and stared at me. At first I could not understand what was wrong. Then I realized I was standing, I had spontaneously stood up, unassisted, as if standing up was a perfectly natural...

I quickly discovered that when I did not smoke marijuana my condition worsened, I suffered more frequent spasms, and the spasms were more intense. When I smoked marijuana my condition stabilized, then dramatically improved. After smoking marijuana my spasms were much more controlled and less severe. Marijuana caused me to feel better. I regained control over my limbs and could walk totally unaided. My vision, often blurred and unfocused, [now] improved. . . .

I do not like breaking the law. I do not like being forced to pay terribly inflated prices for an unregulated, uncontrolled product. I do not like hav-

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ing to purchase marijuana from drug dealers and I do not like having to use marijuana without medical supervision. However, I do like to walk, talk, read, and see. Marijuana allows me to do these simple, human things by controlling the symptoms of my MS. If I am forced to choose between maintaining my health with an illegal drug or obeying the law, I would choose to maintain my health.

—Greg Paufler, May 11, 1987, Testimony submitted to the DEA In the Matter of Marijuana Rescheduling and in Idaho v. Hastings.

B.D.

I was diagnosed with multiple sclerosis in 1988. Prior to that, I was an active person with ballet and swimming. I now have a swimming pool, so I swim each and every day, and smoke marijuana. The government has given me the marijuana to smoke. Each month I pick up a can filled with the marijuana cigarettes rolled by the government.

At one time I weighed 85 lb. and I now weigh 105. Twenty pounds is quite a bit to put on. I could not walk. I did not have the appetite. I use a scooter now for distance. I can get around the house. I have a standard poodle who is kind of like an assistant dog. She is good at it. She helps me.

When I found out that there was a program to get marijuana from the government, I decided that was the answer. I was not a marijuana smoker before that. In fact, I used to consider the people I knew who smoked the marijuana as undesirables. Now, I myself am an undesirable.

But it works. It takes away the backache. With multiple sclerosis, you can get spasms, and your leg will just go straight out and you cannot stop that leg. You may have danced all of your life and put the leg where you wanted it to be, but the MS takes that from you. So I use the swimming pool, and that helps a lot. The kicks are much less when I have smoked a marijuana cigarette. Since 1991, I've smoked 10 cigarettes a day. I do not take any other drugs. Marijuana seems to have been my helper. At one time, I did not think much of the people who smoke it. But when it comes to your health, it makes a big difference.

—B.D. was one of the patients legally allowed to use cannabis as part of the Compassionate IND program.

Nathaniel

I am a patient suffering from multiple sclerosis, and have found amazing amounts of relief from marijuana. I have been through Rebif, Amantadine, Baclofen, Ultram, Provigil, Soma, and Prednisone. All of these medications either provided little or no relief, or had very undesirable side effects for me.

Before learning that I had MS, I had used marijuana maybe 10 times in my whole life. I started using it more regularly, and noticed that I was feeling much better all around when smoking marijuana. I could get around better, I felt better, I was in a better mood, and I ate (something that is often very difficult for me).

Marijuana is now the only medication I am using to treat my condition, and I would be so much less functional without it that I don't know what I would do (or COULD do, for that matter). Being a California resident, I obtained a doctor's recommendation, and am now legal to use medical cannabis in California.

Missi

I had done much research into the helpful benefits of the medicinal use of marijuana, but I did have my doubts since I felt that maybe many of the people who claimed its benefits just really wanted to get 'high'. Well, as God as my witness, (something I don't ever say lightly because I am a bornagain Christian), I was totally amazed at the results.

Everyone around me had witnessed my daily life. They had finally seen first-hand that I had problems just walking across the room. Well, anyway, I smoked a joint with my relative and I am telling you, I was up and about walking everywhere. She has a 3000sq ft house and I walked around it like I was an Olympic athlete. OK, maybe not that great but that is what I felt like. I was happy, moving all over the place, and most importantly I did not need to take my next dosage of Oxycontin! I had no pain at all or any of the associated problems. Not only was I able to go with out that dosage but the next morning dosage as well and I did not experience any withdrawal symptoms either.

I really could not believe it. I had hoped to receive some help but I honestly did not think it would be THAT helpful THAT fast. I was very happy that I had witnesses to this seemingly miraculous recovery. But the sad thing is that I am not using it now and cannot get it. I asked my military Neurologist about medical marijuana and was surprised to hear him say (he is very strict) that if he were not a military doctor that is what he would have me on now. It is safer by far than the other meds I am currently on.

Anonymous

This is just another letter from a fellow MS sufferer vouching for how effective I find cannabis in relieving some of the unpleasant symptoms of MS.

I was first told of the diagnosis of MS in 1991 (on my 35th birthday) this was just a few weeks following an unbelievably acrimonious divorce, my wife having thrown me out claiming that she was sick of me being tired all the

time, and then telling her solicitor that I was a heroin addict, a totally fabricated claim which I, staggering and slurring my speech like a vaudeville drunk, did a very poor job of denying.

Realising that the vicious cycle of anger and frustration in which I found myself caught, was exacerbating my symptoms I decided to try smoking

some pot, after a three year period of abstinence, as to quote Ken Kesey, "it makes you feel pretty philosophical about most things".

I was totally unprepared for the way in which the sensation of 'tight bands and writhing rats' in my legs vanished for the first time in

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

months, as did the pain in my face. Though it did not stop the vertigo, it totally removed the nausea and 'sea sickness' which accompanies it. For the first time in months I slept like a baby, without having to get up and empty my bladder every 2 hours. Though I would not go so far as to say that this was the beginning of my recovery, I would certainly say that it marked the end of my decline!

Anonymous

I was diagnosed as having MS five years ago, when I was 45, and was informed that in my case it would probably just get steadily worse. The forecast proved correct. I had to give up work 2 years ago, and am now confined to a wheelchair. I suffer violent muscle spasms from the waist down, which lock my legs together like magnets, causing increasing pain and discomfort, and I feel as if I have flu permanently.

A year ago a friend showed me an article from the Daily Mail about an MS sufferer who obtained considerable relief from the most distressing symptoms using cannabis, and about her fight to become 'legal' by being prescribed Nabilone. Despite an in built aversion to banned substances, I bowed to family pressure, and have been using it ever since. I find the effects not exactly euphoric, but I can (with concentration) stretch my legs out straight, either sitting on the floor or lying in bed. I can watch TV for a couple of hours without frightening company by snapping myself into a knot while shrieking in pain. I can go on a car journey without fretting about my bladder. I can actually get 3 or 4 hours unbroken sleep sometimes, and more importantly so can my wife. Smoking cannabis is not a problem for me as I roll my own anyway. The main thing is, it works—as a muscle relaxant, a tranquilliser, whatever.

John E. Precup

I was diagnosed with secondary-progressive multiple sclerosis in 1986, after waking up on the morning of April 5th with the worst case of the "bed spins" imaginable. I was unable to keep anything down, even water. On April 6th I was admitted to the hospital for a seven-day stay during which the 'spinning' continued for six days straight.

When I was sent home, the dizziness had subsided a little, but I still could not function well at all. My neurologist prescribed the drugs Compazine and Antivert. They had little affect on the nausea and no affect on the appetite, even after the dosage was doubled. After a couple of weeks of feeling sick and not eating, I had lost 15 pounds and no medication was helping. I was truly in fear for my life. It was then that I decided to try smoking Cannabis/Marijuana.

At first I felt worse, but after the effects of the smoke were gone I began to relax and get an appetite. I could finally eat again. Since that time, I have used cannabis to maintain a healthy body weight and a decent standard of living. For years I left my prescription drugs setting on the counter, as Cannabis was more effective. By November 1993, the disease had progressed to the point that I needed to use a cane and a wheelchair. The damage to the nerves that control the lower part of my body and legs caused my legs to be spastic and ache. Again, I saw a real benefit from using Cannabis, it allowed my muscles to relax. I was given a prescription for the drug Bacoflen in 1993 to help control muscle spasms. I experienced little benefit from the drug, it didn't alleviate the pain in my legs. However with cannabis I got relief and, without the spasms, I could get a good night's sleep.

I briefly discussed the benefits I had been getting from the cannabis with my neurologist, Dr. Vilnius S. Ciemins, upon my initial office visit with him in 1986. After learning of Ohio's medical marijuana defense law in December of 1996, I decided to talk him again about my use of the drug and the short-lived law. Dr. Ciemins, agreed that Cannabis is useful in the treatment of my condition. He provided me with a handwritten recommendation that states: "Told patient that marijuana may relive nausea, realizing that as yet the drug is still illegal." I feel the reason for the prohibition of cannabis is misinformation and the stigma that surrounds this medicine. So I have become active getting people informed and involved.

Today I weigh 155 lbs. and use a wheelchair most of the time. Cannabis has, no doubt, given me a better life than I would have had without it. I didn't ask for this. I would gladly give up using Cannabis and all the other drugs that are prescribed for me if I were miraculously cured. I don't consider myself a criminal just for using the only thing I know that works to try to maintain what quality of life I have left.

Josie Chaplin

I have had three major MS attacks. Each time I have deteriorated more. I had tried smoking pot over the years, but not on many occasions. Last Christmas, I was given a joint to smoke as a present. I had dragged myself, with help, out for Christmas dinner. After a lot of frustration, fretting and struggling, I was installed in my daughter's home. I smoked the joint after my dinner, and for a few hours, I got the old me back again, as I remember me! I have been smoking it on and off since, when things get impossible. It helps with spasticity, sleep, pain and bladder dysfunction. It just helps make life bearable for me. I gave up smoking, as I have Hodgkins, and thought I should do the right thing, then I started again because it helps my MS, so if they legalize cannabis or even better prescribe it in drug form, a lot of people would benefit from it.

How many of us have to convince the world that it helps, and it's not just a drug to get high on! We know what helps our condition, because the people that this is about, are the ones that are suffering. Try walking in my shoes if you can, because sometimes even I can't walk in them! I hope one day soon we will get what we want and not feel like criminals.

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 nor Lioresal are very effective spasm control drugs. Their marginal medical utility, high toxicity, and potential for serious adverse effects, make these drugs difficult to use in spasticity therapy.

As a result, many physicians routinely prescribe tranquilizers, muscle relaxants, mood elevators, and sedatives to patients experiencing spasticity. While these drugs do not directly reduce spasticity, they may weaken the patient's muscle tone, thus making the spasms less noticeable. Alternatively, they may induce sleep or so tranquilize the patient that normal mental and physical functions are impossible.

[Dr. Petro then related his experience with a twenty-seven year-old MS patient who reported he was smoking marijuana for his symptoms. Dr.

Petro and colleagues examined the patient and then asked him to refrain from smoking for six weeks. He continues:]

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 dis-

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 turbing 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.

- Denis Petro, M.D., former FDA Review Officer and principal investigator on spasticity and cannabis studies, in testimony submitted before the DEA In the Matter of Marijuana Rescheduling, October 18, 1987.

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

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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 currently 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. And the U.S. federal government 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.

Even in America cannabis was widely prescribed until the turn of the century. Cannabis is now available by prescription in the Netherlands. Canada has been growing cannabis for patients there and plans to make it available in pharmacies as well. Ironically, the U.S. federal government also grows and provides cannabis for a small number of patients today.

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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. According to a CNN/Time poll in November 2002, 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

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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

- 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).
- 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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PROFESSIONAL ORGANIZATION ENDORSEMENTS

AIDS Action Council

Alaska Nurses Association

American Academy of Family Physicians

American Medical Student Association

American Nurses Association

American Preventive Medical Association

American Public Health Association

American Society of Addiction Medicine

Arthritis Research Campaign (UK)

Australian Medical Association

Australian National Task Force on Cannabis

Belgian Ministry of Health

British House of Lords Select Committee

British Medical Association

California Academy of Family Physicians

California Nurses Association

California Pharmacists Association

Colorado Nurses Association

Federation of American Scientists

Florida Governor's Red Ribbon Panel on AIDS

Florida Medical Association

French Ministry of Health Hawaii Nurses Association

Health Canada

Kaiser Permanente

Lymphoma Foundation of America

Mississippi Nurses Association

Multiple Sclerosis Society (Canada)

National Acad. of Sciences Inst. of Medicine

National Association for Public Health Policy

National Nurses Society on Addictions

Netherlands Ministry of Health

New Jersey State Nurses Association

New Mexico Medical Society

New Mexico Nurses Association

New York State Nurses Association

North Carolina Nurses Association

San Francisco Mayor's Summit on AIDS

San Francisco Medical Society

Virginia Nurses Association

Whitman-Walker Clinic

Wisconsin Nurses Association

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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.



Advancing Legal Medical Marijuana Therapeutics and Research

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