HIV/AIDS AND MEDICAL CANNABIS



Advancing Legal Medical Marijuana Therapeutics and Research

A Note from Americans for Safe Access

We are committed to ensuring safe, legal availability of marijuana for medical uses. Today over one million Americans are legally using medical marijuana—or "cannabis," as it is more properly called—under the care of their medical professional, and nearly half the country lives in a state where this treatment is an option. This publication series is intended to help medical professionals, patients and policymakers better understand how cannabis may be used safely and effectively as a treatment for many medical conditions. You will find information on:

Why Cannabis is Legal to Recommend	3
Overview of the Scientific Research on Medical Cannabis	
Research on Cannabis and HIV/AIDS	
Comparison of Medications: Efficacy and Side-Effects	8
Why Cannabis is Safe to Recommend	10
Testimonials of Patients and Doctors	12
History of Cannabis as Medicine	19
Scientific and Legal References	22

While the federal prohibition of cannabis has limited modern clinical research and resulted in considerable misinformation, a scientific consensus on its therapeutic value has emerged, based on a growing body of successful clinical trials and preclinical research. The experience of patients, medical professionals and research has revealed that cannabis can safely treat a remarkably broad range of medical conditions, often more effectively than conventional pharmaceutical drugs. For some of the most difficult to treat conditions, such as multiple sclerosis and neuropathic pain, cannabis often works when nothing else does.

Many of its therapeutic uses are well known and documented, and medical researchers are learning more each day. Cannabis and its constituent components show potential to fight tumors, autoimmune disorders, and serious neurological conditions for which treatment options are limited. As of July 2014, 23 states and the District of Columbia have laws allowing its use under a doctor's supervision, and cannabis or a dose-controlled whole-plant extract of it is available by prescription in 11 countries and approved for 13 more.

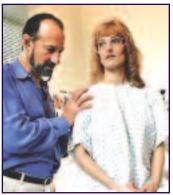
This brochure is only a starting point for the consideration of applying cannabis therapies to specific conditions; it is not intended to replace the training and expertise of medical professionals with regard to medicine, or attorneys with regard to the law. But as advocates for the hundreds of thousands of patients who have found relief with cannabis, we know there are millions more for whom it may be the best medicine. For more information, see **AmericansForSafeAccess.org** or call **1-888-929-4367**.

Why Cannabis is Legal to Recommend

Medical professionals have a legal right to recommend cannabis as a treatment in any state, as protected by the First Amendment. That was established by a 2004 United States Supreme Court decision to uphold earlier federal court rulings that doctors and their patients have a fundamental Constitutional right to freely discuss treatment options. State rules for qualifying an individual patient for legal protections when using medical cannabis differ as to who may make the recommendation and for what conditions, as well as how that recommendation is communicated to state authorities.

Medical professionals and patients should familiarize themselves with the laws and regulations in their state. ASA provides state-by-state resources at: AmericansForSafeAccess.org/state_by_state_recommending cannabis.

Under federal law, cannabis may not be prescribed, but its therapeutic use can be recommended without any legal jeopardy. The court rulings that protect medical professionals stem from a lawsuit brought by a group of doctors and patients led by AIDS specialist Dr. Marcus Conant. The suit was filed in response to federal officials who, within weeks of California voters legalizing medical cannabis in 1996, had threat-



Angel Raich & Dr. Frank Lucido

ened to revoke the prescribing privileges of any physicians who recommended cannabis to their patients for medical use. 1 Dr. Conant contended that such a policy would violate the First Amendment, and the federal courts agreed. 23

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 physicians and other medical professionals may discuss the pros and cons of medical cannabis with any patient, and recommend its use whenever appropriate. They may put that in writing or otherwise participate in state medical cannabis programs without fear of legal reprisal.⁷ This is true even when the recommending medical professional knows the patient will use the recommendation to obtain cannabis through a state program.⁸ What physicians may not do is prescribe or provide cannabis directly to a patient⁹ or say where or how to obtain it.¹⁰

Patients protected under state law, not federal. As of July 2014, 23 states and the District of Columbia provide legal protections for qualified individuals participating in their state medical cannabis program. However, all use of cannabis remains illegal under federal law, and in June 2005, the U.S. Supreme Court in *Gonzales v. Raich* ruled that state medical cannabis laws do not provide protections for patients and providers from federal pros-

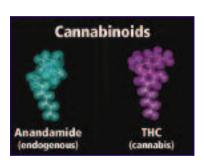
ecution.¹¹ Under the Obama Administration, the Department of Justice has issued three memos providing guidance to federal prosecutors, each indicating that individual patients and caregivers should not be federal enforcement priorities. The latest memo indicates enforcement should be left to states so long as they have effective regulations in place for use and distribution. An analysis by ASA of existing state laws and local regulations found that all reflect the same general enforcement priorities as the 2013 federal guidelines.¹²

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

Medical Professionals Say Cannabis is Medicine

Thousands of studies published in peer-reviewed journals indicate cannabis has medical value in treating patients with such serious conditions as AIDS, glaucoma, cancer, epilepsy, and chronic pain, as well as a variety of such neurological disorders as multiple sclerosis, Parkinsonism, and ALS.

A 2013 poll conducted by the *New England Journal of Medicine* found that three out of four clinicians would recommend the use of medical cannabis for a hypothetical cancer patient.¹³ 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*. The International Cannabinoid Research Society was formally incorporated as a scientific research organization in 1991 with 50 members; as of 2014, there are nearly 500 around the world. The International Association for Cannabinoid Medicines (IACM), founded in 2000, publishes a bi-weekly bulletin and holds international symposia to highlight emerging research in cannabis therapeutics.

The safety and efficacy of cannabis has been attested to by numerous government studies and reports issued over the past 70 years. These include the 1944 LaGuardia Report, the Schafer Commission Report in 1972, a review commissioned by the British House of Lords in 1997, 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.

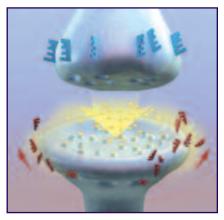
Scientific Research Advances

While modern research has until recently been sharply limited by federal prohibition, the last few decades have seen rapid change. More than 15,000 modern peer-reviewed scientific articles on the chemistry and pharmacology of cannabis and cannabinoids have been published, as well as more than

2,000 articles on the body's natural cannabinoids and the receptors they attach to.14 The discovery of the endocannabinoid system (ECS) opened a door to new understandings of how the body regulates internal systems and how the phytocannabinoids found in the cannabis plant interact with it. Endocannabinoids are crucial to bioregulation, and evidence suggests they

play a role in inflammation, insulin sensitivity, and fat and energy metabolism, as well as chronic neurologic and immune conditions. The cannabinoid receptors CB1 and CB2 are identified targets for treating a remarkable variety of serious medical conditions.¹⁵⁻¹⁸

A 2009 review of controlled clinical studies with medical cannabis conducted over a 38-year period found that "nearly all of the 33 published controlled clinical trials conducted in the United States have shown significant and measurable benefits in subjects receiving the treatment." The review's authors note that the more than 100 different cannabinoids in cannabis have the capacity for analgesia

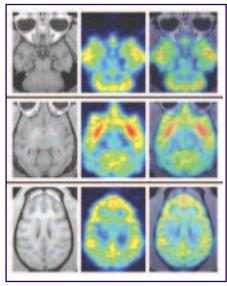


CB1 receptor

through neuromodulation in ascending and descending pain pathways, neuroprotection, and anti-inflammatory mechanisms. Research into the therapeutic potential of cannabis and cannabinoids has expanded considerably in the past decade. As of May 2014, the Center for Medicinal Cannabis Research, a state-funded \$8.7-million research effort at University of California campuses, had completed 13 approved studies. Of those, seven published double-blind, placebo-controlled studies examined pain relief, and each showed cannabis to be effective ²⁰

No adverse health effects related to medical cannabis use have been reported, even among the most seriously ill and immune-compromised patients. Research on CD4 immunity in AIDS patients found no negative effects to the immune systems of patients undergoing cannabis therapy in clinical trials.²¹ A complete health assessment in 2002 of four of the patients enrolled in the U.S. Investigational New Drug program who had used cannabis daily for between 11 and 27 years found cannabis to be clinically effective for each with no negative health consequences.²²

In the United Kingdom, GW Pharmaceuticals has been conducting clinical trials for more than a decade with its cannabis medicine, Sativex® Oromucosal Spray, a controlled-dose whole-plant extract. GW's Phase II and Phase III trials 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 tri-



Cannabinoid receptors in the brain

als for the relief of pain and inflammation in rheumatoid arthritis and also pain relief in brachial plexus injury.²³⁻²⁶

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 opiates, and in 2010 for spasticity related to multiple sclerosis. As of 2014, Sativex has been made available or approved for named patient prescription use in 24 countries, including the UK, Spain, Italy and Germany.

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 opioids. In 2013, GW Pharmaceuticals received FDA approval to test a highly purified cannabinoid extract (cannabidiol or CBD) named Epidiolex® on a limited number of US children with seizure disorders. As of January 2014, seven US pediatric epilepsy specialists have been approved to treat 125 children with Dravet syndrome, Lennox-Gastaut syndrome, and other pediatric epilepsy syndromes.

CANNABIS AND HIV/AIDS

The effectiveness of cannabis for treating symptoms related to HIV/AIDS is widely recognized. Its value as an anti-emetic and analgesic has been proven in numerous studies and has been recognized by several comprehensive, government-sponsored reviews, including those conducted by the Institute of Medicine (IOM), the U.K. House of Lords Science and Technology Committee, the Australian National Task Force on Cannabis, and others.

The IOM concluded, "For patients such as those with AIDS or who are undergoing chemotherapy and who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication." ²⁷

Research published in 2004 found that nearly one-quarter of AIDS patients were using cannabis. A majority reported relief of anxiety and/or depression

and improved appetite, while nearly a third said it also increased pleasure and provided relief of pain.²⁸

AIDS wasting syndrome was a very frequent complication of HIV infection prior to the advent of protease-inhibitor drugs,²⁹ and has been associated with major weight loss and cachexia, conditions that further debilitate its victims, who are already weakened by immune system failure and opportunistic infections. Cannabis has been a frequently employed alternative medicine for the condition, particularly in the USA,³⁰ because of its reported benefits on appetite and amelioration of other AIDS symptoms. In the rest of the world, where such medications are seldom affordable, AIDS wasting remains a common problem to the extent that it is known in Africa as 'slim disease'.³¹

Research findings on cannabis and HIV/AIDS

Beginning in the 1970s, a series of human clinical trials established cannabis' ability to stimulate food intake and weight gain in healthy volunteers. In a randomized trial in AIDS patients, THC significantly improved appetite and nausea in comparison with placebo. There were also trends towards improved mood and weight gain. Unwanted effects were generally mild or moderate in intensity. The possible benefit of cannabis in AIDS made it one of the lead indications for such treatment in the judgment of the Institute of Medicine in their study.³²⁻³⁸

A preliminary safety trial conducted at the University of California at San Francisco found that inhaled cannabis does not interfere with the effectiveness of protease inhibitors in patients suffering from HIV or AIDS. It also found that patients in the study who used cannabis gained weight.³⁹

Dronabinol (a.k.a. "Marinol" or oral THC) is approved by the U.S. Food and Drug Administration (FDA) as an anti-emetic and appetite stimulant for patients undergoing cancer chemotherapy or suffering from AIDS. The FDA approved the drug for this use in 1992 after several clinical trials determined it stimulated weight gain in HIV-infected patients.⁴⁰ In one study, 70 percent of patients administered Marinol (oral THC) gained weight.⁴¹

The 1999 report by the IOM concluded: "It is well recognized that Marinol's oral route of administration hampers its effectiveness because of slow absorption and patients' desire for more control over dosing. ... In contrast, inhaled marijuana is rapidly absorbed." In a series of U.S. state studies in the 1980s, cancer patients given a choice between using inhaled marijuana and oral THC overwhelmingly chose cannabis. It

While the benefits of cannabis for HIV/AIDS patients are well established, research continues around the world. Current research indicates that cannabis or cannabinoid therapies may provide an effective treatment option

for HIV/AIDs patients suffering from painful neuropathy and wasting syndrome. The appetite-stimulating properties of cannabis are well-known and have been demonstrated in numerous studies, and patients with various pain

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 syndromes report significant relief from cannabis. This is particularly true for patients suffering from neuropathic pain, a difficult-totreat symptom commonly associated with HIV/AIDS and a variety of other illnesses or conditions.

In 2002, researchers began a Canadian government-sponsored trial evaluating the appetite-enhancing effects of smoked cannabis in HIV/AIDS, the safety of short-term exposure cannabis, its interaction with HIV medications,

and its effects on nausea, pain, mood and neuro-cognitive function. Since 2004, New South Wales in Australia has made cannabis available to HIV/AIDS patients and other seriously ill individuals for both research and compassionate use.

The University of California's Center for Medicinal Cannabis Research has conducted three HIV/AIDS related studies: two on cannabis as treatment for neuropathy, a condition which afflicts AIDS, diabetes and other patients with severe tingling and pain in their hands and feet, and one on how repeated treatment with cannabis affects the driving ability of patients with HIV-related neuropathy.

Over 30% of patients with HIV/AIDS suffer from excruciating pain in the nerve endings (polyneuropathies, nueropathy) in response to the antiretroviral therapies that constitute the first line of treatment for HIV/AIDS. 44-46 But, there is no approved treatment for such pain that is satisfactory for a majority of patients. As a result, some patients must reduce or discontinue their HIV/AIDS therapy because they can neither tolerate nor eliminate the debilitating side effects of the antiretroviral first-line medications. 47

In fact, British researchers have recently reported that cannabis extract sprayed under the tongue was effective in reducing pain in 18 of 23 patients who were suffering from intractable pain.⁴⁸ This finding is corroborated by studies in which cannabinoids have been shown to be effective analgesics in animal pain models.⁴⁹

In 2006, the chief of Oncology at San Francisco General Hospital published a clinical study which demonstrated that smoked cannabis can effectively treat HIV associated painful neuropathy, and is comparable to other drugs on the

market. 50 patients completed the study which involved 5 days of smoking 3 joints (3.56% THC) per day and recording pain scores. Over half of the patients found a 30% reduction in pain, and the first cannabis cigarette of each day reduced pain scores by over 70% on average. Unlike conventional therapies, no serious adverse effects were reported.⁵⁰

In the last few years, clinical studies on smoked cannabis for HIV neuropathy

have produced even more promising results. A research team at UC Davis Medical Center conducted a double blind, placebo-controlled crossover study of 38 patients with HIV neuropathic pain. The participants smoked cannabis with a THC content of 7% or 3.5 % THC. They were scheduled for three 6-hour sessions, which were separated by at least 3 days. Their pain was significantly alleviated by cannabis and the side effects were well tolerated.⁵¹



Similar results were obtained by researchers at UC San Diego with a study of 34 patients who were not responsive to other pain medication (i.e. opiates). Over the course of the study, participants received both cannabis (THC of 1-8%) and placebo (no THC) cigarettes, which were smoked four times daily for five days. The patients continued to use their regular pain medication during the whole study. The team found that 46 percent of the patients who completed the study gained pain relief from cannabis of more than 30 percent.⁵²

Basic research has also demonstrated that derivatives of the cannabis plant hold promise for for slowing the progression of HIV/AIDS. Researchers from Germany and Spain have investigated the effects of various cannabis extracts on the virus in vivo and found that certain extracts could inhibit HIV replication. Upon further research, a non-cannabinoid component of cannabis called Denbinobin was demonstrated to be mostly responsible for the inhibition of HIV replication. Denbinobin was shown to directly interfere with a replication protein called NF-KB (NF-kappa B), which is considered a good target for HIV therapies because it contributes to a wide variety of cellular processes.

Efficacy and side effects: how cannabis compares

The many medications currently employed to fight HIV/AIDS include many that produce serious side effects, including severe nerve pain, nausea and wasting. These side effects frequently threaten the health of the patient and require other medications to combat them.

Drugs commonly prescribed against AIDS-related weight loss include **megestrol acetate** (Megace), an anticachectic. Serious side effects of this medicine include high blood pressure, diabetes, inflammation of the blood vessels, congestive heart failure, seizures, and pneumonia. Less serious side effects of this

medicine include diarrhea, flatulence, nausea, vomiting, constipation, heartburn, dry mouth, increased salivation, and thrush; impotence, decreased libido, urinary frequency, urinary incontinence, urinary tract infection, vaginal bleeding and discharge (including breakthrough bleeding); disease of the heart muscle, palpitation, chest pain, chest pressure, and edema; shortness of breath, cough, pharyngitis, lung disorders, and rapid breathing; insomnia, headache, weakness, numbness, confusion, seizures, depression, and abnormal thinking.

Synthetic human growth hormones, such as **Somatropin**, also known as Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Saizen, and Serostim, are also prescribed for AIDS wasting syndrome. Serious side effects of this medicine include: abdominal pain or swelling of the stomach; cancer; decrease in red blood cells; diarrhea; enlargement of face, hands, or feet; fever; headache; high blood pressure; high blood sugar; increased sweating; limp or pain in hip or knee; loss of appetite; pain in ear(s); pain and swelling where the shot was given; pain and tingling of fingers and toes; protein in the urine; rapid heart beat; severe tiredness; skin rash or itching; stomach upset; swelling of lymph nodes; trouble sleeping; vision changes; and vomiting. Less serious side effects of this medicine include: enlargement of breasts; increased growth of birthmarks; joint pain; muscle pain; swelling of hands, feet, or lower legs; unusual tiredness or weakness; and wrist pain.

Testosterone and anabolic steroids are being studied for use against AIDS wasting, as is **Thalidomide**, a drug that was taken off the market in the 1960s when it was found to cause severe birth defects.

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

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 mat-

ter 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 mailorder), and recent research



Angel Raich using a vaporizer in the hospital

attests to their efficacy and safety.⁵⁴ 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. ⁵⁵ 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. ⁵⁶

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 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 review of state clinical trials conducted in the 70's and 80's published in 2001 reports that "...the data reviewed here suggested that the inhalation of THC appears to be more effective than the oral route... Patients who smoked marijuana experienced 70-100% relief from nausea and vomiting, while those who used THC capsules experienced 76-88% relief."⁵⁷ 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 states, "Some users of both find cannabis itself more effective."

THE EXPERIENCE OF PATIENTS

Keith Vines

I am an Assistant District Attorney for the City and County of San Francisco, a position I have held since 1985. I am a retired Air Force Captain and JAG Corps prosecutor, a former foot soldier in the war on drugs, and the proud father

of a son who will turn 18 this summer. I am also an AIDS patient who credits medical marijuana as an important link to saving my life.

To stimulate my appetite one of my physicians prescribed Marinol, a synthetic derivative of THC, which is one of the main active ingredients of marijuana. I found, however, that I could not tolerate Marinol's harsh and unpredictable

side effects—side effects that I tried to endure despite only a marginal improvement in appetite. Not infrequently, a single Marinol capsule would make me feel "stoned" for several hours, such that I was unable to function at a level at which I felt comfortable or competent. Other times the Marinol put me right to sleep. Because I continued to work full-time as an Assistant District Attorney, this was for me an unacceptable state of affairs. I need to be at the top of my game. Marinol deprived me of something I have always val-

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

ued deeply: a sense of control over my mind and body.

I informed my physicians that I could no longer tolerate the Marinol because of the unacceptable side effects. At that point, two of my doctors suggested that I try marijuana. They explained that in their practices, they had observed that for many AIDS patients, smoking marijuana stimulated appetite better than its synthetic cousin, and did so without many of the deleterious side effects of Marinol....

I found that it took only two or three puffs from a marijuana cigarette for my appetite to return. Moreover, the beneficial effect took place within minutes rather than the hours that I sometimes waited after swallowing a Marinol capsule. Because I only required a small dose to stimulate my appetite, I did not need to get stoned in order to eat. ... I remain on my growth hormone therapy and I continue to take 15-20 pills a day as part of my antiviral and vitamin regimens. I also use medical marijuana as needed to stimulate my appetite.

My marijuana use is quite modest. I find that I need to take a couple of puffs only two or three times a week, in the evenings, in order to eat. There are also periods of weeks at a time when the marijuana is unnecessary. I do not smoke before or during business hours. I have not become addicted to marijuana.

I continue to work, as I have for the past 12 years, as a city and county pros-

ecutor. The thought processes and motor skills that I use on the job are not the least impaired by the couple of puffs of cannabis I occasionally take before an evening meal. I am not a danger to myself or others. Perhaps most important, I am not wasting away. I am still contributing to society rather than draining its resources. I am thriving on my own, rather than existing as a burden—either financially or emotionally—to my family, friends, or the government.

Daniel J. Kane

Wasting syndrome, in combination with other HIV-related symptoms and conditions, left me thoroughly disabled and desperate to obtain relief. I suffered severe nausea, chronic exhaustion and physical weakness, neurological complications, persistent anxiety, and a total loss of appetite. It was my impression, confirmed by my doctor, that these symptoms were likely caused, or exacerbated, by one or more of the 11 different prescription drugs I had taken for some time. I was dangerously malnourished and the symptoms persisted. I became too ill to ingest the pills that lay at the core of my treatment. Despite my attempts, I simply could not swallow them with any regularity. When I did swallow them, I rarely kept them down. I also tried suppositories for the nausea and the pain, but I was physically unable to tolerate them either. I was warned that my treatment would not work if I could not comply with the protocol.

... In August of 1996, after several prescription medications had given me no relief, my doctor informed me that marijuana, in small quantities, might act as both an anti-nauseant and an appetite stimulant. I tried smoking marijuana to combat the nausea. I found that it reduced my nausea and restored my appetite, allowing me to eat and regain my strength with no noticeable side effects. Having tried the other medications, I know from personal experience that, at least for me, nothing compares to marijuana in terms of results. I use marijuana only a few times a week—sometimes less—but since I started, I have been able to eat and I've regained weight, muscle mass and hope. That small amount of marijuana has enabled me to function in the world again.

Michael Cheslosky

I am a resident of Santa Cruz diagnosed with HIV/AIDS. I also suffer from several other chronic medical conditions associated with the disease, including Kaposi's sarcoma, Hepatitis C, thrush, liver disease, a damaged spleen, gastrointestinal disorders, neuropathic illnesses, and degenerative disk disease. Recurrent pneumonia, chronic pain, and wasting syndrome are also aspects of my deteriorating health....

On January 20, 1984, I was diagnosed with Kaposi's sarcoma (KS). KS is an often fatal cancer that strikes individuals with compromised immune systems.

... At that time, most patients diagnosed with KS died soon thereafter. My doctor told me that I only had six months to live....From 1984-1990, dozens of KS lesions appeared all over my legs, arms, trunk, back, neck and face.... My doctor in Seattle advised me that the only treatment for Kaposi's sarcoma was Interferon. I began taking AZT because the doctors insisted that the Interferon would not work against KS without AZT.

I did not question the wisdom of this treatment and I complied with the regime. However, the side effects were debilitating. For more than two years, I lived with constant nausea, frozen and painful joints, and intense body sweats that left me exhausted and dehydrated.... The Interferon treatments severely damaged my liver and caused episodes of severe anemia, an enlarged spleen, and chronic thrombocytopenia....

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.

In 1991, I received some sample pills of Marinol from my physician to address the pain and the nausea from the Interferon treatments. Since I am quite sensitive to medications and had experienced the side effects of other drugs, I only took one pill at first, as prescribed. The instructions allowed me to supplement the dosage as needed. After several hours, I felt no effects at all. Two days later after my next Interferon injection, I took two Marinol pills, and was literally unable to move for hours. This was obviously more than I needed. I tried on other occasions to find a dose that I could tolerate, but the medicine was unpredictable and prevented me from functioning normally.... As for nausea, swallowing a pill with water to stop vomiting will NOT work at least not in my experience. The pills I took for episodes of nausea didn't stay in my stomach for more than five minutes.

Medical marijuana was originally recommended to treat my nausea and chronic pain and has proven to be more effective than any of the numerous other treatments I have tried. Applied as a spray, it effectively relieves the pain caused by arthritis and the severe nerve damage in my hands and back. ... It is effective without the debilitating grogginess, nausea and lethargy I experienced with other prescribed pain medications (Vicodin, Percocet, Neurontin, Codiene, and of course aspirin), including those prescribed specifically for spastic pain and neuropathy (such as Bentyl, Klonopin, Prednisone, and NuLev). Marijuana also acts as an appetite stimulant, helping me eat enough to avoid "wasting" and the malnutrition that results.

Before using marijuana, vomiting, nausea, and stomach pains dominated my

daily life. They were unpredictable and uncontrollable, often so severe that I was literally housebound for days at a time. The nausea came in waves, usually with headaches and dizziness. It prevented me from eating regular meals and frequently left me sleepless. There have been periods when nausea, vomiting, or both were so persistent that I was unable to keep down my HIV medications. If I vomited my medications, I would have to take a second dose immediately after vomiting to keep the drug levels in my blood consistent for the therapies to work effectively. Although I never smoked tobacco, smoking medical marijuana provides almost instant relief from the nausea without the incapacitating side effects that often occur with prescription drugs. At times, it causes throat problems, but considering the health benefits and the alternatives, I think this is a fair trade.

I have a chronic, potentially fatal, autoimmune disorder. Ongoing sleep disruptions, chronic pain, anxiety, as well as malnutrition, were destroying my health, leaving me extremely vulnerable to infections and respiratory diseases. Medical marijuana has controlled my gastrointestinal symptoms to the point where they no longer control my daily activities. This became more important when it was discovered that I was also infected with Hepatitis C (HCV). At one point, the gastritis from HIV medications left me so weak and dehydrated that I was unable to digest proteins or benefit from either food or medications. Medical marijuana has enabled me to adhere to the various HIV regimens. Unlike Marinol, medical marijuana is more easily controlled and I can avoid the mental confusion and lethargy from over-medication.

THE EXPERIENCE OF DOCTORS

Kate Scannell, M.D.

From working with AIDS and cancer patients, I repeatedly saw how marijuana could ameliorate a patient's debilitating fatigue, restore appetite, diminish pain, remedy nausea, cure vomiting and curtail down-to-the-bone weight loss. The federal obsession with a political agenda that keeps marijuana out of the hands of sick and dying people is appalling and irrational.

Kate Scannell, M.D. is the author of Death of the Good Doctor: Lessons from the Heart of the AIDS Epidemic.

Marcus A. Conant, M.D.

Medical marijuana has been used extensively by physicians throughout the United States in the treatment of cancer and AIDS patients. It stimulates the appetite and promotes weight gain, in turn strengthening the body, combating chronic fatigue, and providing the stamina and physical well-being necessary to endure or withstand both adverse side effects of ongoing treatment and other opportunistic infections. It has been shown effective in reduc-

ing nausea, neurological pain and anxiety, and in stimulating appetite.

When these symptoms are associated with (or caused by) other therapies, marijuana has been useful in facilitating compliance with more traditional therapies. It may also allow individual patients to engage in normal social interactions and avoid the despair and isolation which frequently accompanies long-term discomfort and illness....

In my practice, marijuana has been of greatest benefit to patients with wasting syndrome.... Likewise, for some of my patients undergoing chemothera-

py, when conventional drugs fail to relieve the severe nausea and vomiting, I often find that marijuana provides the patient with the ability to eat and to tolerate aggressive cancer treatments....

I was one of the principal investigators of an FDAsupervised trial conducted by Unimed, Inc. on the safety and efficacy of Marinol as an appetite stimulant in HIV/AIDS patients suffering from wast-

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

ing syndrome. Marinol is a form of THC, one of the key active components of marijuana; it is essentially a marijuana extract. It was approved by the FDA five years ago, and has been widely prescribed by physicians treating both AIDS and cancer patients....

I am aware, however, that Marinol (like any medication) is not effective in treating all patients. In some cases, the reason is simple: Marinol is taken orally, in pill form. Patients suffering from severe nausea and retching cannot tolerate the pills and thus do not benefit from the drug. There are likely other reasons why smoked marijuana is sometimes more effective than Marinol. The body's absorption of the chemical may be faster or more complete when inhaled. Means of ingestion is often critical in understanding treatment efficacy.

Dr. Marcus Conant is a physician who has practiced medicine for 33 years in San Francisco. Dr. Conant is Medical Director of the Conant Medical Group, one of the largest private AIDS practices in the United States. He is a professor at the University of California Medical Center in San Francisco and is the author or co-author of over 70 publications on treatment of AIDS. He and his colleagues provide primary care for over 5,000 HIV patients, including 2,000 with AIDS.

Neil M. Flynn, M.D., MPH

I participate in the care of approximately 1,500 AIDS patients. I am the primary physician for 200 AIDS patients.

Intractable nausea and wasting syndrome are frequent symptoms associated with AIDS and the treatment of AIDS. The nausea, which can last for days, weeks or months, is one of the most severe forms of discomfort or pain that the human being can experience. It destroys the quality of life of the patient,

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

whose sole objective is to make it through the next hour, the next day. Racked by intense vomiting and queasiness, time for the patient seems to stand still. Wasting can take a similar psychological and physical toll. ...

If I am unable to relieve the patient's nausea with [con-

ventional] remedies, I next prescribe Marinol, a synthetic version of THC, one of the main active compounds found in marijuana. Marinol is also helpful in stimulating appetite in patients suffering from AIDS wasting, as are other drugs, Megace, anabolic steroids, and human growth hormone.

If Marinol does not provide adequate relief from nausea and/or wasting, I may suggest that the patient try a related remedy, marijuana. I firmly believe that medical marijuana is medically appropriate as a drug of last resort for a small number of seriously ill patients. Over 20 years of clinical experience persuade me of this fact. The anecdotal evidence is overwhelming. Almost every patient I have known to have tried marijuana achieved relief from symptoms with it. That success rate far surpasses that for Compazine. Accordingly, as with any other medication that I consider potentially beneficial to my patients, I must discuss the option of medical marijuana in detail when appropriate. Anything less is malpractice....

In my nearly thirty years of clinical experience caring for the HIV/AIDS patients, many near to or at the end of life, I have found marijuana to be a valuable medication for the alleviation of intense suffering associated with nausea, wasting, and neuropathic pain. Marijuana has helped patients overcome these potentially life threatening symptoms, and has done so safely and without the debilitating side effects induced by many mainline therapies. I have seen marijuana restore patients' will to live by restoring their ability to eat, gain strength, and perform simple, daily activities free from crippling nausea or pain.

There is no doubt in my mind that for some seriously ill patients, marijuana

can help make the difference between life and death; and that for other terminally ill patients, marijuana can make the difference between exercising control over their final months and days and passing in relative peace and comfort, or dying in constant and severe agony (or incapacitated in a prolonged sedated haze, unaware of their surroundings).

Marijuana, in short, can help sick and dying persons achieve autonomy over their lives by alleviating the intense suffering caused by their illnesses or the side effects of their medications.

For some patients (for example those suffering from operable cancer), medical marijuana may allow them to continue their treatments and thus serve as a bridge to eventual cure; for others marijuana may help promote relative well-being and prolong a life free from intolerable pain; and for still other patients, marijuana may help them control the manner and timing of their deaths consistent with their values, beliefs and dignity.

Dr. Neil M. Flynn is a Professor of Clinical Medicine at the University of California at Davis School of Medicine where he established the UCD AIDS and Related Disorders Clinic and is a member of the Chancellor's Committee on AIDS. He is attending physician in the University Medical Center's Infectious Diseases Clinic and at the Center for AIDS Research, Education and Services. He is the author of numerous articles and a member of many professional organizations.

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." ⁵⁸



The first state medical cannabis law was passed in 1996 by California voter initiative. Since then, 23 states, the District of Columbia, and the US Territory of Guam have removed criminal penalties for their citizens who use cannabis on the advice of a physician and established legal means of obtaining it. Ten of those states plus the District of Columbia established their medical cannabis laws through voter ballot initiative, while the legislatures in 13 others have enacted similar bills. Limited bills that allow only the use of specific cannabis extracts for highly restricted conditions have been passed by the legislatures in 15 other states. Currently, nearly 50 percent of the U.S. population resides in a state with a medical

cannabis program, and legislation is introduced in more states each year.

Federal Policy is Contradictory

Federal policy on medical cannabis is filled with contradictions. Cannabis was widely prescribed until the turn of the century, and an estimated one million Americans currently use it under medical supervision. Congress in 1970 classified cannabis is a Schedule I drug, defined 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. The U.S. federal government also grows and provides free cannabis for a small number of patients today as part of an Investigational New Drug (IND) compassionate access research program created by court order in 1976. Though the program provided up to nine pounds of cannabis a year to these patients, and all reported being substantially helped by it, the application process was extremely complicated, and few physicians became involved. In the first twelve years, the government accepted only a handful of patients. But in 1989 the FDA was deluged with new applications from people living 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, four surviving patients still receive medical cannabis from the federal government.

Despite this successful federal program, thousands of scientific articles, and dozens of successful clinical trials, as well as an unparalleled safety record, cannabis remains classified 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 in order to remove barriers to medical research and patient access. The DEA stalled hearings for 16 years, but after exhaustive hearings 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 insist cannabis is a substance with no medical use. In 2009 the American Medical Association, the nation's largest organization for physicians with a quarter million members, joined the chorus of professional medical groups calling on the federal government to reconsider the classification of cannabis and urging comprehensive clinical trials.

20 Americans for Safe Access

Widespread support, state laws passed, new policy issued

Public opinion is strongly in favor of ending the prohibition of medical cannabis and has been for some time, with every national poll conducted over the past two decades showing a substantial majority in support. A CBS News national poll in January 2014 found that 86 percent of Americans think doctors should be allowed to prescribe cannabis for patients suffering from serious illnesses. In 2004, the 35 million-member American Association of Retired Persons (AARP) released a national poll of older Americans showing 72 percent of seniors agreed that "adults should be allowed to legally use marijuana for medical purposes if a physician recommends it." Every national poll for more than a decade has found similar super-majorities of support.

The refusal of the federal government to act on this widespread public support has meant that advocates have had to turn to the states for action. Currently, laws that effectively remove state-level criminal penalties for growing and/or possessing medical cannabis are in place in: Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, the District of Columbia, and Guam. Another fifteen states have established limited laws that allow the legal medical use of a cannabis plant extract. Thirty-six states have symbolic medical cannabis laws (laws that support access to medical cannabis but do not provide patients with legal protection under state law).

On August 29, 2013, the U.S. Department of Justice issued new guidance to federal prosecutors, telling them medical cannabis dispensaries should no longer automatically be considered targets for prosecution. The memo from Deputy Attorney General James M. Cole to all U.S. Attorneys reverses previous federal policy on prosecuting medical cannabis providers and businesses. The new guidance says state and local officials can avoid federal interference in their medical cannabis programs if they "implement strong and effective regulatory and enforcement systems" that reflect eight federal enforcement priorities. The memo does not change federal law, nor does it preclude prosecution of any individual or business, as the U.S. Attorneys' offices are autonomous, and federal prosecutors make independent decisions about which cases to pursue.

Legal Citations

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- 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 "in some 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).
- 11. Gonzales v. Raich, 545 U.S. 1 (2005) 352 F.3d 1222.
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22 Americans for Safe Access

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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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