# 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. 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**.

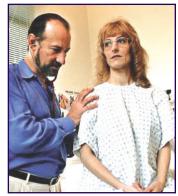
# Is Cannabis Legal to Recommend?

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. 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 Amend-ment.<sup>2</sup> The federal courts agreed at first the district level,<sup>3</sup> 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, 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. But it remains illegal for a doctor to "aid and abet" a patient in obtaining



Angel Raich & Dr. Frank Lucido

cannabis.<sup>6</sup> This means a physician may discuss the pros and cons of medical cannabis with any patient, and issue a written or oral recommendation to use cannabis without fear of legal reprisal.<sup>7</sup> This is true regardless of whether the physician anticipates that the patient will, in turn, use this recommendation to obtain cannabis.<sup>8</sup>

What physicians may not do is actually prescribe or dispense cannabis to a patient<sup>9</sup> 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.

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

The safety of the drug has been attested to by numerous studies and reports, including the LaGuardia Report of 1944, the Schafer Commission Report of 1972, a 1997 study conducted by the British House of Lords, the



Institutes of Medicine report of 1999, research sponsored by Health Canada, and numerous studies conducted in the Netherlands, where cannabis has been quasi-legal since 1976 and is currently available from pharmacies by prescription.

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

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

#### **Recent Research Advances**

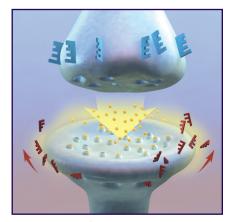
While research has until recently been sharply limited by federal prohibition, the last few years have seen rapid change. The International Cannabinoid Research Society was formally incorporated as a scientific research organization in 1991. Membership in the Society has more than tripled from about 50 members in the first year to over 500 in 2010. The International Association for Cannabis as Medicine (IACM) was founded in March 2000. It publishes a bi-weekly newsletter and the IACM-Bulletin, and holds a bi-annual symposium to highlight emerging research in cannabis therapeutics. In 2001, the State of California established the Center for Medicinal Cannabis Research to coordinate an \$8.7-million research effort at University of California campuses. As of 2010, the CMCR had completed six of 14 approved studies. Of those, five published double-blind, placebo-controlled studies studied pain relief; each showed cannabis to be effective.

In the United Kingdom, GW Pharmaceuticals has been conducting clinical trials with its cannabis-based medicine for the past decade. GW's Phase II

and Phase III trials of cannabis-based medicine show positive results for the relief of neurological pain related to: multiple sclerosis (MS), spinal cord injury, peripheral nerve injury (including peripheral neuropathy secondary

to diabetes mellitus or AIDS), central nervous system damage, neuroinvasive cancer, dystonias, cerebral vascular accident, and spina bifida. They have also shown cannabinoids to be effective in clinical trials for the relief of pain and inflammation in rheumatoid arthritis and also pain relief in brachial plexus injury.

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



**CB1** receptor

whose pain is not fully alleviated by opiods, and in 2010 for spasticity related to multiple sclerosis. Sativex has been made available either for named patient prescription use or for clinical trials purposes in a total of 22 countries. In the US, GW was granted an import license for Sativex® by the DEA following meetings in 2005 with the FDA, DEA, the Office for National Drug Control Policy, and the National Institute for Drug Abuse. Sativex® is currently an investigational drug in FDA-approved clinical trials as an adjunctive analgesic treatment for patients with advanced cancer whose pain is not relieved by strong opioids.

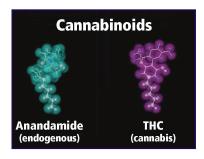
## **CANNABIS AND HIV/AIDS**

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." <sup>12</sup>

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.<sup>13</sup>



AIDS wasting syndrome was a very frequent complication of HIV infection prior to the advent of protease-inhibitor drugs, <sup>14</sup> 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,<sup>15</sup> 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'.<sup>16</sup>

# **Research findings on cannabis and HIV/AIDS**

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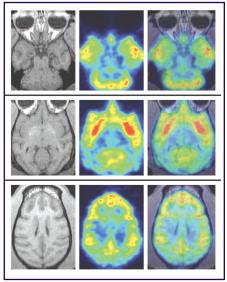
# Research findings on cannabis and HIV/AIDS

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.<sup>17-23</sup>

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.<sup>24</sup>

Dronabinol (a.k.a. "Marinol" or oral THC) is approved by the U.S. Food and Drug Administration (FDA) as an anti-



**Cannabinoid receptors in the brain** 

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.<sup>25</sup> In one study, 70 percent of patients administered Marinol (oral THC) gained weight.<sup>26</sup>

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."<sup>27</sup> 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.<sup>28</sup>

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 syndromes report significant relief from cannabis. This is particular-

ly true for patients suffering from neuropathic pain, a difficult-to-treat 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

## 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 safety of short-term exposure cannabis, its interaction with HIV medications, and its effects on nausea, pain, mood and neurocognitive 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.<sup>29-31</sup> 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.<sup>32</sup>

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.<sup>33</sup> This finding is corroborated by studies in which cannabinoids have been shown to be effective analyses in animal pain models.<sup>34</sup>

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 con-

ventional therapies, no serious adverse effects were reported.35

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.<sup>36</sup>

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.<sup>37</sup>

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.<sup>38</sup> 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 **mege-strol 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); dis-

ease 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 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 mailorder) and recent research attests to their efficacy and



Angel Raich using a vaporizer in the hospital

safety. 39 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.<sup>40</sup> Similarly, a study comparing 1,200 patients with lung, head and neck cancers to a matched

group with no cancer found that even those cannabis smokers who had consumed in excess of 20,000 joints had no increased risk of cancer.<sup>41</sup>

As Dr. Grinspoon notes, "the greatest danger in medical use of marihuana is its illegality, which imposes much anxiety and expense on suffering people, forces them to bargain with illicit drug dealers, and exposes them to the threat of criminal prosecution." This was the 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." 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 mari-

juana. 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 valued 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,

#### **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

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 prosecutor. 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 treat-

ments severely damaged my liver and caused episodes of severe anemia, an enlarged spleen, and chronic thrombocytopenia....

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,

#### 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.

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 reducing 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 chemotherapy, 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 FDA-supervised trial conducted by Unimed, Inc. on the safety and efficacy of Marinol as an appetite stimulant in HIV/AIDS patients suffering from wasting syndrome. Marinol is a form of THC, one of the key

#### 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

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, 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

#### 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

to stand still. Wasting can take a similar psychological and physical toll. ...

If I am unable to relieve the patient's nausea with [conventional] 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."

In 1937, the American Medical Association opposed the first federal law against cannabis with an article in its leading journal. Their representative, Dr. William C. Woodward, testified to Congress that "The American Medical Association knows of no evidence that marihuana is a dangerous drug," and that any prohibition "loses sight of the fact that future investigation may show that there are substantial medical uses for Cannabis." Cannabis remained part of the American pharmacopoeia until 1942 and is 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. But the U.S. federal government

also grows and provides cannabis for a small number of patients today.

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

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

Despite this successful medical program and centuries of documented safe use, cannabis is still classified in America as a Schedule I substance. Healthcare advocates have tried to resolve this contradiction through legal and administrative channels. In 1972, a petition was submitted to reschedule cannabis so that it could be prescribed to patients.

The DEA stalled hearings for 16 years, but in 1988 their chief administrative law judge, Francis L. Young, ruled that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known... It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance." The DEA refused to implement this ruling based on a procedural technicality and continues to classify cannabis as a substance with no medical use.

# Widespread public support; state laws passed

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

# 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

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

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

# 2005 U.S. Supreme Court ruling

In June 2005, the U.S. Supreme Court overturned a decision by a U.S.



appeals court (Raich v. Ashcroft) that had exempted medical marijuana from federal prohibition. The 2005 decision, now called Gonzales v. Raich, ruled that federal officials may prosecute medical marijuana patients for possessing, consuming, and cultivating medical cannabis. But according to numerous legal opinions, that ruling does not affect individual states' medical marijuana programs, and only applies to prosecution in federal, not state, court.

# **Petitions for legal prescriptions pending**

The federal Department of Health and Human Services (HHS) and the FDA are currently reviewing two legal petitions with broad implications for medical marijuana. The first, brought by ASA under the Data Quality Act, says HHS must correct its statements that there is no medical use for marijuana to reflect the many studies which have found it helpful for many conditions. Acknowledging legitimate medical use would then force the agency to consider allowing the prescribing of marijuana as they do other drugs, based on its relative safety. A separate petition, of which ASA is a co-signer, asks the Drug Enforcement Administration for a full, formal re-evaluation of marijuana's medical benefits, based on hundreds of recent medical research studies and several 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).
- 3. See id.; Conant v. McCaffrey, 2000 WL 1281174 (N.D. Cal. 2000); Conant v. Walters, 309 F.3d 629 (9th Cir. 2002).
- 4. 309 F.3d 629 (9th Cir. 2002).
- 5. Id. at 634-36.
- 6. Criminal liability for aiding and abetting requires proof that the defendant "insome sort associate[d] himself with the venture, that he participate[d] in it as something that he wishe[d] to bring about, that he [sought] by his action to make it succeed."Conant v. McCaffrey, 172 F.R.D. 681, 700 (N.D. Cal. 1997) (quotation omitted). A conspiracy to obtain cannabis requires an agreement between two or more persons to do this, with both persons knowing this illegal objective and intending to help accomplish it. Id. at 700-01.
- 7. 309 F.3d at 634 & 636.
- 8. Conant v. McCaffrey, 2000 WL 1281174, at \*16 (N.D. Cal. 2000).
- 9. 309 F.3d at 634.
- 10. See id.. at 635; Conant v. McCaffrey, 172 F.R.D. 681, 700-01 (N.D. Cal. 1997).

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## DEA CHIEF ADMINISTRATIVE LAW JUDGE

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

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

# ADDITIONAL RESOURCES

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

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



Advancing Legal Medical Marijuana Therapeutics and Research

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