CANCER
AND
MEDICAL CANNABIS
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:

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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](http://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 threatened 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.2,3

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 prosecution. 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.

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. 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.\textsuperscript{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.\textsuperscript{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."\textsuperscript{19} The review's authors note that the more than 100 different cannabinoids in cannabis have the capacity for analgesia through neuromodulation in ascending and descending pain pathways, neuroprotection, and anti-inflammatory mechanisms. 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 trials for the relief of pain and inflammation in rheumatoid arthritis and also pain relief in brachial plexus injury.\textsuperscript{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 alle-
viated 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 CANCER

Cannabis has been found to help cancer patients with the symptoms that usually accompany cancer such as pain, nausea, wasting, and loss of appetite. Notably, in a meta-analysis of 30 clinical studies on the therapeutic use of cannabis for chemotherapy-induced nausea and vomiting, Delta9-THC (dronabinol, AKA marinol) proved superior to modern anti-emetics. Additionally, patients showed a clear preference for cannabinoids as anti-emetic medication over conventional drugs, when receiving chemotherapy.

Only one clinical trial has ever been published on the effects of Delta9-THC on cancer growth in humans. Doctors administered oral Delta 9-THC to nine patients who experienced tumor progression despite surgical therapy and radiation treatments. The major finding of the study was that Delta 9-THC was safe and did not cause any obvious psychoactive effects in a clinical setting. Furthermore, extensive pre-clinical research clearly indicates that cannabinoids can have tumor-reducing and anti-cancer properties.

Research on cannabis and chemotherapy

One of the most widely studied therapeutic applications for cannabis and the pharmaceutical drugs derived from cannabinoids is in the treatment of nausea and vomiting associated with cancer chemotherapy. Numerous clinical and preclinical studies conducted over nearly three decades have consistently reported that the use of cannabis reduces pain, nausea, vomiting, and stimulates appetite, thereby reducing the severity of cachexia, or wasting syndrome, in patients receiving chemotherapy treatment.

The 1999 Institutes of Medicine report noted that for “patients already experiencing severe nausea or vomiting, pills are generally ineffective, because of the difficulty in swallowing or keeping a pill down, and slow onset of the
drug effect. Thus an inhalation (but, preferably not smoking) cannabinoid drug delivery system would be advantageous for treating chemotherapy-induced nausea.” For certain individuals unresponsive to conventional anti-emetic drugs, the use of smoked or vaporized cannabis can provide relief more effectively than oral THC (Marinol) which may be difficult to swallow or be vomited before taking effect. The IOM report concluded, “nausea, appetite loss, pain and anxiety … all can be mitigated by marijuana.”40

A 1997 inquiry by the British Medical Association found cannabis more effective than Marinol, and a 1998 review by the House of Lords Science & Technology Select Committee concluded that “Cannabinoids are undoubtedly effective as anti-emetic agents in vomiting induced by anti-cancer drugs. Some users of both find cannabis itself more effective.”41, 42

In 2009, a clinical trial involving 177 patients, with intractable cancer pain and experienced inadequate relief from opiates, showed remarkable reductions in pain scores from using a cannabis extract which contained THC and CBD. This THC:CBD extract was more effective than an extract containing only THC.43

The effects of cannabis may also provide an improvement in mood. In addition to THC, other cannabinoids on the plant such as CBD, can inhibit the side effects of THC, as well provide relief from anxiety and depression. By contrast, several conventional medications commonly prescribed for cancer patients, e.g. phenothiazines such as haloperidol (known as “major tranquillizers”) may produce unwanted side effects such as excessive sedation, flattening of mood, and/or distressing physical “extrapyramidal” symptoms such as uncontrolled or compulsive movements.

**Anti-cancer potential of cannabis and cannabinoids**

Recent scientific advances in the study of cannabinoid receptors and endocannabinoids have produced exciting new leads in the search for anti-cancer treatments. Several hundred research articles have been published on the effects of cannabinoids on cancer cells.44-69 We now know cannabinoids stop many kinds of cancers from growing and spreading, including brain, breast, leukemic, melanoma, phaeochromocytoma, liver, and other kinds of cancer. Cannabinoids have been repeatedly shown in animal and other studies to promote apoptosis (programmed cell death of the tumor cells) and halt angiogenesis (blood vessel production to the tumor) in many types of human cancers.70-74 In one study, injections of synthetic THC eradicated malignant brain tumors in one-third of treated rats, and prolonged life in another third by as much as six weeks.75

Scientists have established that the anti-cancer properties of cannabinoids are
mediated through cannabinoid receptors. CB1 and CB2 cannabinoid receptors are abundantly expressed throughout the human body, making them an excellent target for disease treatment. Research on the complex interactions of endogenous cannabinoids and receptors is leading to greater scientific understanding of the basic mechanisms by which cancers develop. Research studies on pituitary cancers suggest that cannabinoids may be the key to regulating human pituitary hormone secretion that affects tumor development. 76-79

The mechanism of the anti-cancer activity of cannabinoids has been repeatedly demonstrated with breast cancers, with numerous studies showing that cannabinoids are effective in fighting breast cancer tumors and metastatization. 80-84

Recent research has found that the non-psychoactive cannabinoid cannabidiol (CBD) inhibits the invasion of both human cervical cancer and human lung cancer cells. By manipulating cannabidiol’s up-regulation of a tissue inhibitor, researchers may have revealed the mechanism of CBD’s tumor-fighting effect. A further in vivo study demonstrated "a significant inhibition" of lung cancer metastasis in mice treated with CBD.85-87

In 2009, scientists reported on the anti-tumor effects of the cannabinoid THC on cholangiocarcinoma cells, an often-fatal type of cancer that attacks the liver’s bile ducts. They found that "THC inhibited cell proliferation, migration and invasion, and induced cell apoptosis." At low levels, THC reduced the migration and invasion of cancer cells, while at high concentrations, THC triggered cell-death in tumors. In short, THC reduced the activity and number of cancer cells. 88

Laboratory research on the effects on cancer tumors of the non-psychoactive cannabinoid cannabidiol (CBD) has found that it inhibits human glioma and glioblastoma multiforme cells, the most common and aggressive forms of brain cancer, in part by cutting of blood supply to tumors. Research on cannabinoids and gliomas, a type of aggressive brain cancer for which there is no cure, holds promise for future treatments. A study that examined both animal and human glioblastoma multiforme (GBM) tumors, the most common and aggressive form of brain cancer, describes how cannabinoids controlled glioma growth by regulating the blood vessels that supply the tumors.89 In another study, researchers demonstrated that the administration of the non-psychoactive cannabinoid cannabidiol (CBD) significantly inhibited the growth of subcutaneously implanted U87 human glioma cells in mice. The authors of the study noted that "... CBD was able to
produce a significant antitumor activity both in vitro and in vivo, thus suggesting a possible application of CBD as an antineoplastic agent. The targeted effects of cannabinoids on GBM were further demonstrated in 2005 by researchers who showed that the cannabinoid THC both selectively inhibited the proliferation of malignant cells and induced them to die off, while leaving healthy cells unaffected. While CBD and THC have each been demonstrated to have tumor-fighting properties, research published in 2010 shows that CBD enhances the inhibitory effects of THC on GBM cell proliferation and survival.

Similarly, researchers reported in 2010 that the way cannabinoid and cannabinoid-like receptors in brain cells "regulate these cells' differentiation, functions and viability" suggests cannabinoids and other drugs that target cannabinoid receptors can "manage neuroinflammation and eradicate malignant astrocytom as," a type of glial cancer. This research confirms the findings of multiple studies which have indicated the effectiveness of cannabinoids in fighting gliomas.

Indications of the remarkable potential of cannabinoids to fight cancer in humans have also been seen in three large-scale population studies done recently. The studies were designed to find correlations between smoking cannabis and cancers of the lung, throat, head and neck. Instead, the researchers discovered that the cancer rates of cannabis smokers were at worst no greater than those who smoked nothing at all or even better. One study found that 10-20 years of cannabis use significantly reduced the incidence of head, neck and throat cancers. Researchers suggest that cannabinoids may produce a prophylactic effect against cancer development, as seen in the anti-proliferation effect that has been demonstrated in vitro and in vivo.

While clinical research on using cannabis medicinally has been severely limited by federal restrictions, the accumulated data speaks strongly in favour of considering it as an option for most cancer patients, and many oncologists do. A random-sample anonymous survey conducted by researchers at Harvard Medical School in 1990, years before any states had approved medical use, found that 44 percent of oncologists had recommended cannabis to at least some of their patients, and more said they would do so if the laws were changed. Of the oncologists expressing an opinion in 1990, a majority (54 percent) thought cannabis should be available by prescription.

According to the American Cancer Society's data, more than 1.6 million
Americans will be diagnosed with cancer each year. At least 400,000 of them will undergo chemotherapy, meaning as many as 200,000 patients annually may have cannabis recommended to them to help fight the side effects of conventional treatments.

The authors of the 1999 Institute of Medicine report *Marijuana and Medicine: Assessing the Science Base* acknowledged that there are certain cancer patients for whom cannabis would be a valid medical option. Current research on cannabinoids has shown that activation of both cannabinoid receptors has a well-established anti-proliferative effect on cancer cells and may also have anti-angiogenic, anti-adhesive, anti-invasive, and anti-metastatic properties. Since cannabinoids are generally well tolerated, and patients do not develop the toxic side effects associated with conventional treatments, more studies are warranted to develop a cannabis-based cancer treatment.

**How cannabis compares to other medications**

The American Cancer Society lists more than 300 medications currently prescribed to treat cancer and its symptoms, and to treat the side effects of other cancer drugs. Some drugs are prescribed for pain caused by cancer, and cancer patients report pain relief with cannabis therapy. Many chemotherapy agents cause severe nausea and more than a dozen drugs are currently prescribed to treat nausea, including *Marinol*, a synthetic form of delta-9-THC, one of the active ingredients in cannabis.

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

*Reglan*, a substituted benzamide, increases emptying of the stomach, thus decreasing the chance of developing nausea and vomiting due to food remaining in the stomach. When given at high doses, it blocks the messages to the part of the brain responsible for nausea and vomiting resulting from chemotherapy. Side effects include sleepiness, restlessness, diarrhea and dry mouth. Rarer side effects are rash, hives and decreased blood pressure.
**Haldol** and **Inapsine** are tranquilizers that block messages to the part of the brain responsible for nausea and vomiting. Possible side effects include decreased breathing rate, increased heart rate, decrease in blood pressure when changing position and, rarely, change in electrical activity of the heart.

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

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

**Decadron** (dexamethasone), a corticosteroid, is given with other chemotherapy drugs as an adjunct medication. Common side effects include increased appetite, irritation of stomach, euphoria, difficulty sleeping, mood changes, flushing, increased blood sugar, decreased blood potassium level. Possible side effects upon discontinuing the drug include adrenal insufficiency, weakness, aches, fever, dizziness, lowering of blood pressure when changing position, difficulty breathing, and low blood sugar.

Benzodiazepine drugs **Ativan** and **Xanax** are also prescribed to combat the effects of chemotherapy. Ativan causes amnesia. Abruptly stopping the drug can cause anxiety, dizziness, nausea and vomiting, and tiredness. It can cause drowsiness, confusion, weakness, and headache when first starting the drug. Nausea, vomiting, dry mouth, changes in heart rate and blood pressure, and palpitations are possible side effects.

In addition, in April 2003 the FDA approved the drug **Emend** (aprepitant) to help control delayed-onset nausea. It is given along with two other anti-nausea drugs. A regimen of three pills costs $250. The most common side effects with Emend are fatigue, nausea, loss of appetite, constipation, diarrhea.

**Cannabis vs. Other Medications**

**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, though it can also provide symptomatic relief in refractory schizophrenia. Cannabinoids impede cognitive and psychomotor performance, resulting in temporary impairment. Chronic use can lead to the development of tolerance. Tachycardia and hypotension are frequently docu-
mented as potentially 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 extremely rare and are not usually reported during the use of cannabinoids for medical indications.

**Why cannabis is 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 a 1995 article in the *Journal of the American Medical Association*:

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.106

The technology Dr. Grinspoon imagined in 1995 now exists in the form of “vaporizers,” (which are widely available through stores and by mail-order) and recent research attests to their efficacy and safety.107 Additionally, pharmaceutical companies have developed sublingual sprays and capsule 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.108 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.109

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

In January 2013, the American Herbal Products Association (AHPA), which has a 30-year history of developing standards for the herbal products industry, issued recommendations for effectively regulating all aspects of cannabis distribution for patients. The regulatory recommendations, developed over two years by the AHPA Cannabis Committee address guidelines for cultivation, quality-assurance, analytics, cannabis product manufacture and labeling, storefront and delivery services, and personnel training.

In December 2013, the American Herbal Pharmacopeia released a monograph identifying cannabis as a botanical medicine. Written and reviewed by the world’s leading experts on cannabis, the monograph provides a full scientific understanding of the plant, its constituent components, and its biologic effects. It also establishes comprehensive standards for the plant’s identity, purity, quality, and botanical properties.

Following the release of the monograph, ASA launched Patient Focused Certification, the first non-profit, third-party certification program based on the AHPA regulatory recommendations and the AHP standards. Patient Focused Certification (PFC) audits cultivators, distributors, manufacturers and laboratories to verify compliance with best-practice standards. PFC includes employee training, compliance inspections, ongoing monitoring, and an independent complaint process for customers, as well as comprehensive reviews of formulations and materials, independent testing, and facility inspections.

**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 more than 100 cannabinoids in addition to THC. Recent research conducted by GW Pharmaceuticals in Great Britain has shown that Marinol is simply not as effective for pain management as the whole plant; a balance of cannabinoids, specifically CBC and CBD with THC, is what helps patients most. In fact, Marinol is not labeled for pain, only appetite stimulation and nausea control. THC and

**Angel Raich using a vaporizer in the hospital**
other cannabinoids have been shown to be effective in controlling nausea, but many severely nauseated patients experience difficulty in swallowing and keeping a pill down, a problem avoided by use of inhaled cannabis, which decades of studies have shown to be highly effective for treating nausea.

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 percent relief from nausea and vomiting, while those who used THC capsules experienced 76-88 percent 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." That is at least in part because the various cannabinoids and terpenes found in cannabis work in concert with one another to create an “entourage effect” that provides enhanced therapeutic efficacy.

THE EXPERIENCE OF PATIENTS

Judith Cushner, Breast Cancer

In 1989, I was diagnosed with breast cancer. After a brief period of recovery from the surgeries, I was placed on an aggressive protocol of chemotherapy, which lasted for eight months. That protocol was referred to as “CMF,” because it consisted of heavy doses of Cytoxan, methotrexate, and 5 fluorouracil.

The treatment caused severe and persistent side effects which were thoroughly disabling: chronic nausea, joint pain and weakness; a debilitating lack of energy and motivation; loss of appetite and a resulting unwanted weight loss; sleep disruption; and eventually my withdrawal from social situations and interpersonal relationships. The cumulative effect of these symptoms often rendered it impossible (or painfully difficult) to take the huge number of medications essential to my treatment regimen.

Right from the start, I was given Compazine as part of my chemotherapy protocol. I took it both orally (in pill form) and intravenously, but it too caused severe adverse side effects, including neuropathy. Moreover, the Compazine provided little, if any, relief from the nausea that had persisted since my treatment began. Hoping for better results, my doctor discontinued the Compazine and prescribed Reglan. That, too, had no effect on the nausea and we decided to discontinue it after a fairly short time. By then, I had developed chronic mouth sores (also from the chemotherapy), which made it extremely painful to take pills or swallow anything. Rather than providing relief, the Reglan increased my discom-
fort and pain.

Yet another drug I tried was Marinol, which gave me no relief from the unrelenting nausea. If anything, taking yet another pill increased my discomfort. The pills themselves irritated the sores in my mouth. It also made me quite groggy, yet my sleep disturbance persisted, in part because my nausea and anxiety were so distracting. My doctor prescribed Lorazepam to help me sleep, but it was just one more medication with unpleasant effects of its own.

During this time, a friend of mine (who happened to be a nurse) gave me a marijuana cigarette. She had seen my suffering and thought it might help. I took her advice and it worked. I took just a few puffs and within minutes, the nausea dissipated. For the first time in several months, I felt relief. I also felt hope. I smoked small amounts of marijuana for the remainder of my chemotherapy and radiation treatment. It was not a regular part of my day, nor did it become a habit. Each time I felt nausea coming on, I inhaled just two or three puffs and it subsided.

As my nausea decreased, my ability to eat and retain food increased. I saw a marked weight gain and my energy increased. As my general health improved, my sleeping habits also improved. In retrospect, one of the greatest benefits from the marijuana was that it decreased my use of other, more disabling and toxic medications, including the Compazine, Reglan and Lorazepam.

My cancer has been in remission now for just under a year. I lived to see my son’s Bar Mitzvah, and I am proud to say that the risks I took to save my life, while technically illegal, have earned me the respect of both my children. They have learned the difference between therapeutic treatment and substance abuse, and (unlike many of their peers) that knowledge has helped them resist the temptations of recreational drugs.

My decision to use marijuana and save my own life has educated many, including my rabbi and my congregation.

**Jo Daly, Colon Cancer**

In 1980, I was appointed by Dianne Feinstein, then Mayor of San Francisco, to serve as police commissioner for the city of San Francisco, an office which I held for six years. On May 24, 1988, I was diagnosed with Phase IV cancer of the colon. By the time it was diagnosed, it had already spread to my ovaries and lymph nodes. My oncologist at the UCSF
Hospital prescribed an aggressive regimen of chemotherapy, which lasted six months. I was given large doses of the chemicals, four hours a day, five days a week in the first week of each month.

Each day, when I returned home from the hospital following treatment, at about 5:00 p.m., my whole body turned quite warm, as if a fever were coursing through me. My fingernails even burned with heat. Invariably, I was overcome by a sudden wave of intense nausea—like a nuclear implosion in my solar plexus—and I rushed desperately for the bathroom where I would remain for hours, clutching the toilet and retching my guts out. I had no appetite. I could not hold down what little food that I managed to swallow. And I could not sleep at night. This intense nausea persisted for the two weeks following the treatment. By the third week after treatment, the side effects of the chemicals began to wear off, and I started to feel better. The next week, however, I had to return to the hospital where the chemicals were administered once more, beginning my hell all over again.

To combat the nausea, I tried Marinol, a synthetic version of THC, one of the primary chemicals found in marijuana. However, I was often unable to swallow the Marinol capsule because of my severe nausea and retching. A friend then gave me a marijuana cigarette, suggesting that it might help quell my nausea. I took three puffs from the cigarette. One-half hour later, I was calm, my nausea had disappeared, my appetite returned, and I slept that evening.

I told my oncologist about how well marijuana quelled my nausea. My doctor was not surprised. In fact, he told me that many of his patients had made the same discovery. My doctor encouraged me to continue using marijuana if it worked. Although it occasionally produced a slight euphoria, it was not a painful sensation and I was careful never to leave the house during those rare moments.

My use of medical marijuana had a secondary, though by no means minor benefit: I was able to drastically reduce my dependence on more powerful prescription drugs that I was prescribed for pain and nausea. With the help of medical marijuana, which I ingest only occasionally and in small amounts, I no longer need the Compazine, Lorazepam, Ativan and Halcion. No combination of these medications provided adequate relief. They also caused serious side effects that I never experienced with marijuana.

—Jo Daly was formerly a San Francisco Police Commissioner
Anonymous, Breast Cancer

I have used medicinal cannabis legally in California for a year, after being diagnosed and treated for breast cancer. I have also been given prescription drugs that were not effective, that irritated my stomach, for which they wanted to prescribe more drugs. These medications were neither cost-effective nor useful, and I choose to use medicinal cannabis through a vaporizer as recommended by my physician, thereby bypassing the sometimes-harmful effects of smoking. I, personally, would rather the federal government use their resources to go after the true criminals and terrorists that we have in our country, as opposed to persecuting the sick for whatever relief they may have from medical cannabis.

Lyn Nofziger, Father of Cancer Patient

When our grown daughter was undergoing chemotherapy for lymph cancer, she was sick and vomiting constantly as a result of her treatments. No legal drugs, including Marinol, helped her. We finally turned to marijuana. With it, she kept her food down, was comfortable and even gained weight. Those who say Marinol and other drugs are satisfactory substitutes for marijuana may be right in some cases but certainly not in all cases. If doctors can prescribe morphine and other addictive medicines, it makes no sense to deny marijuana to sick and dying patients when it can be provided on a carefully controlled, prescription basis.

—Lyn Nofziger was formerly senior adviser to President Ronald Reagan

THE EXPERIENCE OF DOCTORS

Howard D. Maccabee, M.D.

In my practice, I commonly use radiation therapy to treat the whole spectrum of solid malignant tumors. Radiation therapy is often used after surgery or chemotherapy, as a second stage in treatment. Sometimes, however, radiation therapy is used concurrently with chemotherapy, or even as the first or only modality of treatment.

I treat approximately 20 patients each day and provide follow-up care and/or consultation with another 5 or so patients a day. I currently have approximately 2,000 patients in various stages of follow-up to their initial treatment. Most of these are long-term survivors.

Because of the nature of some cancers, I must sometimes irradiate large portions of my patients' abdomens. Such patients often experience nausea, vomiting, and other side effects. Because of the severity of these side effects, some of my patients choose to discontinue treatment altogether, even when they know that ceasing treatment could lead to death.

During the 1980s, I participated in a state-sponsored study of the effects of marijuana and THC (an active ingredient in marijuana) on nausea. It was my observation during this time that some patients smoked marijuana while hospitalized, often with the tacit approval of physicians.
also observed that medical marijuana was clinically effective in treating the nausea of some patients.

During my career as a physician, I have witnessed cases where patients suffered from nausea or vomiting that could not be controlled by prescription anti-emetics. I frequently hear similar reports from colleagues treating cancer and AIDS patients. As a practical matter, some patients are unable to swallow pills because of the side effects of radiation therapy or chemotherapy, or because of the nature of the cancer (for instance, throat cancer). For these patients, medical marijuana can be an effective form of treatment.

**Debasish Tripathy, M.D.**

Since 1993, I have been a physician at the UCSF Mount Zion Breast Care Center in San Francisco. My practice is devoted exclusively to breast cancer patients. I treat more than 1,000 patients. Approximately 100 of these patients are currently undergoing chemotherapy, a treatment utilizing various combinations of powerful medications. In some cases, the therapeutic dose of the medication we use is not far from the potentially lethal dose. Although chemotherapy is a widely used treatment in the treatment of many cancers, it can also cause severe adverse affects, which some patients are simply unable to tolerate. The most common adverse effects of chemotherapy are nausea and retching.

The nausea and retching associated with chemotherapy are often disabling and intractable. The severity of the symptoms and their medical consequences vary from patient to patient. In many cases, the immediate results are weight loss, fatigue, and chronic discomfort. The consequences can be far graver in patients whose health and functioning is already compromised. For example, the dangers associated with weight loss and malnutrition are greater in patients whose cancer has metastasized and attacked other parts of the body.

... I have prescribed Marinol to some of my patients and it has proven effective in some cases. However, scientific and anecdotal reports consistently indicate that smoking marijuana is a therapeutically preferable means of ingestion. Marinol is available in pill form only. Moreover, Marinol contains only one of the many ingredients found in marijuana (THC). It may be that the beneficial effects of THC are increased by the cumulative effect of additional substances found in cannabis. That is an area for future research. For whatever reason, smoking appears to result in faster, more effective relief, and dosage levels are more easily titrated and controlled in some patients.

**Kate Scannell, MD**

Because I was a cancer patient receiving chemotherapy at the same hospital where I worked, the women with whom I shared the suite quickly surmised that I was also a doctor. The clues were obvious: the colleagues dropping by, the “doctor” salutations from co-workers and the odd coin-
cidence that one of my suite mates was also one of my patients.

I braced myself for this woman's question, both wanting to make myself available to her but also wishing that the world could forget that I was a doctor for the moment. After receiving my cancer diagnosis, dealing with surgery and chemo-therapy and grappling with insistent reminders of my mortality, I had no desire to think about medicine or to experience myself as a physician in that oncology suite. And besides, the chemotherapy, anti-nauseants, sleep medications and prednisone were hampering my ability to think clearly.

So, after a gentle disclaimer about my clinical capabilities, I said I'd do my best to answer her question. She shoved her IV line out of the way and, with great effort and discomfort, rolled on her side to face me. Her belly was a pendulous sack bloated with ovarian cancer cells, and her eyes were vacant of any light. She became short of breath from the task of turning toward me.

"Tell me," she managed, "Do you think marijuana could help me? I feel so sick."

I winced. I knew about her wretched pain, her constant nausea and all the prescription drugs that had failed her —some of which also made her more constipated, less alert and even more nauseous. I knew about the internal derangements of chemotherapy, the terrible feeling that a toxic swill is invading your bones, destroying your gut and softening your brain. I knew this woman was dying a prolonged and miserable death.

And, from years of clinical experience, I —like many other doctors —also knew that marijuana could actually help her. 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. I could firmly attest to its benefits and wager the likelihood that it would decrease her suffering.

Still, federal law has forbidden doctors to . . . prescribe marijuana to patients [though doctors may legally recommend it.] In fact, in 1988 the Drug Enforcement Agency even rejected one of its own administrative

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"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
law judge's conclusions supporting medicinal marijuana, after two full years of hearings on the issue.

Judge Francis Young recommended the change on grounds that “marijuana, in its natural form, is one of the safest therapeutically active substances known to man,” and that it offered a “currently accepted medical use in treatment.”

Doctors see all sorts of social injustices that are written on the human body, one person at a time. But this one — the rote denial of a palliative care drug like marijuana to people with serious illness — smacks of pure cruelty precisely because it is so easily remediable, precisely because it prioritizes service to a cold political agenda over the distressed lives and deaths of real human beings.

Washington bureaucrats — far removed from the troubled bedside of sick and dying patients — are ignoring what patients and doctors and health care workers are telling them about real world suffering. The federal refusal to honor public referendums like California’s voter-approved Medical Marijuana Initiative is bewildering. Its refusal to listen to doctors groups like the California Medical Association that support compassionate use of medical marijuana is chilling.

In a society that has witnessed extensive positive experiences with medicinal marijuana, as long as it is safe and not proven to be ineffective, why shouldn’t seriously ill patients have access to it? Why should an old woman be made to die a horrible death for a hollow political symbol?

—Dr. Scannell is co-director of the Ethics Department of Kaiser-Permanente.

THE HISTORY OF CANNABIS AS MEDICINE

While the federal government has resisted restoring cannabis to its place in the US Pharmacopoeia, its own research studies acknowledge that the “use of cannabis for purposes of healing predates recorded history” and that it was included in “the 15th century BC Chinese Pharmacopoeia, the Rh-Ya.” Ancient Egypt, India and Persia all made medical use of it more than 2,000 years ago. British herbalists in the 17th century noted its medicinal properties, but it did not become widely used in British medicine until the mid-19th century. In 1890, Queen Victoria’s personal physician, Sir Russell Reynolds, wrote in the first issue of The Lancet, “When pure and administered carefully, [it is] one of the most valuable medicines we possess.”

William O’Shaughnessy, a British East Indian Company surgeon who studied its use while posted in India, expanded western understanding of its range of applications and championed its use upon his return to Britain in 1841 and election to the Royal Society, the scientific advisory body to the British government. Between 1840 and 1900, European and American medical journals published more than 100 articles on the therapeutic applications of cannabis, known then as Cannabis Indica or Indian hemp. Common indications for its
use in the nineteenth century included “muscle spasms, menstrual cramps, rheumatism, and the convulsions of tetanus, rabies and epilepsy; it was also used to promote uterine contractions in childbirth, and as a sedative to induce sleep.”

The American Medical Association in an article on the first federal law restricting legal access to cannabis noted that “No evidence has been produced to show the existence of addiction to cannabis arising out of the medicinal use of the drug.” The AMA’s lobbyist, 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."

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, 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 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.

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

Research Citations


122. Reynolds JR (1890). Op Cit.
123. House of Lords (1898). Op Cit.
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.