tongue or face, thirst, tingling in hands or feet, tremors, unpleasant taste in the mouth, urinating more or less than usual, vague feeling of bodily discomfort, vertigo, vomiting, weakness, and yellow eyes and skin.

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.

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**

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. 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.

Benzodiazepine drugs **Ativan** and **Xanax** are prescribed to combat the anxiety associated with chronic pain. 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.

Cannabis: By comparison, the side effects associated with cannabis are typically mild and are classified as "low risk." Euphoric mood changes are among the most frequent side effects. Cannabinoids can exacerbate schizophrenic psychosis in predisposed persons. Cannabinoids impede cognitive and psychomotor performance, resulting in temporary impairment. Chronic use can lead to the development of tolerance. Tachycardia and hypotension are frequently documented as adverse events in the cardiovascular system. A few cases of myocardial ischemia have been reported in young and previously healthy patients. Inhaling the smoke of cannabis cigarettes induces side effects on the respiratory system. Cannabinoids are contraindicated for patients with a history of cardiac ischemias. In summary, a low risk profile is evident from the literature available. Serious complications are very rare and are not usually reported during the use of cannabinoids for medical indications.

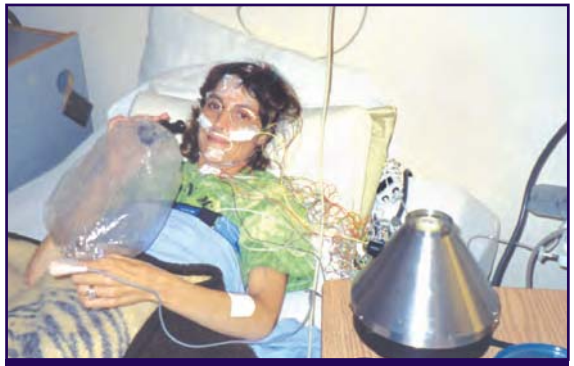
Is cannabis safe to recommend?

"The smoking of cannabis, even long term, is not harmful to health...." So began a 1995 editorial statement of Great Britain's leading medical journal, *The Lancet*. The long history of human use of cannabis also attests to its safety—nearly 5,000 years of documented use without a single death. In the same year as the *Lancet* editorial, Dr. Lester Grinspoon, a professor emeritus at Harvard Medical School who has published many influential books and articles on medical use of cannabis, had this to say in an article in the *Journal of the American Medical Association* (1995):

> "One of marihuana's greatest advantages as a medicine is its remarkable safety. It has little effect on major physiological functions. There is no known case of a lethal overdose; on the basis of animal models, the ratio of lethal to effective dose is estimated as 40,000 to 1. By comparison, the ratio is between 3 and 50 to 1 for secobarbital and between 4 and 10 to 1 for ethanol. Marihuana is also far less addictive and far less subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics. The chief legitimate concern is the effect of smoking on the lungs.

Cannabis smoke carries even more tars and other particulate matter than tobacco smoke. But the amount smoked is much less, especially in medical use, and once marihuana is an openly recognized medicine, solutions may be found; ultimately a technology for the inhalation of cannabinoid vapors could be developed."

The technology Dr. Grinspoon imagined in 1995 now exists in the form of "vaporizers," (which are widely available through stores and by mail-order) and recent research attests to their efficacy and safety.[35] 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. As Dr. Grinspoon goes on to say, "the greatest danger in medical use of marihuana is its illegality, which imposes much anxiety and expense on suffering people, forces them to bargain with illicit drug dealers, and exposes them to the threat of criminal prosecution." This was the same conclusion reached by the House of Lords report, which recommended rescheduling and decriminalization, both of which were enacted in Great Britain in 2004.



Angel Raich using a vaporizer in the hospital

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 New Mexico state research program conducted from 1978 to 1986 provided cannabis or Marinol to about 250 cancer patients for whom conventional medications had failed to control the nausea and vomiting associated with chemotherapy. At a DEA hearing, a physician with the program testified that cannabis was clearly superior to both Chlorpromazine and Marinol for these patients. Additionally, patients frequently have difficulty getting the right dose with Marinol, while inhaled cannabis allows for easier titration and avoids the negative side effects many report with Marinol. As the House of Lords report states, "Some users of both find cannabis itself more effective."

THE EXPERIENCE OF PATIENTS

Angel McClary Raich

I have been permanently disabled since September 1995. I am a mother of two teenage children. My children know more than anyone how medical cannabis brought their mommy back to them. The hardest part of being disabled is watching the suffering in your children's eyes as they watch you endure such suffering with no end in sight.

In late 1997, my doctor felt cannabis would be an effective medication to treat my many complicated and complex medical conditions. I was in a wheelchair from January 1996 to August 1999. Cannabis was responsible for getting me out of my wheelchair and restoring mobility on the whole right side of my body. For years I felt as if I was suffering in Hell. What I had to endure was unbelievable and indescribable torture.

I suffer greatly from severe chronic pain every single day. The prolonged pain and suffering from my medical conditions significantly interferes with my quality of life. My treatment is complicated by the fact that I am violently allergic and have severe multiple chemical sensitivities to almost all pharmaceutical medicines. This interferes with the treatment of all of my medical conditions, and it means my suffering cannot be controlled by synthetic medications. This makes it extremely difficult for doctors to effectively help me combat my diseases. Without cannabis my life would be a death sentence.

Dorothy Gibbs

In 1911, at the age of one, I contracted the polio virus. . . The early onset of polio caused permanent damage in my legs, spine, and back, resulting in significant weakness and atrophy in my legs. As a result, I have never been able to walk without the assistance of crutches and braces or a wheelchair. Approximately 30 years ago, my condition began

to deteriorate. I began to suffer from increasing levels Angel Raich using a vaporizer in the hospital of pain and weakness in my legs and back as well as severe osteoarthritis in my hands, arms, and joints. Over time, my deteriorating medical condition has been exacerbated by my pain, leaving me increasingly immobilized....

By May, 1996, my physician [Dr. Arnold Leff, M.D.] had tried various prescription medications to relieve my pain, including: Tylenol #3, Ultram, Daypro, Tegretol, Soma, Valium, steroid injections into the trigger point, Dilantin, Duragesic, Zofran and Comapazine for the nausea caused by the opioid pain relievers, and Doloboid and Lodine as nonsteroids. Nothing seemed to work, and the pain persisted. I was growing increasingly depressed by the inability of anything to relieve my pain....

During this period it was clear to me, my caretaker, and my physician that nothing was working to combat my pain. My caretaker, Pat, had heard of the success some people experience with the medicinal use of marijuana for pain management. Sometime during the end of 1997, she obtained a sample for me. Although I had never used marijuana in my previous eighty-seven years of life, I was willing to try anything that could alleviate even part of the pain.

The relief I experienced from medical marijuana was almost immediate. I was so pleased with the result that I wrote to Dr. Leff about my use of medical marijuana and we talked about the benefits of the medicine. Dr. Leff examined me and noted that medical marijuana helped me experience less chronic pain and nausea, leading him to recommended medical marijuana as part of my daily pain care regimen....

I strongly feel that I should have the right to use anything that may relieve any or some of my pain, and my last days should not be spent suffering. In 1998, around the time that I had to stop using the Duragesic patch, Dr. Leff prescribed 5 milligram tablets of Marinol, to be taken as needed, for pain management. He explained that Marinol was like marijuana, which I was already using on occasion. Although Marinol provided me with some minor relief from muscle spasms and bodily pains, its effect was slow and unpredictable.... At times, however, I am stricken with severe spasms of pain, and medical marijuana is the only medication that provides quick and effective relief.... Medical marijuana also combats the nausea that accompanies many of the oral medications I am prescribed, including anti-inflammatory medications such as Motrin.

Ever since trying medical marijuana, my life has drastically improved. Although chronic pain, related to my post-polio syndrome will always be a part of my life, medical marijuana had helped me manage this pain by providing fast and effective relief for my muscle spasms, acute pains, and arthritis....

Since I began using medical marijuana, my pain is no longer persistent or debilitating. When I do suffer from pain, I am usually able to "get ahead of it" by using medical marijuana and make it manageable....

James Daniel Baehr

In 1994, I was diagnosed with inoperable prostate cancer.... the cancer had metastasized to my spine, hips, and ribcage. The neuropathic back pain was excruciating, emanating from my spine to my hips and ribcage. I also experienced an overall loss of strength that substantially limited my ability to work. Employment in the transportation industry involves a considerable amount of carrying, lifting, and other manual labor that requires flexibility and mobility. The performance of these requirements exacerbated the magnitude and amount of pain I experienced on a daily basis and depleted any energy that had not already been beaten down by the disease itself.

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.

I began taking numerous medications to treat the cancer, the excruciating pain that it caused, and the depression I felt as a result of my prognosis and the profound restrictions on my life. My medications included a daily dosage of 7.5 mg of Lortab (a painkiller), .25 mg of Xanax (which combats depression and anxiety), 40 mg of Paxil (an anti-depressant), and 250 mg of Eulexin (which treats the cancer by reducing the testosterone emitted from adrenal glands), and monthly shots of 7.5 mg of Lupron Depot (a testosterone blocker/hormonal therapy). I suffered various side effects from these medications, including persistent exhaustion, general pain, a lack of mental focus, and overall body tenderness. In combination, these side effects were quite debilitating....

From September through December of 1995, I endured nine weeks of radiation. The treatment left me with continued back pain, intense nausea, loss of appetite, diverticulitis, sleep abnormalities, and digestive and intestinal complications. It also left me increasingly depressed.

In late 1994 or 1995, a physician at the Radiology Department at Stanford University Hospital prescribed Marinol to alleviate my pain and nausea from the radiation. I tried the Marinol but did not respond

well to it. Not only did Marinol make me feel drugged and not in control of my thoughts or body, but it failed to relieve my painful symptoms.

In fact, Marinol just made me feel sicker, upsetting my stomach, disrupting my mental acuity, and causing me to hallucinate. During this period, I was also taking 7.5 mg of Lortab, an opioid analgesic, several times a day and Ambien to help me sleep. These drugs alleviated the pain somewhat, but also made me disoriented, constipated, and caused me to lose my short-term memory and fine motor skills.

Perhaps sensing that my hope was receding as my misery was increasing, a nurse at Stanford Hospital suggested that medical marijuana could alleviate my nausea, restore my appetite, and even help me manage my pain - all potentially without the negative side effects I experienced with Marinol and other medications..

I decided to try a small amount of medical marijuana, and when I did I found that it provided significant relief from the side effects of the cancer medications and the radiation treatment. In addition, it helped reduce the pain I was experiencing from the cancer itself. This new combination of therapies, which included medical marijuana, turned my health around. Where before I had been doubled over with nausea, couldn't eat, or sleep, I was now not only able to handle my medications, but could sleep, eat and manage my pain. I found that a small amount of medical marijuana taken in the evening enabled me to sleep through the entire night so that I no longer needed to take Ambien.

Over time, the pain got progressively worse. In February 1997 I began to take morphine to help with the pain. The amount of morphine that I need to take to adequately control my pain leaves me utterly incapacitated, mentally and physically. Medical marijuana helps me manage my pain, while limiting my dependence on more powerful narcotics.

When I smoke medical marijuana, I can achieve the same degree of pain relief with a much smaller amount of morphine and with far fewer and less harsh side effects. The coupling of medical marijuana with my prescription analgesics has been one of the most significant and successful aspects of my medical treatment.

THE EXPERIENCE OF DOCTORS

Dr. Harvey L. Rose

Both my research and my many years as a clinician have convinced me that marijuana can serve at least two important roles in safe and effective pain management. Ample anecdotal evidence and clinical observations, as well as significant research findings, strongly indicate that marijuana, for whatever reason, is often effective in relieving pain. This is true across a range of patient populations, including the elderly, the terminally ill seeking comfort in their final days, young adults stricken with life-threatening conditions, and cancer patients unable to tolerate the devastating effects of potentially life-saving therapies. Marijuana is also widely recognized as an antiemetic that reduces the nausea and vomiting often induced by powerful opioid analgesics prescribed for chronic, severe pain, as well as the nausea, vomiting and dizziness which often accompany severe and/or prolonged pain. I have had the benefit of consultations on this subject over many years with a range of treatment providers, including physicians, oncologists, pharmacologists, family practitioners, hospice workers, and pain specialists....

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

Specifically, I have found that cannabis can have an important opioid-sparing effect for pain patients. That is to say that patients who are prescribed high doses of opioid analgesics can significantly reduce their reliance on these medications and improve their daily functioning by incorporating cannabis into their pain care regimen.

Marijuana not only has important analgesic properties but it also is an effective and important adjuvant therapy for patients suffering acute and/or chronic pain. No experienced and respected physician will deny that for such patients opioid therapy is central to palliative care. By the same token, the same experienced physicians will readily acknowledge that opioids often induce nausea and vomiting. For a number of pain patients, standard prescription antiemetics (e.g., Compazine, Zofran and Reglan) simply do not substantially reduce their nausea. For many, those medications are substantially less effective, or produce more debilitating side effects, than marijuana....

Quite simply, marijuana can serve much the same function for pain patients undergoing opiate therapy that it does for cancer patients undergoing chemotherapy: it suppresses the nausea and vomiting associated with treatment, and reduces the pain associated with prolonged nausea and retching, thereby increasing the chances that the patient will remain compliant with the primary treatment. With both chemotherapy and long-term pain management, failure to obtain and

continue proper palliative and adjutant care can have dire, even fatal, consequences....

Finally, it is important to note that in my clinical experience observing patients who ingest cannabis for relief from pain and nausea and/or to stimulate appetite, I have witnessed no adverse complications. By contrast, many of the first-line pharmaceuticals used to combat cancer, HIV/AIDS, and pain associated with these and other illnesses can induce a variety of iatrogenic effects, including, in some instances, death. While patients may face serious legal implications related to their use of medical marijuana, as a physician I have yet to encounter a medical downside to their cannabinoid therapy....

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

[A]gainst the backdrop of a growing body of scientific research, the reports of myriad pain patients, and the burgeoning clinical experience of physicians like myself, it is my considered opinion that cannabis can constitute an acceptable and sometimes necessary medicine to alleviate the immediate suffering of certain patients.

Dr. Rose served as a medical officer in the Air Force before entering private practice as a specialist on chronic pain. During his 40-year career, he has taught at the UC Davis School of Medicine, consulted with state legislative bodies in California, Idaho, Nevada, Washington and Oregon on pain management and the appropriate role of regulatory agencies, and received numerous awards.

Richard I. Gracer, M.D.

For a small number of patients, even aggressive opiate therapies are not sufficient. Unless alternative pain treatments are found for such patients, they will continue to suffer. For those individuals, their daily lives are often tortuous. As a physician, I am acutely aware of the disturbing connection between intractable pain, overwhelming despair, and suicide.

I can state confidently, as a physician with an extensive practice and specialized expertise in pain management, that marijuana can prove (and has proven) medically useful to at least some chronic pain patients. Accordingly, I believe that physicians should be able to recommend and/or prescribe marijuana to patients for whom it is medically appropriate. Absent that authority, my ability to treat my patients and provide relief from horrific pain is undermined, as is the trust essential to therapeutic relationship.

Dr. Gracer is Director of Orthopedic Medicine for ChiroView. He is a Fellow of the American Academy of Family Physicians and a Diplomate of the American Academy of Pain Management.

Robert V. Brody, M.D.

As a physician responsible for the care and treatment of those who live in horrible pain, I believe that these patients need, above all else, the broadest possible range of therapeutic options and as full and accurate information as possible regarding those options as they relate to the individual patient. In recent years, I have noted that the public and the government have become increasingly aware of these needs, and one hopes that measures have been taken to promote adequate pain care for the seriously ill and injured. Several states, including California, have adopted laws and/or guidelines for the prescribing of controlled substances, which seem to permit physicians to treat pain patients without fear of sanction or interference from state authorities.

Insofar as The Compassionate Use Act passed in 1996 expressly provides that "chronic pain" is a condition for which physicians are authorized to recommend marijuana without threat or fear of punishment, the Act appears to be an additional assurance for physicians like myself that we can rely upon a full range of treatment modalities to care for patients in pain. The IOM Report provides still further support for doctors insofar as it recognizes the potential medical benefits of marijuana....

Marijuana has a place in any pain physician's armamentarium.

Dr. Brody is Chief of the Pain Consultation Clinic at San Francisco General Hospital. He is a peer reviewer for the Western Journal of Medicine, Journal of General Internal Medicine, Annals of Internal Medicine, *and the* Journal of Law, Medicine and Ethics.

THE HISTORY OF CANNABIS AS MEDICINE

The history of the medical use of cannabis dates back to 2700 B.C. in the pharmacopoeia of Shen Nung, one of the fathers of Chinese medicine. In the west, it has been recognized as a valued, therapeutic herb for centuries. In 1823, Queen Victoria's personal physician, Sir Russell Reynolds, not only prescribed it to her for menstrual cramps but wrote in the first issue of *The Lancet*, "When pure and administered carefully, [it is] one of the of the most valuable medicines we possess." (Lancet 1; 1823).

The American Medical Association opposed the first federal law against cannabis with an article in its leading journal (108 J.A.M.A. 1543-44; 1937). Their representative, Dr. William C. Woodward, testified to Congress that "The American Medical Association knows of no evidence that marihuana is a dangerous drug," and that any prohibition "loses sight of the fact that future investigation may show that there are substantial medical uses for Cannabis." Cannabis remained part of the American pharmacopoeia until 1942 and is currently available by prescription in the Netherlands and Canada.

Federal Policy is Contradictory

Federal policy on medical cannabis is filled with contradictions. 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.

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

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

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, eight surviving patients still receive medical cannabis from the federal government, grown under a doctor's supervision at the University of Mississippi and paid for by federal tax dollars.

Despite this successful medical program and centuries of documented safe use, cannabis is still classified in America as a Schedule I substance.

Healthcare advocates have tried to resolve this contradiction through legal and administrative channels. In 1972, a petition was submitted to reschedule cannabis so that it could be prescribed to patients.

The DEA stalled hearings for 16 years, but in 1988 their chief administrative law judge, Francis L. Young, ruled that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known... It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance."

The DEA refused to implement this ruling based on a procedural technicality and continues to classify cannabis as a substance with no medical use.

Widespread public support; state laws passed

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

The refusal of the federal government to act on this support has meant that patients have had to turn to the states for action. Since 1996, voters have passed favorable medical cannabis ballot initiatives in nine states plus such cities as Ann Arbor, Michigan and the District of Columbia, while the legislatures in Hawaii, Rhode Island, Vermont and Maryland have enacted similar bills. As of June 2006, medical cannabis legislation is under consideration in several states.

Currently, laws that effectively remove state-level criminal penalties for growing and/or possessing medical cannabis are in place in Alaska, California, Colorado, Hawaii, Maine, Maryland, Montana, Nevada, Oregon, Rhode Island, Vermont and Washington. Thirty-six states have symbolic medical cannabis laws (laws that support medical cannabis but do not provide patients with legal protection under state law).

2005 U.S. Supreme Court ruling

In June 2005, the U.S. Supreme Court overturned a decision by a U.S. appeals court (*Raich v. Ashcroft*) that had exempted medical marijuana from federal prohibition. The 2005 decision, now called *Gonzales v.*

Raich, ruled that federal officials may prosecute medical marijuana patients for possessing, consuming, and cultivating medical cannabis. But according to numerous legal opinions, that ruling does not affect individual states' medical marijuana programs, and only applies to prosecution in federal, not state, court.

Petitions for legal prescriptions pending

The federal Department of Health and Human Services (HHS) and the FDA are currently reviewing two legal petitions with broad implications for medical marijuana. The first, brought by ASA under the Data Quality Act, says HHS must correct its statements that there is no medical use for marijuana to reflect the many studies which have found it helpful for many conditions. Acknowledging legitimate medical use would then force the agency to consider allowing the prescribing of marijuana as they do other drugs, based on its relative safety.

A separate petition, of which ASA is a co-signer, asks the Drug Enforcement Administration for a full, formal re-evaluation of marijuana's medical benefits, based on hundreds of recent medical research studies and two thousand years of documented human use.

Legal Citations

1. See "The Administration's Response to the Passage of California Proposition 215 and Arizona Proposition 200" (Dec. 30, 1996).
2. See Conant v. McCaffrey, 172 F.R.D. 681 (N.D. Cal. 1997).
3. See id.; Conant v. McCaffrey, 2000 WL 1281174 (N.D. Cal. 2000); Conant v. Walters, 309 F.3d 629 (9th Cir. 2002).
4. 309 F.3d 629 (9th Cir. 2002).
5. Id. at 634-36.
6. Criminal liability for aiding and abetting requires proof that the defendant "insome sort associate[d] himself with the venture, that he participate[d] in it as something that he wishe[d] to bring about, that he [sought] by his action to make it succeed."Conant v. McCaffrey, 172 F.R.D. 681, 700 (N.D. Cal. 1997) (quotation omitted). A conspiracy to obtain cannabis requires an agreement between two or more persons to do this, with both persons knowing this illegal objective and intending to help accomplish it. Id. at 700-01.
7. 309 F.3d at 634 & 636.
8. Conant v. McCaffrey, 2000 WL 1281174, at *16 (N.D. Cal. 2000).
9. 309 F.3d at 634.
10. See id.. at 635; Conant v. McCaffrey, 172 F.R.D. 681, 700-01 (N.D. Cal. 1997).

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DEA CHIEF ADMINISTRATIVE LAW JUDGE

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

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

ADDITIONAL RESOURCES

Americans for Safe Access maintains a website with more 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.

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. ASA works in partnership with state, local, and national lawmakers to overcome barriers and create policies that improve access to cannabis for patients and researchers. We have more than 30,000 active members with chapters and affiliates in more than 40 states.

ASA provides medical information and legal training for patients, attorneys, health and medical professionals, and policymakers throughout the United States.

AmericansFor SafeAccess
FOUNDATION
Advancing Legal Medical Marijuana Therapeutics and Research

888-929-4367 **www.AmericansForSafeAccess.com**
1322 Webster Street, Suite 402, Oakland, California 94612

ATTACHMENT 5-4

CANCER
AND
MEDICAL MARIJUANA

AmericansFor SafeAccess FOUNDATION
Advancing Legal Medical Marijuana Therapeutics and Research

A Note from Americans for Safe Access

We are committed to ensuring safe, legal availability of marijuana for medical uses. This brochure is intended to help doctors, patients and policymakers better understand how marijuana—or "cannabis" as it is more properly called—may be used as a treatment for people with serious medical conditions. This booklet contains information about using cannabis as medicine. In it you'll find information on:

We recognize that information about using cannabis as medicine has been difficult to obtain. The federal prohibition on cannabis has meant that modern clinical research has been limited, to the detriment of medical science and the wellness of patients. But the documented history of the safe, medical use of cannabis dates to 2700 B.C. Cannabis was part of the American pharmacopoeia until 1942 and is currently available by prescription in the Netherlands and Canada.

Testimonials from both doctors and patients reveal valuable information on the use of cannabis therapies, and supporting statements from professional health organizations and leading medical journals support its legitimacy as a medicine. In the last few years, clinical trials in Great Britain, Canada, Spain, Israel, and elsewhere have shown great promise for new medical applications.

This brochure is intended to be a starting point for the consideration of applying cannabis therapies to specific conditions; it is not intended to replace the training and expertise of physicians with regard to medicine, or attorneys with regard to the law. But as patients, doctors and advocates who have been working intimately with these issues for many years, Americans for Safe Access has seen firsthand how helpful cannabis can be for a wide variety of indications. We know doctors want the freedom to practice medicine and patients the freedom to make decisions about their healthcare.

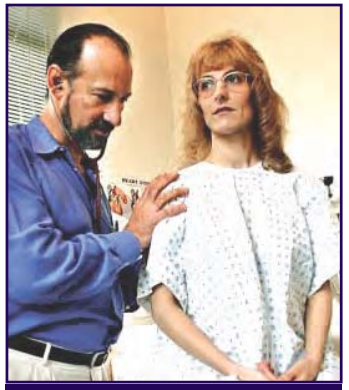
For more information about ASA and the work we do, please see our website at **AmericansForSafeAccess.org** or call **1-888-929-4367**.

Cannabis Legal to Recommend?

In 2004, the United States Supreme Court upheld earlier federal court decisions that doctors have a fundamental Constitutional right to recommend cannabis to their patients.

The history. Within weeks of California voters legalizing medical cannabis in 1996, federal officials had threatened to revoke the prescribing privileges of any physicians who recommended cannabis to their patients for medical use.[1] In response, a group of doctors and patients led by AIDS specialist Dr. Marcus Conant filed suit against the government, contending that such a policy violates the First Amendment.[2] The federal courts agreed at first the district level,[3] then all the way through appeals to the Ninth Circuit and then the Supreme Court.

What doctors may and may not do. In *Conant v. Walters*,[4] the Ninth Circuit Court of Appeals held that the federal government could neither punish nor threaten a doctor merely for recommending the use of cannabis to a patient.[5] But it remains illegal for a doctor to "aid and abet" a patient in obtaining cannabis.[6] This means a physician may discuss the pros and cons of medical cannabis with any patient, and issue a written or oral recommendation to use cannabis without fear of legal reprisal.[7] This is true regardless of whether the physician anticipates that the patient will, in turn, use this recommendation to obtain cannabis.[8] What physicians may not do is actually prescribe or dispense cannabis to a patient[9] or tell patients how to use a written recommendation to procure it from a cannabis club or dispensary.[10] Doctors can tell patients they may be helped by cannabis. They can put that in writing. They just can't help patients obtain the cannabis itself.



Angel Raich & Dr. Frank Lucido

Patients protected under state, not federal, law. In June 2005, the U.S. Supreme Court overturned the *Raich v. Ashcroft* Ninth Circuit Court of Appeals decision. In reversing the lower court's ruling, *Gonzales v. Raich* established that it is legal under federal law to prosecute patients who possess, grow, or consume medical cannabis in medical cannabis states. However, this Supreme Court decision does not overturn or supersede the laws in states with medical cannabis programs.

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

Scientific Research Supports Medical Cannabis

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

The safety of the drug has been attested to by numerous studies and reports, including the *LaGuardia Report* of 1944, the *Schafer Commission Report* of 1972, a 1997 study conducted by the British House of Lords, the Institutes of Medicine report of 1999, research sponsored by Health Canada, and numerous studies conducted in the Netherlands, where cannabis has been quasi-legal since 1976 and is currently available from pharmacies by prescription.

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**

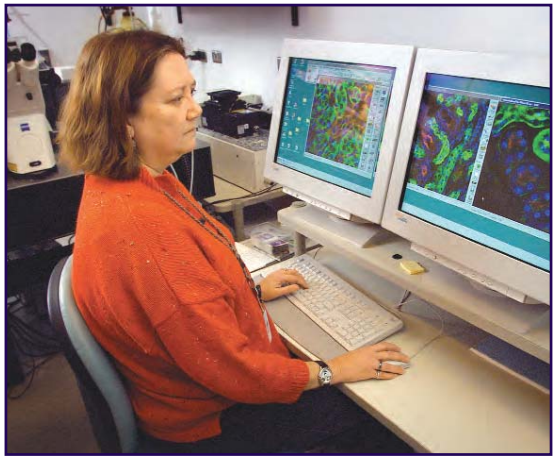
Recent published research on CD4 immunity in AIDS patients found no compromise to the immune systems of patients undergoing cannabis therapy in clinical trials.[11]

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 300 in 2005. 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. The University of California established the Center for Medicinal Cannabis Research in 2001. As of June 2006, the CMCR has 17 approved studies, including research on cancer pain, nausea control in chemotherapy, general analgesia and a proposed study on refractory cancer pain.

In the United Kingdom, GW Pharmaceuticals has been granted a clinical trial exemption certificate by the Medicines Control Agency to conduct clinical studies with cannabis-based medicines. The exemption includes investigations in the relief of pain of neurological origin and defects of neurological function in the following indications: multiple sclerosis (MS), spinal cord injury, peripheral nerve injury, central nervous system damage, neuroinvasive cancer, dystonias, cerebral vascular accident and spina bifida, as well as for the relief of pain and inflammation in rheumatoid arthritis and also pain relief in brachial plexus injury.



GW has completed Phase III studies in patients with MS neuropathic pain and spasticity, and Phase II trials on perioperative pain, rheumatoid arthritis, peripheral neuropathy secondary to diabetes mellitus or AIDS, and patients with neurogenic symptoms.

These trials have provided positive results and confirmed an excellent safety profile for cannabis-based medicines. In 2002, GW conducted five Phase III trials of its cannabis derivatives, including a double-blind, placebo-controlled trial with a sublingual spray containing THC in more than 100 patients with cancer pain. In total, more than 1,000 patients are currently involved in phase III trials in the UK.

In 2002 GW Pharmaceuticals received an IND approval to commence phase II clinical trials in Canada in patients with chronic pain, multiple sclerosis and spinal cord injury, and in April 2005 GW received regulatory approval to distribute Sativex in Canada for the relief of neuropathic pain in adults with Multiple Sclerosis. Following meetings with the FDA, DEA, the Office for National Drug Control Policy, and the National Institute for Drug Abuse, GW was granted an import license from the DEA and has imported its first cannabis extracts into the U.S., and in

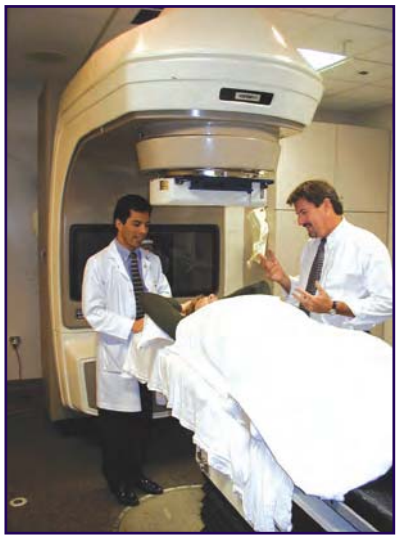
January of 2006 was granted permission to begin Phase III clinical trials into cancer pain.

CANNABIS AND CANCER

Cannabis has been found to help cancer patients with pain and nausea, and recent research indicates it has tumor-reducing and anti-carcinogenic properties properties as well. It has proven highly effective at controlling the nausea associated with chemotherapy, and its appetite-stimulation properties help combat wasting. Cannabis can also help control the pain associated with some cancers, as well as that resulting from radiation and chemotherapy treatment.

Cannabis and chemotherapy side effects

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 studies have reported that the use of cannabis reduces nausea and vomiting and stimulates appetite, thereby reducing the severity of cachexia, or wasting syndrome, in patients receiving chemotherapy treatment.



The 1999 Institutes of Medicine report concluded: "In 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."[12]

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."[13,14]

In the last three years, there have been major advances in both cannabinoid pharmacology and in understanding of the cancer disease process. In particular, research has demonstrated the presence of numerous cannabinoid receptors in the nucleus of the solitary tract, a brain center important in control of vomiting.

Although other recently developed anti-emetics are as effective or more effective than oral THC, nabilone or smoked cannabis, for certain individuals unresponsive to conventional anti-emetic drugs, the use of smoked cannabis can provide relief more effectively than oral preparations which may be difficult to swallow or be vomited before taking effect, as the IOM report notes.

The psychoactive/euphoriant effects of THC or inhaled cannabis may also provide an improvement in mood. 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.

While clinical research on using cannabis medicinally has been severely limited by federal prohibition,the accumulated data speaks strongly in favor of considering it as an option for most cancer patients, and many oncologists do. Survey data from a Harvard Medical School study in 1990, before any states had approved medical use, shows that 44% of oncologists had recommended cannabis to at least some of their patients. Nearly half said they would do so if the laws were changed. According the American Cancer Society's 2003 data, more than 1,300,000 Americans are diagnosed with cancer each year.[15] At least 300,000 of them will undergo chemotherapy, meaning as many as 132,000 patients annually may have cannabis recommended to them to help fight the side effects of conventional treatments.

As the Institutes of Medicine report concluded, "nausea, appetite loss, pain and anxiety … all can be mitigated by marijuana."

Research on cannabis and chemotherapy

Cannabis is used to combat pain caused by various cancers and nausea induced by chemotherapy agents. Over 30 human clinical trials have examined the effects of cannabis or synthetic cannabinoids on nausea, not including several U.S. state trials that took place between 1978 and 1986.[16] In reviewing this literature, Hall et al. concluded that ". . . THC [delta-9-tetrahydrocannabinol] is superior to placebo, and equivalent in effectiveness to other widely-used anti-emetic drugs, in its capacity to reduce the nausea and vomiting caused by some chemotherapy regimens in some cancer patients."[17] A 2003 study found "Cannabinoids—the active components of cannabis sativa and their derivatives—exert

palliative effects in cancer patients by preventing nausea, vomiting and pain and by stimulating appetite. In addition, these compounds have been shown to inhibit the growth of tumor cells in culture and animal models by modulating key cell-signaling pathways. Cannabinoids are usually well tolerated, and do not produce the generalized toxic effects of conventional chemotherapies."[18]

Authors of the Institute of Medicine report, "Marijuana and Medicine: Assessing the Science Base," found that there are certain cancer patients for whom cannabis should be a valid medical option.[19] A random-sample anonymous survey conducted in the spring of 1990 measured the attitudes and experiences of oncologists concerning the antiemetic use of cannabis in cancer chemotherapy patients. Of the respondents expressing an opinion, a majority (54%) thought cannabis should be available by prescription.[20]

Cancer-fighting properties of cannabis

More than twenty major studies published between 2001 and 2006have shown that the chemicals in cannabis known as cannabinoids have a significant effect fighting cancer cells. We now know cannabinoids arrest many kinds of cancer growths (brain, breast, leukemic, melanoma, phaeochromocytoma, et al.) through promotion of apoptosis (programmed cell death) that is lost in tumors, and by arresting angiogenesis (increased blood vessel production).

Recent scientific advances in the study of cannabinoid receptors and endocannabinoids have produced exciting new leads in the search for anti-cancer treatments.

There is growing evidence of direct anti-tumor activity of cannabinoids, specifically CB1 and CB2 agonists, in a range of cancer types including brain (gliomas), skin, pituitary, prostate and bowel. The antitumor activity has led in laboratory animals and in-vitro human tissues to regression of tumors, reductions in vascularisation (blood supply) and metastases (secondary tumors), as well as direct inducement of death (apoptosis) among cancer cells. Indeed, the complex interactions of endogenous cannabinoids and receptors are leading to greater scientific understanding of the mechanisms by which cancers develop.

The findings of these studies are borne out by the reports of such patients as Steve Kubby, whose cannabis use is credited with keeping a rare, terminal cancer in a state of remission for decades beyond conventional expectations.

Research on tumor reduction

Although cannabis smoke has been shown to have precancerous-causing effects in animal tissue, epidemiological studies on humans have failed to link cannabis smoking with cancer.[21,22] If smoke inhalation is a concern, cannabis can be used with a vaporizer, orally in baked goods, and topically as a tincture or a suppository.

Cannabinoids, the active components of cannabis, have been shown to exhibit anti-tumor properties. Multiple studies published between 2001 and 2006 found that cannabinoids inhibit tumor growth in laboratory animals.[23-27] In another 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.[28] Other journals have also reported on cannabinoids' antitumoral potential.[29-35] Italian research teams reported in 1998 and 2001 that the endocannabinoid anandamide, which binds to the same brain receptors as cannabis, "potently and selectively inhibits the proliferation of human breast cancer cells in vitro" by interfering with their DNA production cycle.[36-38] Cannabis has been shown in recent studies to inhibit the growth of thyroid, prostate and colorectal cancer cells.[39-41] THC has been found to cause the death of glioma cells.[42,43] And research on pituitary cancers shows cannabinoids are key to regulating human pituitary hormone secretion.[44-47]

In 2004 an Italian research team demonstrated that the administration of the non-psychoactive cannabinoid cannabidiol (CBD) to nude mice significantly inhibited the growth of subcutaneously implanted U87 human glioma cells. The authors of the study concluded 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 (an agent that inhibits the growth of malignant cells.)"[48]

More recently, investigators at the California Pacific Medical Center Research Institute reported that the administration of THC on human glioblastoma multiforme cell lines decreased the proliferation of malig-

nant cells and induced apoptosis (programmed cell death) more rapidly than did the administration of an alternative synthetic cannabis receptor agonist.[49]

How cannabis compares to other medications

The American Cancer Society lists 269 medicines 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 13 drugs are currently prescribed to treat nausea, including Marinol, a synthetic form of delta-9-THC, one of the active ingredients in cannabis.

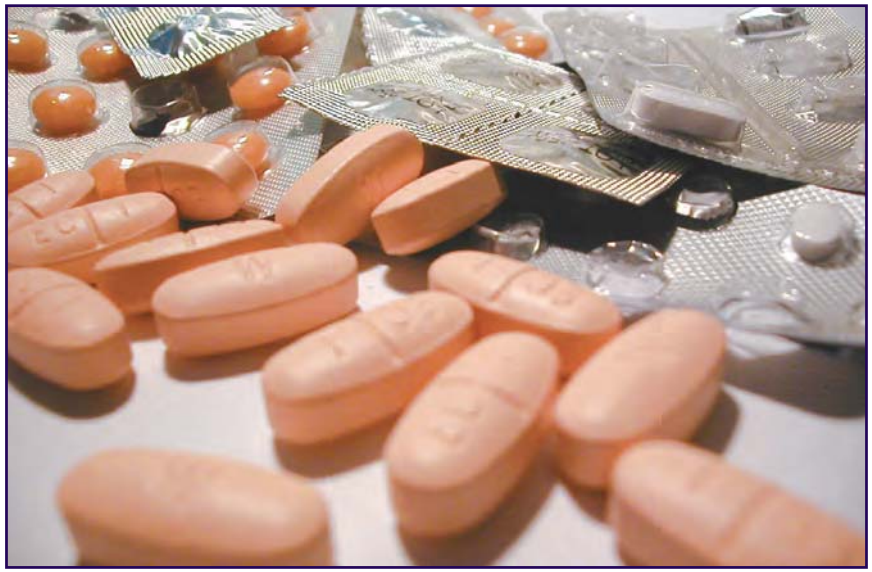
The newer antiemetics, Anzamet, Kytril and Zofran, are serotonin antagonists, blocking the neurotransmitter that sends a vomiting signal to the brain. Rare side effects of these drugs include fever, fatigue, bone pain, muscle aches, constipation, loss of appetite, inflammation of the pancreas, changes 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.

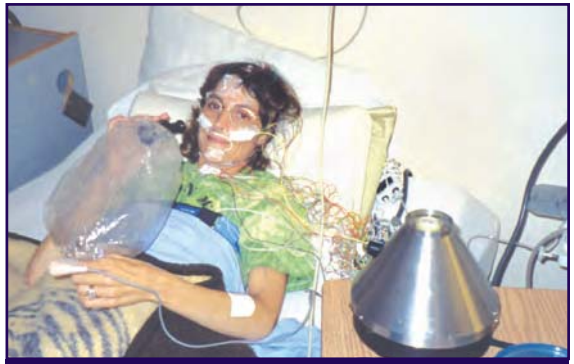
In addition, in April 2003 the FDA approved the drug Emend (aprepitant) to help control delayed-onset nausea. It is given along with two other anti-nausea drugs. A regimen of three pills costs $250. The most common side effects with Emend are fatigue, nausea, loss of appetite, constipation, diarrhea.

Cannabis: 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...."



Angel Raich using a vaporizer in the hospital

So began a 1995 editorial statement of Great Britain's leading medical journal, *The Lancet*. The long history of human use of cannabis also attests to its safety—nearly 5,000 years of documented use without a single death. In the same year as the *Lancet* editorial, Dr. Lester Grinspoon, a professor emeritus at Harvard Medical School who has published many influential books and articles on medical use of cannabis, had this to say in an article in the *Journal of the American Medical Association* (1995):

> "One of marihuana's greatest advantages as a medicine is its remarkable safety. It has little effect on major physiological functions. There is no known case of a lethal overdose; on the basis of animal models, the ratio of lethal to effective dose is estimated as 40,000 to 1. By comparison, the ratio is between 3 and 50 to 1 for secobarbital and between 4 and 10 to 1 for ethanol. Marihuana is also far less addictive and far less subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics. The chief legitimate concern is the effect of smoking on the lungs. Cannabis smoke carries even more tars and other particulate matter than tobacco smoke. But the amount smoked is much less, especially in medical use, and once marihuana is an openly recognized medicine, solutions may be found; ultimately a technology for the inhalation of cannabinoid vapors could be developed."

The technology Dr. Grinspoon imagined in 1995 now exists in the form of "vaporizers," (which are widely available through stores and by mail-order) and recent research attests to their efficacy and safety.[35] 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. As Dr. Grinspoon goes on to say, "the greatest danger in medical use of marihuana is its illegality, which imposes much anxiety and expense on suffering people, forces them to bargain with illicit drug dealers, and exposes them to the threat of criminal prosecution." This was the same conclusion reached by the House of Lords report, which recommended rescheduling and decriminalization, both of which were enacted in Great Britain in 2004.

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 New Mexico state research program conducted from 1978 to 1986 provided cannabis or Marinol to about 250 cancer patients for whom conventional medications had failed to control the nausea and vomiting associated with chemotherapy. At a DEA hearing, a physician with the program testified that cannabis was clearly superior to both Chlorpromazine and Marinol for these patients. Additionally, patients frequently have difficulty getting the right dose with Marinol, while inhaled cannabis allows for easier titration and avoids the negative side effects many report with Marinol. As the House of Lords report states, "Some users of both find cannabis itself more effective."

THE EXPERIENCE OF PATIENTS

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, methotraxate, 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 discomfort 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.

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.

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.

-Sworn testimony by Judith Cushner in Conant v. McCaffrey, 2/14/1997

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

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

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, former 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.

—Anonymous patient

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, former 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 nau-

sea, 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. I also observed that medical marijuana was clinically effective in treating the nausea of some patients.

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

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.

—Howard D. Maccabee, M.D.

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 coincidence 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

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 (United Kingdom)
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

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 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 bedsides 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

The history of the medical use of cannabis dates back to 2700 B.C. in the pharmacopoeia of Shen Nung, one of the fathers of Chinese medicine. In the west, it has been recognized as a valued, therapeutic herb for centuries. In 1823, Queen Victoria's personal physician, Sir Russell Reynolds, not only prescribed it to her for menstrual cramps but wrote in the first issue of *The Lancet*, "When pure and administered carefully, [it is] one of the of the most valuable medicines we possess." (Lancet 1; 1823).

The American Medical Association opposed the first federal law against cannabis with an article in its leading journal (108 J.A.M.A. 1543-44; 1937). Their representative, Dr. William C. Woodward, testified to Congress that "The American Medical Association knows of no evidence that marihuana is a dangerous drug," and that any prohibition "loses sight of the fact that future investigation may show that there are substantial medical uses for Cannabis." Cannabis remained part of the American pharmacopoeia until 1942 and is currently available by prescription in the Netherlands and Canada.

Federal Policy is Contradictory

Federal policy on medical cannabis is filled with contradictions. 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.

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

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

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, eight surviving patients still receive medical cannabis from the federal government, grown under a doctor's supervision at the University of Mississippi and paid for by federal tax dollars.

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

The DEA stalled hearings for 16 years, but in 1988 their chief administrative law judge, Francis L. Young, ruled that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known... It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance."

The DEA refused to implement this ruling based on a procedural technicality and continues to classify cannabis as a substance with no medical use.

Widespread public support; state laws passed

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

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**

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, voters have passed favorable medical cannabis ballot initiatives in nine states plus such cities as Ann Arbor, Michigan and the District of Columbia, while the legislatures in Hawaii, Rhode Island, Vermont and Maryland have enacted similar bills. As of June 2006, medical cannabis legislation is under consideration in several states.

Currently, laws that effectively remove state-level criminal penalties for growing and/or possessing medical cannabis are in place in Alaska, California, Colorado, Hawaii, Maine, Maryland, Montana, Nevada, Oregon, Rhode Island, Vermont and Washington.

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.

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

A separate petition, of which ASA is a co-signer, asks the Drug Enforcement Administration for a full, formal re-evaluation of marijuana's medical benefits, based on hundreds of recent medical research studies and two thousand years of documented human use.

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

ADDITIONAL RESOURCES

Americans for Safe Access maintains a website with more 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.

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. ASA works in partnership with state, local, and national lawmakers to overcome barriers and create policies that improve access to cannabis for patients and researchers. We have more than 30,000 active members with chapters and affiliates in more than 40 states.

ASA provides medical information and legal training for patients, attorneys, health and medical professionals, and policymakers throughout the United States.

AmericansFor SafeAccess
FOUNDATION
Advancing Legal Medical Marijuana Therapeutics and Research

888-929-4367 **www.AmericansForSafeAccess.com**
1322 Webster Street, Suite 402, Oakland, California 94612

ERBA Wellness

Patient Care Guide for the Responsible Use of Medical Marijuana

ERBA Wellness August 2015

Self - Assessment Checklist Date_____

Please indicate below your typical level of severity of the following symptoms:

Symptom	Severity (low to high)	Comments
Pain	1 2 3 4 5	
Cachexia or Wasting Syndrome	1 2 3 4 5	
Nausea	1 2 3 4 5	
Seizures	1 2 3 4 5	
Muscle Spasms	1 2 3 4 5	
Agitation	1 2 3 4 5	
Other	1 2 3 4 5	

Notes:

Copy this page to keep an on-going log of your symptoms
Enigami Systems at enigamisystems.com has symptom tracking software at a nominal cost.

MEDICATION TRACKING CALENDAR **DATE:**

Monday
Strain:

Dose: (frequency, amount & method of MMJ used)

Effects:

Tuesday:
Strain:

Dose:

Effects:

Wednesday
Strain:

Dose:

Effects:

Thursday
Strain:

Dose:

Effects:

Friday
Strain:

Dose:

Effects:

Saturday:
Strain:

Dose:

Effects:

Sunday:
Strain:

Dose:

Effects:

Weekly Comments:

Bring this sheet & your symptom tracking sheets to your appointment with your recommending doctor. These will help determine the effectiveness of your medication.

Copy this page to keep an on-going log of your medicine usage.

INTRODUCTION

The objective of this manual is to give Patient Service Providers all the tools necessary to understand medical cannabis, be able to identify strains, and use this knowledge to better their daily health and wellness.

CANNABIS OVERVIEW:

Cannabis is natural herb that may now be the most studied plant ever worldwide. In the United States, the FDA has been approving numerous studies and the Federal Government has recently authorized NIDA to double its cultivation facilities in order to grow more cannabis to supply the many FDA approved studies currently underway. The effects of cannabis are wide-ranging and substantial in therapeutic value, while physical side effects are very minimal. Cannabis is used to treat symptoms rather than curing diseases. Understanding how cannabis works is the key to utilizing marijuana as medicine. As many patients are new to this experience, we feel a need to explain the reasons why we suggest a certain strain for specific medical benefit. We hope this information helps us build lasting relationships with our well-informed patients.

THE BASICS:

Marijuana consists of 86 known cannabinoids but studies have been done on only a few:

THC (delta-tetrahydrocannabinol)

THC is the most famous cannabinoid, is known for its psychoactive traits. The potency of marijuana is measured by the THC levels. There are glandular, resinous hairs on the inflorescences and floral bracts of female plants (trichomes) that contain this phenol component. These are not generally found on the male cannabis plant. THC is the most potent cannabinoid and is technically an alcohol because it is not an alkaloid and lacks nitrogen. As a result, it is not recommended that ALCHOL beverages not be consumed with cannabis as this combination can create a disorienting effect. The interaction of a natural compound in the brain called anandmide, attaches to specific receptors in the brain that THC also binds to causing the intoxicating effect felt by the user.

THC has shown to have a wide range of medical benefits associated to it. THC is most associated with the high and Euphoria feeling when using cannabis. THC potency is far higher today than back in the seventies or eighties. Today's medical grade cannabis typically features THC ranging from 5 to 25 percent. ***Over medicating with THC can cause adverse side effects, including disorientation and even hallucinations.*** Although less common, studies have shown additional side effects to include depression, anger, anxiety, and even short term memory loss. We caution all medical users to GO SLOW on dosing themselves if thery have not used marijuana in recent years. Think about dose the same way a doctor and pharmastist doses pill medication. Take one or two periodically, and wait to see if it helps. Typically 15 to 20 milligrams of THC (one of two hits off of a pipe or blunt) is all that is required for effective pain relief. **Too strong a dose can actually reduce pain relief effectiveness.**

Studies have show THC's particular medicinal values:

- Helps with controlling pain
- Helps with relaxation
- Suppresses pain from nerve damage
- Helps reduce risk of nerve damage
- Helps control anxiety
- Suppresses muscle spasms and convulsions
- Helps control certain cancers
- Helps with nausea
- Slows inflammation
- Helps fight free radicals in the blood stream
- Encourages eating and appetite stimulation
- Stimulates new growth in nerve tissue
- Relieves chronic eye pressure and pain caused from glaucoma and other eye disorders

CBD's (Cannabidiol)

Spurred by growing reports of the medical efficacy of Cannabidiol (CBD), the second leading active ingredient in marijuana, patients are increasingly seeking out high-CBD varieties for treatment of conditions ranging from severe epilepsy and multiple sclerosis to anxiety and cancer pain.

CBD has long been overshadowed by delta-9-THC (tetrahydrocannabinol), the primary active ingredient in marijuana, because unlike THC, it does not produce a psychoactive "high." CBD has nonetheless long been known to have useful anti-spasmodic, anti-epileptic, anti-anxiety, and anti-psychotic properties.

Although CBD lacks noticeable effects when taken alone, it has a calming, sedative effect when combined with THC, cutting down on the anxiety, paranoia, and memory impairment that many users find unpleasant or debilitating with regular marijuana. CBD has been found to give the most medical benefits of all the components found in medical cannabis. CBD can also decrease the social isolation characteristics introduced by THC. CBD have low psychoactive characteristics associated to it ranging from 0.1 – 12 percent. CBD-rich strains accordingly have particular appeal to older users and medical patients who are uncomfortable with the THC high.

Contrary to popular misconception, so-called indica varieties are no more likely to have CBD than Sativas. Lab studies by the WercShop, co-sponsored by California NORML, found no relation between chemical profiles, as measured by cannabinoid and terpene content, and varietal types, whether indica or sativa. Breeders have developed special high-CBD hybrids from various genetic stocks. Some have virtually pure CBD, while others typically have THC; CBD ratios ranging from 2:1 to 1:2.

The optimal dosage levels of CBD are uncertain due to a lack of human studies. Chronic high doses of up to 1500 mg per day are well tolerated and produce no noticeable physiological effects. However,

there is evidence to suggest that the medical benefits of CBD disappear when dosages become excessive. For inhaled medical use, most users prefer varieties with THC: CBD ratios between 2:1 and 1:2. Extremely low-THC varieties are useful for making CBD extracts and tinctures. Unlike THC, CBD does not show up positive on standard drug tests for marijuana.

Studies have shown CBD's particular medicinal values:

- Helps control certain cancers
- Helps with controlling pain
- Stimulates bone growth
- Stops growth of bacteria
- Suppresses muscle spasms and convulsions
- Slows Inflammation
- Helps with nausea
- Reduces the risk of artery obstructions
- Decreases pressure in the blood vessel walls
- Reduces blood sugar levels
- Assists in controlling epileptic seizures
- Helps reduce risk of nerve damage
- Decreases the social isolation caused by THC

CBN's (Cannabinol)

There is very little CBN present in fresh marijuana plants. The more CBN the less THC, medical cannabis containing high levels can also indicate its age and improper handling of medicine. High CBN levels also have shown undesirable symptoms like confusion, lightheadedness, and acts as a weak agonist of the cannabinoid receptors. CBN have a mildly psychoactive characteristics associated to it.

Studies have shown CBN's particular medicinal values:

- Acts as a sleep aid
- Slows inflammation
- Helps with controlling pain
- Suppresses muscle spasms and convulsions
- helps fight free radicals in the blood stream

CBC's (Cannabichromene)

Very little is known about CBC however research has shown to have valuable medicinal properties. CBC has no psychoactive characteristics associated to it.

Studies have shown CBC's particular medicinal values:

- Helps with controlling pain
- Stops growth of Fungi
- Slows inflammation
- Stimulates bone growth
- Encourages cell growth
- Stops growth of bacteria
- Assists in contraction of blood cells

THCA (Tetrahydrocannabinolic Acid)

THCA is a precursor of THC. THCA is typically the main constituent found in fresh cannabis and will decarboxylate to its active form while drying or when heated. THCA does not have psychoactive effects but can be used as an anti-inflammatory or neuroprotective medication.

Studies have shown THCA's particular medicinal values:

- Slows inflammation
- Help control cancer cell growth
- Suppresses muscle spasms and convulsions

THCU (Tetrahydrocannabiuarin)

THCV is an analogue to THC and shares characteristics that help to increase additional benefits of THC in smaller doses. Recently studies have shown THCV in larger doses reduce the medicinal effects of THC. THCV have medium psychoactive characteristics associated to it.

Studies have shown THCV's particular medicinal values:

- Effective in appetite suppressant
- Helps control obesity
- Type II diabetes human testing currently underway

CBG's (Cannabigerol)

CBG are not found too often in medicinal cannabis but more commonly found in higher concentrations of hemp. CBG have no psychoactive characteristics associated to it.

Studies have shown CBG's particular medicinal values:

- Stops growth of bacteria
- Stimulates bone growth
- Encourages cell growth

Understanding the differences between Indica and Sativa Cannabis

SATIVA (DAY CHOICE)

The name Sativa comes from a Swedish scientist Carolus Linnaeus, who was the first to classify the plant. He called it Cannabis Sativa L (for Linnaeus). Originated mainly in Asia, the Americas, and Africa Cannabis sativa is a tall, slower growing and maturing plant that typically has long thin leaves which may vary in color from light green to darker greens. Sativa buds are long and thin and turn red as they mature in warmer environments. In cooler environments the buds may be slightly purple. Sativa plants usually smell sweet, fruity, and floral where the smoke is generally mild.

Sativa plants usually have a high THC to CBD ratio that produces a soaring and energetic feeling. It is said to be focusing, energizing, inspirational, and mostly a cerebral high. Sativas give a feeling of optimism and well-being, as well as providing a good measure of pain relief for certain symptoms. These strains have been found to work well with creative minds and good choice for daytime medication.
Sativa is known for treating multiple sclerosis, Tourette syndrome, and glaucoma.
Common Sativa strains are: sour diesel, blue dream, silver haze, and lambs bread.

INDICA (NIGHT CHOICE)

The name Indica comes from a French biologist named Jean-Baptiste de Lamarck who discovered a second species of cannabis and named it Cannabis Indica Lam. It is said that he named it Indica because the plant specimen he classified was from India.

Originated mainly in Pakistan and India, Cannabis Indica is a short to moderate height, bushy plant, generally between three and six feet. The leaves have short broad fingers and are generally dark green and are sometimes tinged with purple. This is a very strong pungent plant with dry, acrid, even "stinky" or "skunky" smell. Indicas are more relaxing, sleep-inducing, anti-nauseant, and relieving of stress and pain. Indicas are the traditional source of hashish and the most popular for indoor cultivation as they are seen as hardy and yield a larger harvest.

Having a high CBD to THC ratio, Indicas give calm and relaxing feeling often described as a body "buzz". They are also effective for overall body pain relief and often used in the treatment of insomnia. It is said that Indicas are for treating anxiety, inflammation, schizophrenia, nausea, and convulsions. There are so many hybrids now that testing is the only real way to know the ratios, but knowing the base strains helps in the development of opinions on the different strains.

TIME EXPECTATIONS

The effects of cannabis are experienced almost immediately (10-15 minutes) after inhaling or smoking. When smoked, the effects are most pronounced for the first hour or two, declining gradually over the next three or four hours. They normally disappear after a good night's sleep and do not produce an unpleasant "hangover" effect, the high just fades away. When digested the effects are delayed an hour or more.

POSSIBLE SIDE EFFECTS

- Anxiety – Most associated with Sativa strains
- Panic Attacks – Most associated with Sativa Cannabis
- Increased chance of lung infection – Smoking related
- Depersonalization – Most associated with over-medicating with Cannabis
- Dryness of the throat -
- Redness of the eye's outer coating, or conjunctiva, due to dilation of the small blood vessels there.

Despite marijuana's ability to induce these side effects, many suffering from hundreds of diseases have claimed to find therapeutic benefit to its use. In the past few decades the medical and scientific communities have discovered numerous mechanisms by which the components of marijuana can both alleviate and cure certain diseases.

WHY USE MARIJUANA

Marijuana's therapeutic is well documented as effective treatment for those experiencing pain, nausea, and many other condition that caused discomfort. Now legal in 23 states, many patients use medical cannabis as an alternative for FDA approved pharmaceuticals to which they did not find satisfactory results or could not bear the side effects.

MARIJUANA AS A MEDICINE

Marijuana has been used for thousands of years as both a medicine and intoxicant. Cannabis has been known to be relatively harmless; however, there have been some documented cases of users with pre-existing health conditions experiencing harmful side effects. Patients with cardiovascular diseases should take special consideration when trying new medicine, particularly Sativa strains of Cannabis.

CAUTION: different strains of marijuana may contain various levels (6- 28%) of THC, the psychoactive ingredient in medical marijuana. Please use caution while taking medicine.

CAUTION: Do not operate Heavy Machinery or a Motor Vehicle while using medications. The care of children and work performance may be compromised

while using medications.

DO NOT USE MMJ IN PUBLIC OR ON DISPENSARY GROUNDS

WHAT ARE MY OPTIONS TO ADMINSTER MY MEDICINE?

There are several methods for administering medical marijuana including:

- Vaporization
- Smoking dried buds or extracts
- Transdermal or topical application (i.e. lotion, oil)
- Drinking teas or concentrated extracts
- Eating medicine-infused food products (i.e. candy, brownies, cookies, butter)
- Taking capsules

There are a variety of apparatuses available to deliver marijuana into the body

- Rolling Papers to roll cigarettes
- Pipe
- Water Pipe
- Vaporizer
- Vaporizer Pen

METHODS OF CONSUMPTION

There are several types of ways to consume cannabis; most are some form of smoking or oral consumption:

SMOKING- This is the most common form of cannabis consumption and it is the inhalation of vapors released by heating the flowers, leaves, or extracts of the cannabis plant. Smoking releases chemicals (THC, CBD's etc…) which are absorbed in your blood stream via the lungs. When marijuana is smoked the

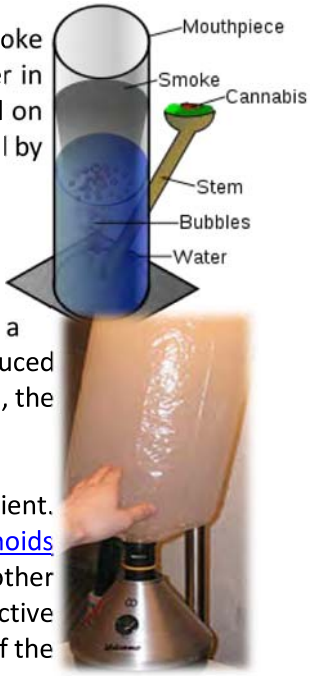
effects are almost instantaneously. There are several ways in which cannabis can be smoked which are joints, blunts, pipes, bongs, and vaporizers.

JOINTS- "Joint" is a slang term used to for a cigarette rolled using marijuana. The papers in which are used for cigarette rolling are usually made from hemp or rice paper. This is definitely a healthier choice in comparison to a blunt.

BLUNT- A blunt is cannabis rolled in a tobacco leaf (cigar wrapper). Essentially, as the blunt burns, a mixture of tobacco smoke and marijuana smoke is inhaled by the user.

PIPES- Pipes made for smoking cannabis, sometimes called pieces or bowls, are made of a variety of materials, including blown glass, metal fittings (except aluminum), ceramic, borosilicate, stone, wood, bamboo and other materials. Subtypes of pipes include one-hitters, bubblers, chillums, glass blunts, corn cob pipes.

BONG- A bong is similar to a pipe, only it has a water chamber through which cannabis smoke passes prior to inhalation. Users fill the bong with water, sometimes adding ice in the water in order to cool the smoke. Some bongs have a "choke" or "carb", a small hole usually located on the side of the bowl above water level, used to clear the pipe of smoke or to conserve material by stopping burning when enough smoke has been created.



VAPORIZER- A vaporizer is a device used to extract for inhalation the active ingredients of plant material. Vaporizing is an alternative to burning (smoking) that avoids the inhalation of many irritating toxic and carcinogenic by-products. The extracted vapor may be collected in a jar or inflatable bag, or inhaled directly through a hose or pipe. With little to no smoke produced and cooler temperatures, less material is required to achieve a given level of effect. Therefore, the irritating and harmful effects of smoking are reduced.

EDIBLES- Edibles are food products made with cannabis in herbal or resin form as an ingredient. They are consumed as an alternate delivery means to experience the effects of cannabinoids without smoking marijuana. Instead, the cannabinoids are put into cake, cookie, brownie, or other foods, and are consumed. Oral consumption of cannabinoids can result in a similar psychoactive effect or "high" as smoking marijuana, although it may be delayed due to slower absorption of the THC from the digestive tract.

The EVOLUTION OF THE MMJ COMMUNITY

In November 2010, voters passed the Arizona Medical Marijuana Act. The citizen initiative (Proposition 203) called on the Arizona Department of Health Services to create a medical marijuana program to help patients that desired alternatives from traditional pharmaceutical medications and their potential side effects. Twenty Three (23) states now officially recognize the specific medical benefits of cannabis. As of March, 2014, over 50,000 citizens in Arizona have utilized the program they have voted-in to get a doctor's recommendation to be certified as an MMJ Patient by Arizona's Department of Health Services, and to carry a "Patient Card that allows for the consumption of medical marijuana purchased

through an ADHS licensed dispensary. Although some patients are still nervous about going into dispensaries, it is our job, through the use of professionalism, friendliness, education, and compassion, to make every patient feel at home and comfortable with the decision they have made to use medical marijuana. This is our expressed goal with every patient visit.

HEALTH CONDITIONAL AND THE BENEFITS FROM CANNABIS (MMJ)

Medical use of cannabis goes back over 3,500 years within several civilizations ranging from China, India, Europe and Africa. These were among the first to widely use several strains of the medicinal plants, but medical marijuana use has now spread worldwide. Treatment for both mental and physical illnesses have been proven effective in relieving many symptoms associated with a variety of health challenges.

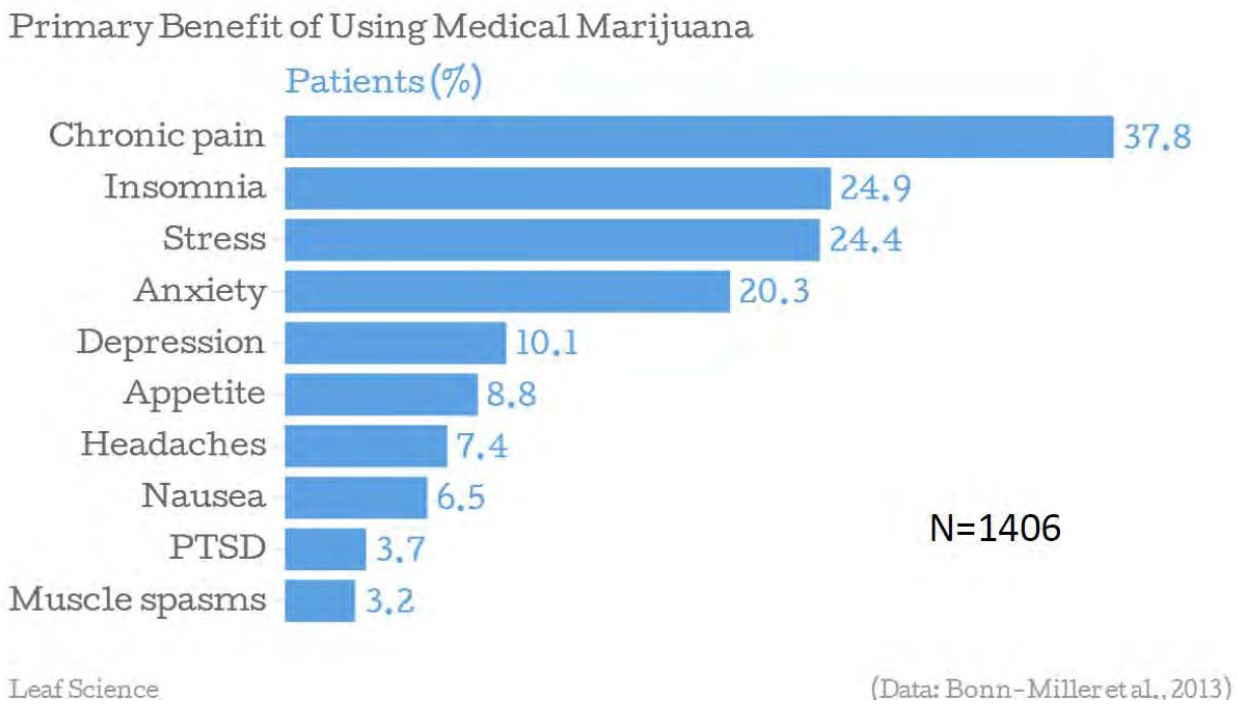
Cannabis is a nut-like fruit that contains proteins that provide excellent nutritional balance and bolster the immune system. Marijuana Sativa strains have been shown to have a stimulant effect followed by relaxation and overall stress reduction. It can also enhance ones sense of well-being. Certain cannabinoids found in medicinal marijuana have an analgesic effect that reduces inflammation, pain and sooth joints. Many patients with neurological or movement disorders can benefit from the cannabis to help them relax their muscles, and reduce muscle cramps or spasms. Smoked or vaporized cannabis works as a bronchodilator by dilating the bronchia, alveoli and blood vessels with improved oxygen intake.

When ingested safely, cannabis is one of the most useful medicines for a range of qualifying conditions approved by The Arizona Department of Health Services including:

- AIDS/HIV: Helps reduce fatigue, appetite loss, and depression.
- Alzheimers: MMJ acts as a nureoprotector, thus slowing the progression of Alzheimers
- Anorexia/Cachexia/Wasting Syndrome: Cannabis helps increase appetite as well sooth the stomach.
- Nausea: Symptom relief for lack of appetite.
- Arthritis, MS, Osteoarthritis: An excellent 2 in 1 treatment. Medical marijuana provides relief for pain and joint stiffness as well as act as an anti-inflammatory. MUSEC Trial showed relief from muscle stiffness over placebo was four times (4X) greater. Satieum has now been approved in Canada and throughout most of Europe. FDA testing currently underway in the U.S.
- Cancer, Chemotherapy: Cannabinoids help boost the immune system; in leukemia and breast cancer it inhibits tumor growth. Excellent to help soothe the side effects of chemotherapy. Helps ease nausea and vomiting.
- Crohn's Disease/Gastrointestinal Disorders: Cannabis soothes and settles the gastrointestinal tract and relaxes the colon. Cramping, inflammation and diarrhea are reported to be relieved by use of MMJ.

- Chronic Pain: There are many causes of chronic pain; several medical conditions associated with chronic pain are well managed with the use of cannabis and its analgesic effect. Excellent as an anti-inflammatory and pain reliever, MMJ can truly help improve a pain sufferer's quality of life. Studies have proven MMJ add +27% greater pain relief effectiveness with opioid pain reliever Oxycodone.
- Glaucoma: Helps reduce pressure and pain caused by fluid buildup in the eye.
- Hepatitis C: The effectiveness of hepatitis C therapy is improved by reliving nausea, loss of appetite, fatigue and depression.
- Fibromyalgia: Many symptoms of this condition such as; chronic pain, fatigue, depression, anxiety, and insomnia are alleviated by cannabis use.
- Multiple Sclerosis: MMJ has been known to offer pain relief and help sleeping.
- Muscle Spasms: MMJ has been known to give immediate pain/spasm relief.
- PTSD/Mental Health: PTSD will be added to the qualifying conditions list January 1st, 2015. Research has indicated that Cannabis helps stabilize mood swings. Indica Cannabis strains help reduce nightmares and anxiety caused from PTSD. Indicas have also been reported to be a great treatment for the insomnia often cited by PTSD sufferers.
- Seizures: CDB rich Cannabis can lower seizure rates dramatically.

Here are the results of a recent patient survey regarding the medical benefits of Cannabis:



KNOW YOUR RISKS

There are legitimate concerns about long-term marijuana use that must be taken into consideration when deciding to use the plant medicinally. The following is a list of research-derived possible side effects for Sativa forms of marijuana:

- **Anxiety/Panic attacks**
- **Exacerbation of schizophrenia in predisposed individuals**
- **Higher heart rates**

Patients with cardiovascular diseases should avoid all sativa forms of cannabis.

Arrhythmia, Congestive Heart Failure, nerocirculatory syncope, orthostatic hypotension, Beta blockers (high blood pressure medications) - stay away from Sativas Cannabis.

MMJ in any form should not be used with systemic Anticoagulants (risk of. Falling), Erectile Dysfunction Agents (risk of rebound hypotension). MMJ is a natural erectile dysfunction medication on its own, so you may get an exaggerated result.

All forms of smoked cannabis may cause:

- **Increased chances of lung infections**

All forms of high potency THC cannabis, if taken in high doses, could cause:

- **Depersonalization, Amotivational Syndrome**

Contact your certifying doctor if contra-indications or side effects occur.

NEVER USE MARIJUANA IF YOU ARE: PREGNANT or SCHIZOPHRENIC

POTENTIAL DRUG INTERACTIONS WITH MEDICAL MARIJUANA

Sedative Medications (Barbiturates, CNS Depressants, and Alcohol):

Taking marijuana along with sedative medication may cause too much sleepiness.

Theophylline (a Bronchodilator used for asthma & other lung problems):

Smoking marijuana might decrease the effects of theophylline. But there isn't enough information to know if this is a big concern.

Disulfiram (Antabuse, an alcohol antagonist drug):

Taking marijuana along with Disulfiram can cause agitation, trouble sleeping and irritability.

Fluoxetine (Prozac, an antidepressant):

Taking marijuana with fluoxetine (Prozac) might cause you to feel irritated, nervous, jittery, and excited. Doctors call this hypomania.

Warfarin (Coumadin, a blood thinner (anticoagulant)):

Smoking marijuana while taking warfarin (Coumadin) might increase the chance of bruising and bleeding.

Reference: rxlist.com

In Summary, DO NOT use marijuana if:

- ☐ You are pregnant or breast-feeding.
- ☐ You are schizophrenic.
- ☐ You have heart problems or hypertension (high blood pressure).
- ☐ You have lung problems, if you are smoking your medicine.
- ☐ You have seizures (epilepsy).
- ☐ You have immune system problems.

- ☐ You are scheduled for surgery in the next two weeks. Marijuana might cause excessive sedation if combined with medications used during and after surgery.

KNOW THE SIGNS OF SUBSTANCE ABUSE

Please note that we reserve the right to refuse sale of medical marijuana to anyone who we deem to be impaired or who display signs of substance abuse of any kind. Note additionally that this is a reportable offense that may result in the revocation of your marijuana ID card. It is important you review this list of common signs and symptoms of substance abuse.

Common signs and symptoms of drug abuse

- **You're neglecting your responsibilities** at school, work, or home (e.g. flunking classes, skipping work, neglecting your children) because of your drug use.
- **You're using drugs under dangerous conditions or taking risks while high**, such as driving while on drugs, using dirty needles, or having unprotected sex.
- **Your drug use is getting you into legal trouble,** such as arrests for disorderly conduct, driving under the influence, or stealing to support a drug habit.
- **Your drug use is causing problems in your relationships,** such as fights with your partner or family members, an unhappy boss, or the loss of old friends.

Common signs and symptoms of drug addiction

- **You've built up a drug tolerance.** You need to use more of the drug to experience the same effects you used to attain with smaller amounts.
- **You take drugs to avoid or relieve withdrawal symptoms.** If you go too long without drugs, you experience symptoms such as nausea, restlessness, insomnia, depression, sweating, shaking, and anxiety.
- **You've lost control over your drug use.** You often do drugs or use more than you planned, even though you told yourself you wouldn't. You may want to stop using, but you feel powerless.
- **Your life revolves around drug use.** You spend a lot of time using and thinking about drugs, figuring out how to get them, and recovering from the drug's effects.
- **You've abandoned activities you used to enjoy,** such as hobbies, sports, and socializing, because of your drug use.
- **You continue to use drugs, despite knowing it's hurting you.** It's causing major problems in your life—blackouts, infections, mood swings, depression, paranoia—but you use anyway.

ALTERNATIVE OPTIONS TO TREAT SYMPTOMS

There are a number of additional options you may consider pursuing either as an adjunct to or entirely in place of medical marijuana therapy. Below is just a brief list:

- ☐ Hypnosis
- ☐ Acupuncture
- ☐ Massage
- ☐ Chiropractic
- ☐ Non-marijuana-based herbal medicines (Teas, tinctures, and salves)
- ☐ Over-the-counter pharmaceutical medications
- ☐ Homeopathy
- ☐ Bio-feedback
- ☐ Psychological Counseling
- ☐ Life Coaching

ATTACHMENT 5-6:
ERBA WELLNESS NEW
PATIENT PACKET

1. WELCOME

The benefits of medical marijuana can range from suppressing muscle spasms and seizures to topically reducing inflammation beyond. However, medicinal marijuana is not a cure all and patients should be aware that many claims are made regarding its efficacy without the appropriate scientific testing. Dispensaries are responsible for providing patients with access to a range of marijuana-based medicines. It is crucial for patients to understand a provider's limited ability to advise the best products or treatment for such individualized needs. While our staff serve to answer inquiries pertaining to dosage recommendations and known effects of medical marijuana as well as credible knowledge obtained from reliable sources, the patient must work to record those forms of medicine that prove most effective in meeting their individual needs.

2. A BRIEF HISTORY: GENERAL INFORMATION ABOUT MARIJUANA AS MEDICINE

The Marijuana plant originates from Central Asia and grows in several different species, each varying in physical appearance and compositional attributes. *Marijuana sativa* and *Marijuana indica* are the two prominent species of marijuana cultivated for the effects that result from their consumption. Humans have utilized the medicinal properties of the Marijuana plant for thousands of years. Marijuana is one of the oldest psychotropic drugs known to humanity.[1] Non-psychoactive variations of the marijuana plant, referred to as industrial hemp have similarly been harvested for centuries. Hemp is valuable for fibrous stalks that can be used to produce products like paper, textiles, rope and building materials; nutrient-rich seeds used for food and fuel oil; and processed for medicinal components, such as its high-CBD content.[2]

Today, marijuana is illegal in most parts of the world. Our Federal government does not recognize the medicinal benefits of marijuana, despite the growing number of states that have legalized marijuana for medicinal use. Over the past 18 years, nearly half of the states in our country have passed laws allowing for the legal consumption of medical marijuana. With 23 legal medical marijuana states and counting, marijuana remains a Schedule I substance. After more than a century of marijuana prohibition, individuals throughout the U.S. are gaining access to one of humanity's oldest medicines and using it to manage an extensive range of ailments.

Introduction to Ingestion

Medical marijuana is ingested through a number of different methods. Most commonly, the dried flowers (buds) or extracted resin (concentrates) of the plant are smoked or vaporized, but ERBA Wellness discourages all inhalation methods. It can also be consumed through capsules and sublingual tablets. Marijuana can be applied to

the skin through creams, salves, balms and transdermal patches that are infused with activated cannabinoid extracts.

The primary natural chemicals found in the marijuana plant are called cannabinoids and terpenes. The human body is equipped with an entire network of cannabinoid receptors, referred to as the endocannabinoid system. Scientists have isolated 85 different cannabinoids from the plant, and both psychoactive and non-psychoactive cannabinoids are associated with positive health benefits. THC (delta-9-tetrahydrocannabinol) was the first-identified cannabinoid, and is best known for its psychoactive effects. Other cannabinoids like CBD (Cannabidiol) are non-psychoactive, though CBD does share many therapeutic qualities with THC. CBD is known to relieve convulsions, inflammation, anxiety, and nausea in many patients. Terpenes are also being isolated and investigated for their medicinal effects. One such terpene, Myrcene, is believed to function as an anti-inflammatory and analgesic and another, Limonene, is thought to help promote weight loss.

The psychological and physiological effects of medical marijuana include euphoria, pain relief, sedation, memory and cognitive impairment, appetite stimulation, and nausea treatment.[3] Different varieties of marijuana are called strains, with each strain presenting different terpene and cannabinoid profiles and thus each offering different physiological effects. Most marijuana strains cultivated and sold for medical use are pure-bred indicas, pure-bred sativas or quantifiable hybrids.

The medicinal effects of marijuana use are known to benefit individuals suffering from a number of life-altering medical conditions. While the anti-emetic (anti-nausea) and orexigenic (appetite-stimulating) effects of marijuana are becoming common knowledge, recent research has explored in-depth the use of marijuana in treatment of cancer, Multiple Sclerosis, chronic pain, arthritis, gastro-intestinal disorders, movement disorders, HIV/AIDS, PTSD, glaucoma, and conditions related to aging, including Alzheimer's, and dementia.

Establishing an efficient treatment regimen with marijuana requires that users keep a recorded log of their experience with marijuana consumption. Following symptom patterns, treatment behaviors, efficacy and side effects of marijuana medicines will help patients and doctors make the most beneficial treatment decisions.[4] In essence, the patient ultimately needs to be their own advocate in determining what strains and ingestion methods work best for their personal physiology and medical condition.

3. METHODS OF CONSUMPTION: SMOKING, VAPORIZING, VAPE PENS, AND SUBLINGUAL

Smoking and Vaporizing

ATTACHMENT 5-6

Inhalation is the most common method of marijuana consumption. The flowers of the female marijuana plant are dried and smoked via pipes, bongs, rolling papers, vaporizers, and other variations.

Similar to smoking, dried marijuana flowers can alternately be vaporized, frequently in an effort to avoid inhaling irritants or potential carcinogens. Vaporizing devices are available in many forms that run a gamut ranging from tabletop models to portable vaporizer pens. While vaporizing, dried marijuana flowers are typically heated to a temperature between 180-190°C in order to suppress respiratory toxins while administering medicinal vapor comprised of activated cannabinoids.[5]

ERBA Wellness discourages all inhalation methods, and instead encourages patients to use dried marijuana flower to create their own edibles.

Oral Forms of Medical Marijuana

Ingestible products offer patients a method of medicating that does not require the use of the lungs. Patients with respiratory issues or supplemental oxygen dependence frequently turn to ingestible forms of smoking or vaporizing is not a viable option. While our mainstream culture views the act of smoking as an unattractive habit, oral marijuana consumption provides a more discreet method of medicating.

In order for medical marijuana to be effective in oral forms, the cannabinoids must be activated through a process known as decarboxylation. Heating marijuana in an oven has been shown as an effective method of successful decarboxylation and activation of beneficial cannabinoids.[6]

Generally speaking, an orally administered oil will have a delayed onset time, meaning that it can take some time before the user becomes aware of the effects. This is because inhaled marijuana travels directly to the brain while ingested marijuana must be processed by the stomach and liver prior to entering the blood stream. The liver converts THC to 11-hydroxy-THC which is capable of crossing the blood/brain barrier much more efficiently than THC resulting in stronger and longer lasting therapeutic effects. Therefore, an overall higher dose is required as compared to an inhaled dose. However, there is a much longer duration of effectiveness allowing the patient to medicate less frequently than if the marijuana was inhaled. Additionally, tolerance levels will develop independently for inhaled and ingested medical marijuana as the actual chemical interacting with your brain is slightly different in each case.

Sublinguals

Much like orally administered oils, sublingual tinctures infused with activated cannabinoids present a method alternative to smoking. Tinctures are able to absorb through the tissues in the mouth and tongue allowing for faster absorption and relief when compared to oils that need to be digested.

Topicals, Balms, and Salves

Marijuana can be topically applied through infused lotions, creams, balms, salves and patches. Topical marijuana applications do not induce psychoactive effects. Cannabinoids combined with a penetrating topical cream can enter the skin and body tissues and allow for direct application to affected areas.[1]

According to an article published in the *Journal of Dermatological Science*, "The abundant distribution of cannabinoid receptors on skin nerve fibers and mast cells provides implications for an anti-inflammatory, anti-nociceptive action of cannabinoid receptor agonists and suggests their putatively broad therapeutic potential."[2] In layman's terms this means that the benefits of using marijuana through topical application have been demonstrated in treating an array of skin ailments ranging from allergic reactions to inflammation and severe pain. Use of topical products with adequate THC and CBD content has been shown to provide notably beneficial pain relief and anti-inflammatory results for many patients.

4. STRAIN DIFFERENTIATION

The primary effects of indica, sativa and hybrid marijuana strains vary based on the genetic and chemical composition of different plant varieties. Sativa is known to primarily influence thoughts and emotions, while indica provides more of an impact on the physical body. Hybrids borrow traits from their parents, so their effects are most often a combination of qualities that are otherwise indica or sativa specific. Hybrids can be indica-dominant, sativa-dominant, or a 50/50 blend.

Sativas grow tall and thin. Sativa strains are optimal for daytime medicating. Their effects are most often stimulating. Sativa strains are suggested to inspire creativity and focus, reduce depression, relieve headaches and increase appetite. Negative side effects that can be present with use of sativa strains include paranoia, anxiety, and loss of memory.[9]

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7. "Guide to Using Medical Marijuana." *Americans for Safe Access.*

8. Sonja Ständer, Roman Rukwied, et al. "Distribution of cannabinoid receptor 1 (CB1) and 2 (CB2) on sensory nerve fibers and adnexal structures in human skin." *Journal of Dermatological Science* 38, no. 3 (2005): 177-188.

Indicas grow short and stout. Indica strains are often used for physical pain relief and sleep-related conditions, as their sedative effects are well known. Indica strains are known to relax users, reduce seizures, reduce stress and calm muscle spasms. Notable side effects of indica use include feelings of tiredness and "fuzzy" thinking.[10]

Endocannabinoid systems vary by the individual, which means the same marijuana strain will affect different people differently. Cannabinoid profiles vary greatly by strain.

5. CANNABINOID PROFILE: CANNABINOID BENEFITS AND EFFECTS, READING TEST RESULTS, APPLYING TEST RESULTS TO CONSUMPTION

Different strains produce different cannabinoid ratios which impact the body in different ways. Methods of ingestion also influence the effects of different cannabinoids on the body.

While THC is the most well-known cannabinoid, primarily for its psychoactive effects, non-psychoactive cannabinoids offer a wide range of therapeutic benefits.

From the *Guide to Using Medical Marijuana* published by Americans for Safe Access:

- Cannabidiol (CBD) relieves convulsions, inflammation, anxiety and nausea—many of the same therapeutic qualities as THC but without psychoactive effects. It is the main cannabinoid in low-THC marijuana strains, and modern breeders have been developing strains with greater CBD content for medical use.
- Cannabinol (CBN) is mildly psychoactive, decreases intraocular pressure, and seizure occurrence.
- Cannabichromene (CBC) promotes the analgesic effects (pain relief) of THC and has sedative (calming) effects.
- Cannabigerol (CBG) has sedative effects and antimicrobial properties, as well as lowers intraocular pressure.
- Tetrahydrocannabivarin (THCV) is showing promise for type 2 diabetes and related metabolic disorders.
- THCA is another cannabinoid with weak or no psychotropic effects and has been shown to exert anti-proliferative (inhibits cell growth) and anti-spasmodic (suppresses muscle spasms) actions.[11]

It is quickly becoming the industry standard for states to require testing of medical marijuana and marijuana products sold through licensed dispensaries. Both mandatory and voluntary testing for contaminants ensures the safest high-quality medicine is being produced and distributed by growers and manufacturers. Testing

for potency, residuals, terpenoids and cannabinoid content helps patients and dispensaries with researching and recommending different products. Popular websites allow dispensaries to publish their lab test results online for users to review. Patients who wish to evaluate necessary dosages and benefits of different cannabinoid ratios should keep a written record of their personal experiences with different products and dosages.

6. DOSING

The amount of marijuana consumed in a sitting will influence the patient's experience. Evaluating the proper dosage of marijuana needed to treat a patient's medical condition requires that patients monitor the effects of low-dose products and slowly increase dosage until the optimal effects are eventually achieved. At present there exists no industry standard relative to dosing recommendations.

The difference in effect between inhaling and ingesting marijuana is substantial. Oral administration causes slower absorption of cannabinoids, as the digestive process causes a variation of THC to metabolize in the liver and produce different effects than those caused by inhaling marijuana.

Smoking and vaporizing offer immediate and fast-acting relief, but present complications in their potential to cause bronchial irritation. Despite common misconceptions, holding smoke does not increase THC uptake. Studies show that 95% of the THC is absorbed in the first few seconds of inhaling.[12]

7. POTENTIAL ADVERSE EFFECTS

As with any medicine, there are potential adverse effects patients may experience with the use of medical marijuana. Patients who choose to use medical marijuana should discuss with their doctor to determine if the benefits outweigh the potential risks. Care should be taken particularly with those under the age of 25 as studies have shown that marijuana use can have permanent detrimental effects on the developing brain. Decreased cognitive abilities are the most widely reported adverse events effecting short-term memory, sensory perception, problem solving, motor control, verbal fluency, reaction time, attention span, and ability to sense time. These effects may be short term or long term, with most patients regaining cognitive abilities once stopping medical marijuana use. However, studies have shown that in some cases patients may experience a permanent decrease in cognitive ability.

Undesirable side effects may also include paranoia and anxiety, including panic attacks. This is largely due to the effects of marijuana on the hypothalamus and pituitary gland which modulates the body's stress reaction. Patients who are prone to anxiety issues may want to avoid sativas as many patients find sativa's tend to cause more stress effects than indicas.

ATTACHMENT 5-6

Patients who require large doses of medical marijuana need to exercise caution to prevent overdose. While no one has ever died from marijuana toxicity, the experience of over consuming can be very unpleasant. Patients who over consume may have difficulty determining what is reality or might experience an existential crisis. This could lead to dangerous behaviors and extreme emotional stress. If you feel you have over-dosed, relax in a safe place with a person you trust and go to sleep, or in severe cases contact poison control; a shower can also help reduce unpleasant symptoms

Use of alcohol or other intoxicants with medical marijuana is not recommended. The effects of each are often felt much stronger when combined than when used alone. Make sure to discuss any other medications you are taking with your doctor to prevent potential drug interactions.

Patients should be aware that smoking medical marijuana can have detrimental effects on your health. When organic matter is burned, it releases carcinogens and toxins similar to tobacco. As such, smoking can cause lung cancer, heart disease, and emphysema. In order to minimize the risk WIM recommends vaporizing over smoking whenever possible.

The safety of medical marijuana use during pregnancy has not been established. Research have shown that use of medical marijuana during pregnancy does not significantly affect the outcome of the pregnancy. However, studies have shown that marijuana use during pregnancy has long term effects on the child's development. In particular, these children tend to exhibit abnormal behaviors and have difficulty with social interactions. Scientists believe this is due to the detrimental effects marijuana use has on developing brains. It is advised that you do not use medical marijuana during pregnancy unless directed otherwise by your doctor.

Patients should not operate a motor vehicle or any heavy machinery while under the influence of medical marijuana. Medical marijuana can slow your reflexes and reduce your attention span which creates very dangerous driving conditions. You put your life and others lives at risk and could be arrested for driving while intoxicated.

It is possible for patients to develop marijuana addiction, particularly in patients who medicate every day. You may have a dependency problem if you need to use marijuana just to feel normal. Other signs include using your medication in higher doses or more frequently than recommended by your doctor, or foregoing other activities in favor of marijuana use. Quitting can be very difficult for patients with marijuana dependency due to withdrawal symptoms of irritability, difficulty sleeping, low appetite, or increased anxiety. If you believe that you may have a

marijuana addiction problem please speak with a member of our staff who can assist you in getting help. Many treatment options are available and patients typically do not need to use traditional drug rehabilitation centers.

8. FEDERAL LAW

Registered patients in Hawaii have no protection from prosecution under federal law and are only protected from arrest by the State of Hawaii. The Federal Controlled Substances Act lists marijuana as a Schedule 1 narcotic which reads as follows, "Schedule 1 drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence." While the current administration has relaxed their stance on persecution of medical marijuana patients, patients still assume all potential risk associated with violation of federal laws.

Patients should take care to ensure they do not transport medical marijuana across state lines as this can increase federal penalties from misdemeanor to felony charges. In addition, when within 1000 feet of a school, playground, public housing or within 100 feet of a youth center, public pool, or video arcade, the possible penalties are doubled. Similarly, any distribution charge involving a minor also doubles the possible penalties. Patients should be cautious when entering federal land such as National Parks as they are subject to federal law and no longer provided any protections for marijuana possession or consumption.

9. RECIPROCITY

Certain states offer reciprocity for medical marijuana patients who are registered in other states. Prior to traveling to another state, patients should determine if reciprocity applies to their individual situation as each state acknowledges different conditions and regulations. Patients are encouraged to discuss any travel plans with our Dispensary Technicians who will be able to advise you accordingly.

ATTACHMENT 5-6

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ATTACHMENT 5-7

Patient Education Plan

The Chief Medical Officer, in conjunction with the Director of Patient Services shall provide and maintain patient education materials. The company may engage the services of a third-party for translation services as necessary. The Director of Patient Services may utilize patient education materials from verified sources including reviewed journals and trusted organizations, including Americans for Safe Access. Erba Wellness will require all qualifying patients and designated caregivers to sign an attestation prior to their first purchase of medical marijuana. This document will serve to educate, set expectations, and ease concerns.

Orientation
Erba Wellness will offer an orientation to introduce all new qualifying patients and designated caregivers to the dispensary, allow them an opportunity to ask questions in private, sign the patient attestation, etc. The dispensary has a private consultation room where qualifying patients and designated caregivers can receive complimentary consulting. All new patients and caregivers shall receive the new patient education packet. The guide shall be updated regularly by the Chief Medical Officer in conjunction with the Director of Patient Services and only include information from credible sources. Usage of all materials must be approved by the source.

Educational Materials
Erba Wellness has patient education and support materials that will be available for free in the dispensing room for qualifying patients and designated caregivers. The Director of Patient Services must ensure an adequate supply of up-to-date educational materials is available for distribution. Dispensary staff will also be trained to offer these materials to patients with every sale and shall be trained to be knowledgeable of the content contained therein. Topics include:

- The various forms and methods of medical marijuana administration.
- The purported effectiveness of specific cannabinoids to treat specific conditions.
- Information describing proper dosage and titration for different routes of administration. Emphasis shall be on using the smallest amount possible to achieve the desired effect.
- Current educational information about the health risks associated with the use or abuse of marijuana.
- Information regarding tolerance, dependence, and withdrawal.
- Signs and symptoms of addiction and abuse including information on how to get help.
- The possible side effects of using medical marijuana.
- Prohibition on smoking medical marijuana in public places.
- Proper medical marijuana storage: protecting medical marijuana from children, theft, and pets.
- Updates to federal or state law relating to medical marijuana.
- Materials to enable patients and their caregivers to track the strains used and their associated effects.
- Any other information required by the Department of Health or deemed appropriate by the dispensary manager.

ATTACHMENT 5-7

Providing Advice on Administration and Storage

Along with the patient education and support materials mentioned above, all dispensary technicians will be trained to provide knowledgeable information on administration options, administration attributes, and storage. Ingestible products, for example, can take a long time to take effect, but the effects are usually stronger and last longer. Erba Wellness staff will help patients navigate the nuances to medicating with medical marijuana and will be trained accordingly.

Providing Advice on Storage

Every patient and caregiver will be offered a handout with proper storage information each time they purchase from the dispensary. Proper storage of medical marijuana and manufactured marijuana products will increase the shelf-life and maintain the quality of their medicine. It's also crucial to remind patients to store purchases away from children and pets. Finally, theft is an important issue. Friends, family, and strangers could be tempted to steal medical marijuana or manufactured marijuana products from a qualifying patient if it's improperly stored. Erba Wellness will recommend patients maintain all medication under lock and key even while in the privacy of their own residence.

Condition Booklets

Erba Wellness will maintain a corporate sponsorship with Americans for Safe Access, the national patient information and advocacy non-profit group. Sponsorship provides the company preferred access to American for Safe Access materials and training services. The sponsorship will provide Erba Wellness with:

1. Discounted publications for patient and caregivers including condition based booklets published by Americans for Safe Access on Cancer, HIV/Aids, Arthritis, Chronic Pain, Movement Disorders, Gastrointestinal Disorders, Multiple Sclerosis, and Aging.
2. Discounted training for company agents.
3. Regular updates and advocacy opportunities.
4. Discounted certification by Americans for Safe Access for Patient Focus Certification.

Classroom Education Program

The Chief Medical Officer, in conjunction with the Director of Patient Services shall coordinate and schedule ongoing educational events specifically for caregivers of medical marijuana patients. Erba Wellness will host quarterly events on topics of interest to the local community. Topics could include "Medical Marijuana and Pregnancy," "Creating Your Own Edibles," "Understanding Cannabinoid Ratios," and "Why Smoking Medical Marijuana is Best Avoided." These events will be held at the dispensary, in a classroom setting. If they become popular, Erba Wellness may increase their frequency to as often as once a month.

All of the owners, directors, shareholders with at least twenty-five percent ownership interest or more, members and managers at ERBA Wellness have completed the background check requirement and submitted the E-Crim registration number as part of this application, in compliance with Haw. Rev. Stat. §329D-7 (2015), Haw. Rev. Stat. §329D-12 (2015) and Haw. Rev. Stat. §846-2.7 (2015). Every owner has also consented to being fingerprinted as part of this application. None have been convicted of any felonies and all have a completely clean criminal record, except Mr. Fred Lau who has a misdemeanor, contempt of court charge from 1974 and Kelly Nguyen, who has a misdemeanor driving under the influence charge from 2006.

At the time of Mr. Lau's incident, he was twenty years old. He was awarded a speeding ticket on the island of Oahu for driving somewhere between ten and fifteen miles over the posted speed limit. He was given a court date, for which he forgot to appear, which resulted in the charge of contempt of court. At that point, Mr. Lau presented himself in court where he paid all of the fines associated with the original ticket as well as the contempt of court charge. Mr. Lau has lived the intervening four decades completely within the confines of the law. He attributes his lapse in judgment to youth and foolishness. Mr. Lau runs a business that occasionally does landscaping on military installations. This charge has never prevented him from gaining access to those military installations.

Kelly Nguyen was charged for driving under the influence with an alcohol content greater than the limited allowed. The incident occurred near Kapiolani Blvd in Oahu in 2006. She was returning to college a few days later and was rushed a court date. She was charged for a petty misdemeanor in the state of Hawaii. She had her license revoked for a year, and paid her dues. A few years later she applied for her DUI charge to get expunged due to pharmacy school

requirements. That was her first and only criminal record and to her knowledge it has been excused.

Additionally, four members of the ERBA Wellness team are military veterans who have received high level security clearance which requires extensive and repetitive background checks and psychological assessments. LT. Mineta, COL. Ernie Takafuji, RADM. Melvin Chiogioji, SGT. Tyler Stratford, and RADM. Ken Moritsugu have all served honorably as high-ranking officers, or non-commissioned officers, within different military branches.

ERBA Wellness has assembled a conscientious team that is absolutely capable of operating this new business within all current regulations.

ERBA Wellnesshas developed operational procedures to control each facility's inventory in compliance with internal policies and procedures, state law and regulations. All supervisors will work collaboratively to assure that inventory is tracked from seed to sale, counted and recorded at required intervals, and that any discrepancies are reported to the appropriate authorities. BioTrackTHC software is capable of producing, upon request, reports on all marijuana and marijuana products in production or that are finished, stored, and dispensed. The BioTrackTHC software is fully capable of interfacing with the state selected inventory tracking system providing the department real time, twenty-four-hour access to all inventory records and will ensure seamless information transfer between departments and stages of development.

INVENTORY MANAGEMENT SYSTEM (BioTrackTHC)

BioTrackTHC software will also be used in all ERBA Wellness facilities to allow for easy tracking of the flow of materials as they move from cultivation, through the production process, to the retail dispensary, and finally to the patient. This means that any single plant can be tracked to determine which products it was used to produce, how much of those products remain in inventory, and precisely which patients purchased products made from that plant. In the unlikely event of a recall, the company will be able to quickly and accurately determine which patients were affected. The system will also inform the company how much of the affected product remains in inventory and in exactly which vault the product is stored.

The software will include a profile for each patient which will also function as the point of sale system. This will allow the software to record the complete purchase history of each patient for review and to ensure no patient purchases product in excess of the legal limits. The software will be able to interface directly with the state selected system to compare patient purchases at other

dispensaries with ERBA Wellness' internal records. Once the patient's combined purchases reach the fifteen-day limit, the system will automatically stop any further sales to that patient.

BioTrackTHC allows the production center to submit to the department, in real time by automatic identification and data capture, all marijuana, marijuana plants, and manufactured marijuana product inventory possessed by the facility from either the seed or immature plant state, including all plants that are derived from cuttings or cloning, or any extracts that are produced from those plants, until the marijuana or manufactured marijuana product is sold or destroyed.

The software will allow the retail dispensing location to submit to the department in real time, the total amount of marijuana and manufactured marijuana product purchased by a qualifying patient and primary caregiver in any fifteen-day period. The BioTrackTHC software shall impose an automatic stopper in real time, which cannot be overridden, on any further purchases if the maximum allowable limit of marijuana has already been purchased for that fifteen-day period with additional purchases not being permitted until the next applicable period.

INVENTORY PROCEDURES

Each department director ensures BioTrackTHC is maintained and provides adequate documentation of the growth for each plant through the cultivation process, the flow of materials through the manufacturing process, and the flow of materials through the dispensing process. When plants/products are moved within the facility or transported to another facility, the supervisor on shift is responsible for ensuring proper documentation in BioTrackTHC in accordance with standard operating procedures (Attachment 7-1).

In cultivation, each plant will be tagged with a barcode when initially sprouted from seed or cut from a mother plant. The individual plant tag will be documented in the BioTrackTHC

software with the strain and date of planting. As the plant matures, details will be added to the software relating to any treatments or chemicals added to the plant as well as any relevant observations or notable incidents relating to the plants development. BioTrackTHC software will be updated to reflect the current location of the plant when it is moved from vegetative growth into its flowering state. When the plant is harvested, the date of harvest, weight of harvest, and person conducting the harvest will be entered into the software. The harvested marijuana will be weighed daily as it cures with inventory updated to reflect changes in weight due to drying. Any change in weight that is unusual will be immediately investigated. The dried flower is then prepared for processing or packaging with the current condition and storage location updated in the BioTrackTHC software.

When marijuana is transferred to the processing department, the software will be updated to reflect the new location. As the product moves through the manufacturing process, its status will be updated at each step to ensure each batch's location is recorded at all times, including in-process, finished, and quarantined product. To facilitate tracking of product as it moves through the manufacturing process, each batch of medical marijuana waiting to be processed, each batch of extract in process, finished or in quarantine, and each batch of marijuana product in progress, finished or in quarantine will be labeled with a barcode which, when scanned, will produce details relating to the exact plant and batch of extract that product was produced from, which manufacturing step it is in and all related test results.

When product is ready to be transported to the dispensary, each product barcode will be scanned and entered into the shipping manifest. All product included in the manifest will be sealed into a larger container and labeled with the contents. The product's status will be labeled as 'In transit' until it is received at the dispensary. As soon as it is received in the dispensary it

will be updated in the BioTrackTHC software to reflect its current location and to ensure the product has been released from quarantine. Each individual product will be added to the corresponding patient profile within the software when it is dispensed. The products status will then be listed as 'Dispensed' but will not be deleted from the system. This will allow for quick and easy recall procedures if an adverse event is reported, as each product will be traceable from the patient, back through the entire process of production and cultivation, to the original seed or cutting.

Detailed cultivation and production records will be maintained for at least six years to allow the company to conduct any necessary root cause analysis.

Product which is returned to cultivation for disposal is labeled as waste in the BiotTrack software and stored in a segregated section of the storage vault. Once it is ready to be transported, each product's barcode is scanned to create a shipping manifest. Inventory is updated to reflect that the product is 'In Transit' until it is received at the production center.

Cycle Counts

The department director will direct supervisors to perform inventory counts on a regular basis utilizing a cycle count method. A cycle count requires a supervisor to perform a complete count of the inventory over a period of time counting inventory groups (i.e. clones, flowers by room, finished flower, curing flower, flower for sale, flowers for processing, extracts in progress, extracts for formulation, marijuana products in progress, finished marijuana products, marijuana products in storage, marijuana products for sale, etc.) individually. Each supervisor will ensure that cycle counts are completed on schedule with minimal possible impact on regular operations.

Discrepancy Procedures

If a supervisor identifies a reduction in the amount of marijuana or marijuana product in inventory is not due to documented causes, it must be reported to the department director and

Chief Executive Officer immediately. The department director, in coordination with a supervisor, will determine where the loss has occurred, and create and implement a corrective action plan approved by the CEO. If the reduction in the amount of marijuana or marijuana product in the inventory is due to suspected criminal activity by any personnel, the CEO will immediately terminate the responsible party and report the finding to the appropriate law enforcement agency.

RECEIVING

Immediately upon arrival to the dispensary, two employees, must weigh in and account for on video and in the BioTrackTHC software, all marijuana and marijuana products. Each employee must confirm by signature: the accuracy of the delivery invoice, the number of containers, the total inventory count received, and the accuracy of entries in the software. Receipt of marijuana and marijuana products received must be recorded in the software. Information recorded includes a description of the marijuana and marijuana products acquired, all testing data, the date of acquisition, the name and identification card number of the employee delivering and the employee receiving.

MONITORING AND RECORDKEEPING

Any practice or procedure that results in non-compliance, inefficiencies, or sub-standard medical marijuana will be revised and the necessary retraining scheduled. The CEO will approve recommended procedural changes. The department director will assign data entry tasks only to qualified and trained employees. Records will fully disclose all activities throughout operations in sufficient detail as to be readily understood and audited, be maintained for no less than six years, be sufficient to demonstrate compliance with applicable regulations, and be made available for inspection and copying during normal business hours by authorized representatives of the business, law enforcement and the Department of Health.

ATTACHMENTS

The following documents will serve as supplemental information to the Department of Health, for the review of the ERBA Wellness Dispensary Application. These documents are intended to show competency and preparedness of the ERBA Wellness team and to highlight areas of particular importance.

Attachment Summary:

7-1. Standard Operating Procedure – Inventory Control and Allocation

ATTACHMENT 7-1

Manufacturing Manual		
ERBA Wellness	Policy Name	**Inventory Control and Allocation of Released Materials**
	Policy Number	**TBD**
	Date this Version Effective	**TBD**
	Responsible for Content	**Vice President of Formulation**

I. Description

a. This document is designed to provide a formal outline of the procedures the company shall follow to ensure the proper compliance to all inventory protocols regarding released materials.

II. Rationale/Purpose

a. It is corporate policy to accurately document the usage and reconciliation of all applicable materials, to ensure the tractability and proper accounting of its production materials, in-process manufacturing, packaging components, labeling and finished products.

III. Responsibilities

a. Warehouse personnel are responsible for maintaining accurate inventory records of all production materials, packaging components, labeling and in-process or finished marijuana containing products.
b. The Vice President of Formulation is responsible for insuring that competent and responsible persons are assigned to the control and allocate of materials and components. He/she is also responsible for insuring that all components and materials are allocated in such a manner that the oldest stock is routinely used first.
c. It is the responsibility of the assigned warehouse personnel to track daily material usage and conduct physical inventory counts to ensure the accuracy of the material inventory system.

IV. Policy and Procedure

a. Procedure
    i. Upon a material's release, warehouse personnel shall prepare inventory skid or container label(s) for each lot of production materials, packaging components and labeling in accordance with its Inventory Control Card.
    ii. One skid label per pallet shall be used, regardless of the number of containers for that item. Additional skid labels for the same item/control number can be used only as a continuation of the original skid label
    iii. The Inventory Control Card will be used to record all material usage. The quantity of material withdrawn for each manufacturing or packaging operation along with its intended usage and remaining balance shall be promptly entered on the Inventory Control Card whenever any materials are removed from inventory for facility operations.
    iv. The Inventory Control Cards must be used to record all unused material returned to inventory upon completion of a manufacturing or packaging

operation. The quantity of material returned to the warehouse and total remaining balance shall be promptly entered on the Inventory Control Card whenever any unused materials are returned to inventory.

v. Separate Inventory Control Cards must be maintained for each control numbers of the same material. Individual Skid Labels will be updated to show the remaining material (if any) prior to returning any unused materials to the warehouse for storage. Different control numbers of the same item must be stored in either separate warehouse locations or clearly segregated on the same skid for smaller quantities of the same material.

vi. Whenever an individual Control Number for any production material, packaging component or labeling is depleted, warehouse personnel shall reconcile its usage and document any loss or gain for that Control/Receiving Number on the Inventory Control Card. The initial acceptable reconciliation limits for all production materials, packaging components or labeling shall be based upon its assigned Item Number utilizing the following criteria:

Classification	Type of Materials	Reconciliation Limits
Item Numbers starting with the letter "A"	Production excipients, diluents, packaging components or other materials directly incorporated into a marijuana product.	Released Quantity +/- 5.0% (95.0% to 105.0%)
Item Numbers starting with the letter "B"	Bulk materials and manufacturing supplies not directly incorporated into a marijuana product including soil nutrients, fertilizers, growth promoters, pesticides, etc…	Not Reconciled. Usage is tracked for purchasing and reordering purposes only.
Item Numbers starting with the letter "C"	Controlled Materials including all Marijuana, Cannabinoid extracts and marijuana containing products	Marijuana: +/- 2% of its initial dried weight (98.0% to 102.5%) Cannabinoid extracts and bulk, unpackaged marijuana products: +/- 1% (99.0% to 101.0%) Packaged marijuana products and labeling +/- 0% (100.0%)

vii. Any gains or losses exceeding reconciliation limits will be immediately reported to the Vice President of Formulation who will promptly and completely investigate this numeric discrepancy.

viii. Unresolved losses of controlled materials (Item Numbers with the letter "C") will be promptly reported to facility security for the investigation of any potential theft, loss or diversion of marijuana, cannabinoid extracts or marijuana containing products.

ix. The Vice President of Compliance will independently confirm all reconciliations and tabulate the actual gain or loss for similar production materials to establish narrow material specific reconciliation limits based on actual historical operating data. Final reconciliation limits for

production materials, marijuana, cannabinoid extracts, in-process bulk product, packaging components or labeling will be documented in the applicable material's written specifications and shall take precedence over the preceding initially acceptable reconciliation limits.

x. Inventory Control Cards may be adjusted based upon periodic physical inventory counts or whenever a material is reweighed for the next manufacturing operation. Any necessary adjustments that exceed the currently specified Reconciliation Limit for that item shall be investigate in accordance with the previous sections.

xi. All production materials and packaging components approved for use shall be rotated so that the oldest approved stock is used first. Exceptions from this requirement are permitted if such deviations are temporary and approved in writing by the Vice President of Formulation. All such variances and their justification will be properly documented.

xii. All reconciled Inventory Control Cards and any associated investigations must be retained for at least six (6) years after distribution of the last batch in which the material was used. These inventory records shall be archived by, or as directed by, the Vice President of Formulation and be readily available during this retention period.

V. Review/Revision

Date	Description of the Revision	Approved

ERBA Wellness understands its responsibility regarding confidential patient records. Patients deserve and are afforded confidentiality by law, and as a licensed healthcare provider ERBA Wellness will be fully compliant with all relevant statutes. The team has a robust plan to educate all staff members about the importance of confidentiality, as well as how to keep and maintain secure records about patients and their medication (Attachment 8-1). ERBA Wellness also plans to use BiotrackTHC, a cloud-based software system, to create and store secure, confidential records. This will be fully compliant with Hawaii Regulations, HIPAA, and all other relevant laws. It will also allow ERBA Wellness to track which products patients have tried and at what doses, which will facilitate future recommendations if the original product or products were not as helpful as intended. ERBA Wellness intends to provide top-notch patient care, and thorough record-keeping is in keeping with this goal.

ERBA Wellness will provide all patients with a copy of its Notice of Privacy Practices (Attachment 8-2), which will explain their rights regarding confidentiality. ERBA Wellness is further required to obtain an acknowledgment from the patient or their personal representative that they have received the Notice of Privacy Practices.

In addition, ERBA Wellness has hired Patient Coordinator, Claire Santos. This person reports to the Chief Managing Officer and will be responsible for patient orientation, data, paperwork and record management, as well as maintaining familiarity with all regulations relevant to privacy, confidentiality and record keeping. This person will further be responsible for training dispensary employees on privacy and confidentiality. This training would include how to counsel patients privately, how to refer to patients when the patient is in the presence of others (by first name only), and how to be sensitive and respectful towards a patient's medical condition. This is a very important position within the retail dispensary and this

position will require someone with a medical background, excellent people-skills, strong research skills, and the ability to create and maintain secure records. ERBA Wellness is also working alongside The National Kidney Foundation of Hawaii to create a Center of Excellence (Attachment 8-3), which will create and maintain a detailed and secure patient registry. This will focus on developing data about patients, medical marijuana strains and typical reactions.

ERBA Wellness has a training program for all staff members that have access to protected health information, (PHI) on the appropriate HIPAA policies and procedures so that they may carry out their jobs in full compliance with the law. New workforce members who will be required to handle PHI are also to be trained immediately after engagement.

All training will be documented in the Green Mountain Solutions online Learning (LMS) and Knowledge (KMS) Management System. These systems allow businesses to keep highly detailed records about employee knowledge and training, including which employees have taken what courses and who is due for a refresher course. Such a system will be perfect for keeping all employees current on all regulations, policies and procedures. This documentation shall be maintained by the Chief Managing Officer. All employees with access to PHI will be trained upon hire, with follow-up classes to occur no less than every six months, or whenever the relevant law or regulations is amended or updated.

The Chief Managing Officer will oversee all record retention protocols of ERBA Wellness. All confidential patient records will be maintained, updated and stored digitally in a software platform. BioTrackTHC is guaranteed to be compliant with HIPAA and all other Hawaii regulations. All physical patient records will be scanned and attached to the patient's record in the same software platform for redundancy. The originals will be kept in a secure, locked filing cabinet in the executive office which is only accessible to manager-level employees

and higher. During hours of operation, dispensary employees may receive physical documentation from patients that must be scanned and added to the patient's record. The secure reception desk area will have a scanner and a lockable filing cabinet to store physical copies until they can be moved to the manager's office at the end of each day.

This software platform tracks every transaction and each day's beginning inventory, acquisitions, sales, disposal and ending inventory. The software records a timestamp with every record and the name and identification number of the agent which performed that action. All records created in this software platform are permanent and cannot be deleted. Paper inventory records will be kept in a locked file cabinet in the manager's office at the end of each day.

All of ERBA Wellness' records will be maintained in an electronic format and stored in a cloud-based storage system for at least five years after the date on which each record is made. All physical records will be scanned and saved in a cloud-based storage system which will only be accessible to the dispensary agent-in-charge and manager-level agents and higher. The original physical copy will be filed in a secure, locked filing cabinet in the manager's office which will also only be accessible to the dispensary agent-in-charge and manager-level agents and higher. All records will be made immediately available to the Hawai'i Department of Health upon request, in compliance with Haw. Rev. Stat. §329D-20 (2015).

Any loss or unauthorized alteration of ERBA Wellness records discovered or suspected by any employee will be reported to the Chief Managing Officer immediately. The Chief Managing Officer will report such incidents to the Department of Health and law enforcement as necessary. Upon discovery of a records security breach, the Chief Managing Officer will review all recordkeeping and security policies to identify deficiencies and necessary corrective measures.

ATTACHMENTS

The following documents will serve as supplemental information to the Department of Health, for the review of the ERBA Wellness Dispensary Application. These documents are intended to show competency and preparedness of the ERBA Wellness team and to highlight areas of particular importance.

Attachment Summary:

8-1. Standard Operating Procedure – Patient Confidentiality
8-2. Notice of Privacy Practices
8-3. Center of Excellence for Chronic Disease Management

ATTACHMENT 8-1

Dispensing Manual		
ERBA Wellness	Policy Name	**Patient Confidentiality**
	Policy Number	**[TBD]**
	Date this Version Effective	**[TBD]**
	Responsible for Content	**Chief Managing Officer**

I. Description

a. This protocol describes the methods for ensuring patient confidentiality is maintained during the dispensing of medical marijuana and manufactured marijuana products at an ERBA Wellness retail dispensing location.

II. Rationale/Purpose

a. This document is designed to provide a formal outline of the procedures ERBA Wellness shall follow to ensure that no patient's individually identifiable health information is disclosed and patient confidentiality is maintained in complete compliance with all HIPAA and State of Hawaii privacy regulations.
    i. "Individually identifiable health information" includes many common identifiers such as name, address, birth date and Social Security Number, and is information, including demographic data, that relates to:
        1. The individual's past, present or future physical or mental health or condition,
        2. The provisions of health care to the individual, or
        3. The past, present or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual

III. Responsibilities

a. Because ERBA Wellness employees will be working with private and sensitive information regarding the health of patients, it is the responsibility of all employees to follow the requirements of this standard operating procedure to ensure confidentiality is maintained and that all individually identifiable patient health information remains protected.
b. It is the responsibility of the Chief Managing Office to ensure that all employees are trained to properly follow this standard operating procedure, and that operations remain in compliance with this standard operating procedure at all times.

IV. Policy and Procedure

a. Policy
    i. No patient or caregiver may have the confidentiality of their individually identifiable health information violated by ERBA Wellness employees.
    ii. ERBA Wellness employees will be required to sign a non-disclosure agreement and maintain strict confidentiality with regards to all of the company's proprietary business information, including patient history and all individually identifiable patient health information (PHI).

b. Procedure
    i. It is the responsibility of dispensary employees with access to patients' individually identifiable health information to protect PHI and ensure it is kept secure and confidential by:
        1. Keeping patient information out of view of others
        2. Concealing patient information on computer screens
        3. Shredding waste documents that contain personal information
        4. Storing printed documentation in a secure locked cabinet
        5. Keeping records in either printed form or electronically for a minimum of 6 years.
    ii. ERBA Wellness will allow limited and reasonable access to patient treatment history and dispensing information. This will only be made available to:
        1. The health department of state and local law enforcement (for the purpose of investigating and enforcing regulations).
        2. Physicians, pharmacists or other retail dispensaries (for the purpose of providing for and monitoring patient care and drug management).
        3. A patient wishing to have access to their personal information
        4. A caregiver with respect to their patient
        5. Any person, the state of federal government or any agency thereof, pursuant to a court-ordered subpoena or search warrant.

V. Review/Revision

Date	Description of the Revision	Approved

Your Information. Your Rights. Our Responsibilities.

This notice describes how medical information about you may be used and disclosed and how you can get access to this information.
Please review it carefully.

Your Rights

When it comes to your health information, you have certain rights. This section explains your rights and some of our responsibilities to help you.

Get an electronic or paper copy of your medical record	• You can ask to see or get an electronic or paper copy of your medical record and other health information we have about you. Ask us how to do this. • We will provide a copy or a summary of your health information, usually within 30 days of your request. We may charge a reasonable, cost-based fee.
Ask us to correct your medical record	• You can ask us to correct health information about you that you think is incorrect or incomplete. Ask us how to do this. • We may say "no" to your request, but we'll tell you why in writing within 60 days.
Request confidential communications	• You can ask us to contact you in a specific way (for example, home or office phone) or to send mail to a different address. • We will say "yes" to all reasonable requests.

continued on next page

Your Rights *continued*

Ask us to limit what we use or share	• You can ask us **not** to use or share certain health information for treatment, payment, or our operations.
	  • We are not required to agree to your request, and we may say "no" if it would affect your care.
	• If you pay for a service or health care item out-of-pocket in full, you can ask us not to share that information for the purpose of payment or our operations with your health insurer.
	  • We will say "yes" unless a law requires us to share that information.

Get a list of those with whom we've shared information	• You can ask for a list (accounting) of the times we've shared your health information for six years prior to the date you ask, who we shared it with, and why. • We will include all the disclosures except for those about treatment, payment, and health care operations, and certain other disclosures (such as any you asked us to make). We'll provide one accounting a year for free but will charge a reasonable, cost-based fee if you ask for another one within 12 months.
Get a copy of this privacy notice	• You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically. We will provide you with a paper copy promptly.
Choose someone to act for you	• If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices about your health information. • We will make sure the person has this authority and can act for you before we take any action.
File a complaint if you feel your rights are violated	• You can complain if you feel we have violated your rights by contacting us using the information on page 1. • You can file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to 200 Independence Avenue, S.W., Washington, D.C. 20201, calling 1-877-696-6775, or visiting **www.hhs.gov/ocr/privacy/hipaa/complaints/.** • We will not retaliate against you for filing a complaint.

Your Choices

For certain health information, you can tell us your choices about what we share. If you have a clear preference for how we share your information in the situations described below, talk to us. Tell us what you want us to do, and we will follow your instructions.

In these cases, you have both the right and choice to tell us to:	• Share information with your family, close friends, or others involved in your care • Share information in a disaster relief situation • Include your information in a hospital directory • Contact you for fundraising efforts *If you are not able to tell us your preference, for example if you are unconscious, we may go ahead and share your information if we believe it is in your best interest. We may also share your information when needed to lessen a serious and imminent threat to health or safety.*
In these cases we *never* share your information unless you give us written permission:	• Marketing purposes • Sale of your information • Most sharing of psychotherapy notes
In the case of fundraising:	• We may contact you for fundraising efforts, but you can tell us not to contact you again.

Our Uses and Disclosures

How do we typically use or share your health information? We typically use or share your health information in the following ways.

Treat you	• We can use your health information and share it with other professionals who are treating you.	*Example: A doctor treating you for an injury asks another doctor about your overall health condition.*
Run our organization	• We can use and share your health information to run our practice, improve your care, and contact you when necessary.	*Example: We use health information about you to manage your treatment and services.*
Bill for your services	• We can use and share your health information to bill and get payment from health plans or other entities.	*Example: We give information about you to your health insurance plan so it will pay for your services.*

continued on next page

How else can we use or share your health information? We are allowed or required to share your information in other ways – usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes. For more information see: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html.**

Help with public health and safety issues	• We can share health information about you for certain situations such as:
	  • Preventing disease
	  • Helping with product recalls
	  • Reporting adverse reactions to medications
	  • Reporting suspected abuse, neglect, or domestic violence
	  • Preventing or reducing a serious threat to anyone's health or safety

Do research	• We can use or share your information for health research.
Comply with the law	• We will share information about you if state or federal laws require it, including with the Department of Health and Human Services if it wants to see that we're complying with federal privacy law.
Respond to organ and tissue donation requests	• We can share health information about you with organ procurement organizations.
Work with a medical examiner or funeral director	• We can share health information with a coroner, medical examiner, or funeral director when an individual dies.

Address workers' compensation, law enforcement, and other government requests	• We can use or share health information about you:
	  • For workers' compensation claims
	  • For law enforcement purposes or with a law enforcement official
	  • With health oversight agencies for activities authorized by law
	  • For special government functions such as military, national security, and presidential protective services

Respond to lawsuits and legal actions	• We can share health information about you in response to a court or administrative order, or in response to a subpoena.

Our Responsibilities

- We are required by law to maintain the privacy and security of your protected health information.
- We will let you know promptly if a breach occurs that may have compromised the privacy or security of your information.
- We must follow the duties and privacy practices described in this notice and give you a copy of it.
- We will not use or share your information other than as described here unless you tell us we can in writing. If you tell us we can, you may change your mind at any time. Let us know in writing if you change your mind.

For more information see: **www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp.html.**

Changes to the Terms of This Notice

We can change the terms of this notice, and the changes will apply to all information we have about you. The new notice will be available upon request, in our office, and on our web site.

ATTACHMENT 8-3

Background
Act 241, Hawaii's newly enacted medical marijuana law, allows for the usage of medical marijuana for a chronic or debilitating disease or medical condition or its treatment that produces one or more of the following:

- Wasting Syndrome
- Severe Pain
- Severe Nausea
- Seizures, including characteristics of epilepsy
- Severe and persistent muscle spasms
- MS
- Crohn's Disease
- PTSD
- Cancer
- AIDS

In keeping with ERBA Wellness' mission, to provide formulations with the highest quality medicinal content specifically engineered to address these ailments and conditions, a collaboration with the National Kidney Foundation of Hawaii (NKFH) to create a patient focused Center of Excellence for Chronic Disease Management (COE-CDM) was forged.

In recent years NKFH has expanded its mission beyond kidney disease to provide education, research, surveillance, screening and other programs that focus on chronic disease in a holistic perspective. This paradigm shift allows for the formation of the COE-CDM, in our case, as it relates to chronically ill patients using medical marijuana.

Situation
In as many years as medical marijuana has been legalized it has not matured to the extent of developing baseline research, utilizing a patient registry to develop specific formulations to treat patients' conditions. ERBA Wellness is fully engaged and prepared to seize this opportunity in Hawaii to develop a dynamic patient registry that, among other things, will record:

a. age
b. sex
c. ethnicity
d. height
e. weight
f. vitals
g. occupation
h. disease/condition
i. medications prescribed
j. patient outcomes with prescribed medications
k. physician's medical marijuana recommendation
l. recommended medical marijuana formulation
m. patient monitoring of outcomes using medical marijuana formulation

n. modification of medical marijuana formulation
o. outcomes based on modification

It is ERBA Wellness' vision to use this tool to continually modify a patient's formulation to provide optimum outcomes using formulations that best treat his or her condition. Patient intake and follow-up will initially be on-site at ERBA Wellness' retail dispensing locations, and thereafter at other participating retail dispensaries.

Plan of Action

A memorandum of understanding will be executed between ERBA Wellness and NKFH to develop this COE - CDM. ERBA Wellness will also assist in obtaining initial seed money to fund this project.

Thereafter, and once ERBA Wellness is operational, a percentage of ERBA Wellness' profits and other research dollars will be used to sustain and expand this effort. Initial team members who will be asked to participate in this project will be Dr. Ken Moritsugu, Dr. Ernie Takafuji, Dr. Wesley Clark and Dr. Sue Sisley. This team will provide guidance in the development of guidelines, protocols and procedures for the COE - CDM.

Producing quality medicine that is safe and effective for patients is a top priority for ERBA Wellness. Patients that seek treatment at ERBA Wellness' facilities may be in medically fragile conditions and thus, contaminated products could wreak further havoc on their health. ERBA Wellness will submit statistically representative samples to a certified lab (in compliance with H.A.R. §11-850-85(a) (2015)), so they can be tested for their chemical profile, possible contaminants, product quality and potency, and anything else that the Department of Health may require.

TESTING OF MARIJUANA FLOWER

A statistically representative sample should be taken of marijuana flowers after the curing process, since during the curing process there is additional risk of contamination. Further, moisture content will be analyzed and maximum of 15% moisture will be allowed.

Marijuana is a natural product and the potency of the flowers can vary. In order to provide the certified lab with a statistically representative sample (as required by H.A.R. §11-850-85(a) (2015)), the number of samples taken from each batch should increase commensurate with the size of the batch in accordance with standard operating procedure (Attachment 9-1). For batches weighing up to ten pounds, nine samples must be taken. For batches weighing between ten and twenty pounds, twelves samples must be taken. For batches weighing between thirty and forty pounds, fifteen samples must be taken. ERBA Wellness has not received instructions about the necessary size of the sample from the Department of Health, but internal research shows that one gram of marijuana will be ample for each test that the certified laboratory conducts. If the certified lab requires a different quantity, ERBA Wellness will comply with that instruction.

Once the sample has been chosen, the sample will be placed in a sealed, plastic container to await transport for testing. The rest of the batch will be quarantined in sealed containers until

the sample can be tested and the certificate of analysis is obtained. Once the certificate of analysis is obtained and the batch has been cleared, the entire batch will be taken out of quarantine, packaged, labeled, and then made available for sale at the retail dispensary or transported to the processing center to be converted to a manufactured marijuana product. ERBA Wellness will maintain records of all laboratory testing, including the certificate of analysis, which is in compliance with H.A.R. §11-850-85(h) (2015).

TESTING OF MANUFACTURED MARIJUANA PRODUCTS

For marijuana extracts, these products can sometimes settle and stratify. A test to ensure homogeneity of the extract should be performed, with a sample taken at variable depths using a coliwasa sampler if necessary (e.g. bottom, middle, and top third of the liquid). The sampling technician must adequately homogenize each batch of extract and take representative samples from three separate areas of the container. In the case of resinous material, it may need to be warmed on a heater/stirring device. This is now a “pooled” sample.

The sampling technician must validate the population being sampled is complete and intact. The employee overseeing the sample collection must make an assertion to the technician that the entire production batch of medical marijuana extract or infused product is present for sampling. This assertion places the process in compliance with H.A.R. §11-850-85(a) (2015), which requires that the sample be statistically representative. The technician must document this positive assertion in the sample collection log, and describe the population each time a sample is taken. The rest of the batch will be quarantined in sealed containers until the sample can be tested. Once the sample of extract or infused product has been tested for possible contaminants, for its chemical components, and has passed those tests, the entire batch will be taken out of quarantine, packaged, labeled, and then made available for sale at the retail dispensary.

Both marijuana and marijuana products will be tested for contaminants in addition to potency testing. This includes testing for heavy metals, pesticides, residual solvents, foreign contaminants and microbiological contaminants, as well as any other testing the Department requires. Further, ERBA will only use a testing lab that has been certified in Hawaii by an accreditation body whose standards are equivalent to ISO 17025 standards and that has established SOPs, including chain of custody SOPs, based on validated methods such as the AHP monograph for cannabis testing or USP protocols on residual solvents (Attachment 9-2).

ENSURING AN UNADULTERATED SAMPLE

All steps should be taken to avoid contamination of the samples by the sampling technician (Attachment 9-3). Sterile equipment and personal protective equipment should be used at all times. The technician should have hair pulled back if it is long, and wear a laboratory coat or plastic painting suit so that nothing may fall off the body or clothes that could cause contamination.

The containers containing the batch samples shall be placed in a temperature controlled environment during transport to discourage microbial growth. The samples will then be delivered to a certified laboratory on the island of Oahu. ERBA Wellness will maintain records of all laboratory testing, including the certificate of analysis, for a minimum of six years, which is in compliance with H.A.R. §11-850-85(h) (2015) and H.A.R. §11-850-41 (2015).

In the event that a sample fails any contamination testing, ERBA Wellness will either request that the original sample is retested, or provide a secondary sample from the same batch for testing, whichever is more appropriate. If the sample fails a second time, then the batch will be removed from the production or processing areas and destroyed according to waste procedures, and in compliance with H.A.R.§ 11-850-85(j) (2015).

ATTACHMENTS

The following documents will serve as supplemental information to the Department of Health, for the review of the ERBA Wellness Dispensary Application. These documents are intended to show competency and preparedness of the ERBA Wellness team and to highlight areas of particular importance.

Attachment Summary:

9-1. Standard Operating Procedure – Sample Collection and Retention
9-2. Standard Operating Procedure – Independent Laboratory Testing
9-3. Standard Operating Procedure – Sampling Risk Mitigation

ATTACHMENT 9-1

Manufacturing Manual		
ERBA Wellness	Policy Name	**Sample Collection and Retention**
	Policy Number	**TBD**
	Date this Version Effective	**TBD**
	Responsible for Content	**Vice President of Formulation**

I. Description

a. The sample collection and retention policy serves to outline procedures for sample collection of marijuana and marijuana products. Proper sampling is crucial to the reliability of analytical test results.
b. This policy shall apply to all medical marijuana production centers in relation to sample collection.

II. Rationale/Purpose

a. This document is designed to provide a formal outline of the procedures the company shall follow in an effort to consistently collect representative samples for testing and sample retention purposes.
b. Ensures accuracy of internal and external testing of products by implementing appropriate sampling policies.
c. Provides a logging mechanism for all collected samples.
d. Protects the interests of the company in regard to compliance with regulations and product safety.

III. Responsibilities

a. The Vice President of Formulation will oversee policy compliance for personnel under his or her supervision.
b. The Chief Medical Officer is responsible for oversight of the Vice President of Formulation and all staffing procedures and facility requirements.
c. All company personnel train in quality assurance will adhere to the policies and SOPs in this manual.

IV. Policy and Procedure

a. Policy
    i. Any employee selecting the sample of marijuana must be independent from the unit providing the sample. Samples for testing may only be collected by personnel trained in quality assurance procedures.
    ii. The cultivation or manufacturing unit will notify the Vice President of Formulation that samples are ready to be collected via email or phone. The following information will be obtained prior to the quality assurance trained employee collecting the sample(s):
        1. Name/location of the unit
        2. Contact person at location who will allow entry
        3. Number of strains harvested/weight of harvest or number of production batches and number of units
        4. Number of tests required/requested

iii. The quality assurance trained employee will gather the required materials and ensure all necessary components are sterilized.
    1. Sterile gloves
    2. Lab coat or disposable painting suit and booties
    3. Isopropanol or ethanol for cleaning gloves and equipment
    4. Small balance (calibration check performed)
    5. Weighing dishes (1 per strain/product per test, sterile)
    6. Scissors (sterile)
    7. Tweezers (sterile)
    8. Scoop (sterile)
    9. Syringes (sterile)
    10. Coliwasas (sterile)
    11. Sample containers (1 per strain per test, sterile)
    12. Sample barcode stickers

iv. The quality assurance trained employee must validate the population being sampled is complete and intact. The cultivation employee or manufacturing employee overseeing the sample collection must make an assertion that the entire harvested batch or production batch is present for sampling. The quality assurance trained employee must document this positive assertion in the sample collection log (Appendix A), and describe the population each time a sample is taken.

v. Representative samples shall be collected from each batch. A representative sample is defined as 2% of the total batch.
    1. A harvest batch is defined as all marijuana flower from the same strain, treated with the same crop applications, harvested in the same shift.
    2. A production batch is defined as all production runs utilizing marijuana material from the same harvest batch, ran in the same work shift, utilizing the same lot of CO2.
    3. A manufacturing batch is defined as all identical products manufactured from the same production batch in the same shift.

vi. Marijuana flowers should be sampled after the curing process, since during the curing process there is additional risk of contamination and mold growth. Samples should be taken as close to the last moment before they are put on the shelf to accurately account for contamination risks after the harvest.

vii. Marijuana inflorescence (fruiting tops or flowers) or “trim” is sampled when testing for potency and/or macrobiotics. The “fan leaves” of the plant are used for pesticide testing. Broad leaf should be collected from each plant in the lot. This sampling may be done at another time prior to harvest.

viii. A test specimen will be comprised of inflorescence taken from a harvest batch, and a representative sample of 10 grams per kilogram (or 2% of the total lot) or trim from the flowers (10 grams per kilogram or 2%).

ix. For oils and concentrates, these products can sometimes settle and stratify. A test to ensure homogeneity of the concentrate should be performed, with

a sample taken a variable depths using a coliwasa if necessary (e.g. bottom, middle, and top third of the liquid).

x. The quality assurance trained employee must adequately homogenize each batch of oil and take representative samples from three separate areas of the container. In the case of resinous material, it may need to be warmed on a heater/stirring device. This is now a "pooled" sample.

xi. If a product is coming off a production run, and the number of products is relatively small and sequential, a random number generator can be used to select one of the sequenced products for testing. If the run is larger, then variance in potency or contaminants may be introduced between the beginning, middle, and end of the production run. At that point, the sample selector should take one sample from each of these strata, with a random number generator providing the sequential number to be taken from each strata in the population.

xii. Due to the variation in production methods, hard rules may not be possible to establish and there should be flexibility afforded to the quality assurance trained employee to determine the proper sample selection process for any given situation. Documentation of the method of selecting the samples is mandatory.

xiii. As it relates to testing for contaminants, the sample selector should use overriding professional judgment to select a sample that upon visual inspection, appears likely to have been contaminated. This should be a rare occurrence, and this is the one case where a random sample need not be taken.

b. Reserve samples
   i. Additionally, reserve samples of three times the quantity needed for testing must be prepared from the representative sample of each batch.

c. Sample collection
   i. At every point where the quality assurance trained employee is handling marijuana product, great care should be taken to avoid introducing contaminants to the sample. The following steps should be taken:
      1. The quality assurance trained employee shall maintain a minimum level of reasonable personal hygiene and cleanliness, including showering each day, and hand washing.
      2. For each sample selected by hand, the sample selector should wear a pair of sterile gloves. After each sample is handled, the glove should be replaced with a new glove.
      3. If an instrument is used to physically select the sample, such as tweezers, the instrument should be sterilized before each sample is taken by spraying it with ethyl or isopropyl alcohol.
      4. For samples of oil or concentrates, a sterile syringe should be used.
   ii. Product containers must be opened, sampled, and resealed in a manner designed to prevent contamination of their contents.
   iii. Using scissors, tweezers, or sterile scoop the sample collection container should be placed on a tared balance whose calibration has been checked and verified. The sample(s) should then be weighed into the container.

These should be separated by test type as well, i.e. each volume for potency, pesticides, microbiological and all required/requested tests should have its own container.

d. Sample storage and transport
    i. The samples must be placed into tamper proof sealed, sterilized containers.
    ii. The sample containers shall be placed in a temperature controlled environment during transport to discourage microbial growth. Bacteria growth is greatly inhibited under 40° Fahrenheit (~4° Celsius).
e. Record keeping and storage
    i. After each sample container is closed a barcode identification sticker should be affixed to the container and the contents logged into the inventory management system as a new sample including all information required (Appendix A). The unit providing the sample shall log out the sample amount from the batch in inventory management.
    ii. Samples shall be checked into the inventory management system and separated in holding containers based on the final destination: internal testing, external testing, or sample storage.
    iii. Samples retained for quality assurance and regulatory purposes shall be stored in an environmentally controlled safe. Storage bins shall be separated for each month of each year. Samples shall be maintained for a minimum of two years after the expiration date of the sampled product. Reserve samples should:
        1. Be stored using an appropriate container-closure to protect against contamination or deterioration during storage;
        2. Be stored under conditions consistent with the typical storage conditions for the constituent or product.
        3. Be retained for the greater of two years or one year past the expiration date of the last batch of marijuana product manufactured or packaged from the lot, for use in appropriate investigations.
f. Sample disposal
    i. When the storage period has expired, the samples are ready for disposal. Samples shall be logged out of the inventory management system as disposed utilizing the barcode identifier. Samples shall then be placed in the respective secure waste container for disposal by the laboratory's approved chemical waste disposal service.

V. Review/Revision

Date	Description of the Revision	Approved

ATTACHMENT 9-2

Manufacturing Manual		
ERBA Wellness	Policy Name	**Independent Laboratory Testing**
	Policy Number	**TBA**
	Date this Version Effective	**TBA**
	Responsible for Content	**Vice President of Formulation**

I. Description

a. The independent laboratory testing policy serves to outline procedures for testing of final products. This policy shall apply to all of the company's medical marijuana production centers.

II. Rationale/Purpose

a. This document is designed to provide a formal outline of the procedures that the company shall follow to comply with testing requirements to be fulfilled by an independent laboratory.
b. Testing is required to comply with Department of Health regulations.
c. Ensure compliance with Department of Health regulations for testing of products by implementing appropriate policies.
d. Detail the recordkeeping requirements for all chain of custody documents and independent laboratory reports.
e. Protect the interests of the company in regard to compliance with regulations and product safety.

III. Responsibilities

a. The Vice President of Formulation will oversee policy compliance for personnel under his or her supervision.
b. The Chief Medical Officer is responsible for oversight of the Vice President of Formulation and all quality assurance activities including independent laboratory testing.
c. All company employees will adhere to the policies and SOPs in this manual.

IV. Policy and Procedure

a. Policy
    i. All marijuana that is unable to be dispensed to a patient will be disposed of properly in accordance to the company's protocols.
    ii. The Vice President of Formulation shall select an approved laboratory with the approval of the Chief Medical Officer.
    iii. Any laboratory utilized by the company must perform the general body of required quality assurance tests to be set forth by the Department of Health.
    iv. No company executive, member, or principal stakeholder will have any financial or other interest in a laboratory providing testing services.
    v. No employee of an independent laboratory providing testing services to the company shall be employed or engaged by the company or receive direct financial compensation from the company in any manner.
    vi. From the time that a batch has been homogenized for sample testing and eventual packaging and sale until the independent testing laboratory

provides the results from its tests and analysis, the manufacturing unit shall segregate and withhold from use the entire batch, except the samples that have been removed for testing.

b. Procedure
   i. The manufacturing unit shall notify the independent laboratory when a production batch is finished and ready for sampling.
   ii. The assigned sampling technician shall collect a sufficient amount samples of finished oils and products in accordance with Sample Collection and Retention and Sampling Risk Mitigation SOPs. A sample must also be retained at the medical marijuana production center for verification testing by the Department of Health.
   iii. The Vice President of Formulation is responsible for preparation of testing samples for submission to an independent laboratory.
   iv. All necessary chain of custody documentation and laboratory management system entries must be completed prior to sample transfer to an independent laboratory. Samples must retain barcode and labeling identification from the collection of the sample to the receipt of results.
   v. Any person transporting samples from the company laboratory to an independent testing facility must be approved by the company for transportation of marijuana products. All transportation must be in accordance with Transportation SOPs.
   vi. The Vice President of Formulation must ensure:
      1. The batch is maintained in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy.
      2. Under no circumstances may the batch of marijuana or marijuana products be sold until testing and analysis is completed, results have been provided in writing, and the laboratory has released the batch for sale.
   vii. Contaminant testing shall include analysis for the following contaminants:
      1. Heavy Metals:
         a. Arsenic 10.0 ppm
         b. Lead 6.0 ppm
         c. Cadmium 4.0 ppm
         d. Mercury 2.0 ppm
      2. Pesticides regulated by the U.S. Environmental Protection Agency 1.0 ppm
      3. Solvents:
         a. Butanes 800 ppm
         b. Heptanes 500 ppm
         c. Benzene** 1 ppm
         d. Toluene** 1 ppm
         e. Hexane** 10 ppm
         f. Total Xylenes (m,o,p-xylene) 1 ppm

         ** Contaminants in solvents
      4. Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic.

5. Moisture content of plant material <15%
6. Microbiological impurities, including but not limited to:
    a. Total Viable Aerobic Bacteria:
        i. Unprocessed and Processed Materials: 10^5 Colony Forming Unit (CFU)/g
        ii. CO_2 and Solvent Based Extracts: 10^4 CFU/g
    b. Total Yeast and Mold:
        i. Unprocessed and Processed Materials: 10^4 CFU/g
        ii. CO_2 and Solvent Based Extracts: 10^3 CFU/g
    c. Total Coliforms:
        i. Unprocessed and Processed Materials: 10^3 CFU/g
        ii. CO_2 and Solvent Based Extracts: 10^2 CFU/g
    d. Bile-tolerant Gram Negative Bacteria:
        i. Unprocessed and Processed Materials: 10^3 CFU/g
        ii. CO_2 and Solvent Based Extracts: 10^2 CFU/g
    e. E. coli (pathogenic strains) and *Salmonella* spp.: Not detected in 1g
    f. *Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger:* <1 CFU/g
    g. Mycotoxins: <20µg (micrograms) of any mycotoxin per kg of materials
7. Additional testing requested at the discretion of the department

viii. The Vice President of Formulation must ensure all required testing is performed in accordance with Department of Health rules. The Vice President of Formulation shall require additional testing as necessary to ensure the safety and quality of all marijuana products. Cannabinoid testing shall include the following analytes:
1. Δ^9 Tetrahydrocannabinol (THC)
2. Tetrahydrocannabinol acid (THCA)
3. Cannabidiol (CBD)
4. Cannabinadiolic acid (CBDA)
5. Cannabinol (CBN)
6. Cannabigerol (CBG)
7. Additional testing requested at the discretion of the department.

ix. Reporting of results
1. Upon receipt of test results from the independent laboratory, the Vice President of Formulation shall enter the results into the inventory management system.
2. The Vice President of Formulation shall transmit the results to the manufacturing unit with a determination of batch status including: approved for labeling and distribution, hold for rework, scrapped for disposal
3. The manufacturing unit shall handle the batch according to the approved status and in accordance with Distribution, Rework, and Disposal SOPs.

4. Any employee discovered falsifying test results or distributing products that have not been released by the laboratory may be terminated immediately by the company.

x. Failed Samples
   1. The Vice President of Formulation may request from the Department of Health an authorization a retest of samples to validate the results of a failed test if he or she believes the results are inaccurate based on internal testing.
   2. All product from the batch in question must remain in quarantine until the Department of Health provides a denial or authorization for a retest.
   3. Upon denial from the Department of Health, the batch shall be deemed a failure. Upon approval for a retest from the Department of Health, all quarantine policies shall remain in effect until a final determination is made.
   4. If a sample provided to laboratory does not pass any test based on the standards of the Department of Health, the Vice President of Formulation must ensure the manufacturing unit disposes of the entire batch from which the sample was taken.
   5. All batch disposals must be properly recorded in the inventory control system and disposed of in accordance with the company's Recordkeeping and Disposal SOPs.

xi. Additional tests required
   1. The Department of Health may require additional testing or request samples for Department of Health testing purposes. The Vice President of Formulation must ensure that the company complies with all published Department of Health testing requirements and provides all samples as requested with proper chain of custody documentation.

V. Review/Revision

Date	Description of the Revision	Approved

ATTACHMENT 9-3

Manufacturing Manual		
ERBA Wellness	Policy Name	**Sampling Risk Mitigation**
	Policy Number	**TBD**
	Date this Version Effective	**TBD**
	Responsible for Content	**Vice President of Formulation**

I. Description

a. The sampling risk policy serves to mitigate sampling risk by outlining procedures to address and prevent the most common sampling problems.
b. This policy shall apply to all company medical marijuana production centers.

II. Rationale/Purpose

a. This document is designed to provide a formal outline of the procedures the company shall follow in an effort to proactively avoid or minimize sampling risk.
b. Ensures accuracy of internal and external testing of products by reducing selection bias, increasing sampling accuracy, reducing contamination and documentation risk.
c. Provides a monitoring mechanism for all reported sampling errors.
d. Protects the interests of the company with regard to product liability.

III. Responsibilities

a. The Vice President of Formulation will oversee policy compliance for personnel under his or her supervision.
b. All company employees will adhere to the policies and SOPs in this manual.

IV. Policy and Procedure

a. Policy
    i. The employee selecting the sample of marijuana must be independent from the unit providing the sample. Samples for testing may only be collected personnel trained in quality assurance procedures.
    ii. Sampling shall be performed using a methodology including an element of randomness in sample selection.
    iii. Sample selectors must have a minimum level of training in audit, statistics, horticulture, or other related field.
    iv. Sterilized gloves and instruments must be used in sample selection.
    v. Sample selectors must maintain a minimum level a personal hygiene.
    vi. Samples must be transported in sterile, sealed containers that are temperature controlled.
    vii. Chain of custody records must be maintained for all samples for both internal and external testing.
    viii. An incident report shall be completed in the event of a sampling error or other notable unusual incident. An incident report is a record of an unintended event that describes the details of what is/was correct and what actually happened. Form attached in Appendix A.
        1. The report shall identify the nature of the incident, involvement of the employee(s) or third-party, and witness accounts if applicable.

2. The report shall be submitted to the Vice President of Formulation. The Vice President of Formulation shall determine, implement, and document corrective actions taken to address the error.
3. The incident log shall be securely maintained by the Vice President of Formulation and accessible to authorized personnel only.

V. Review/Revision

Date	Description of the Revision	Approved

ATTACHMENT 9-3

Appendix A
Sample Incident Log

Date Received:

Date of Initial Occurrence:

Time of Initial Occurrence (if known): _____ a.m. / p.m.

Name and Identification Number of Employee Reporting the Incident:

Describe the Incident:

Note all lot and batch identification numbers involved in the Incident:

Remediation Efforts

Corrective action(s) taken:

Recommendations for preventive actions:

Additional comments:

Reporting employee (print):

Reporting employee (signature):

Date:

ERBA Wellness has dutifully studied the regulations regarding packaging, labeling, signage, and the chain of custody of all of its products. The executive team and Star Protection has put together a plan to fully comply with all such regulations, which includes limiting the size of the sign displayed outside the retail dispensary, maintaining detailed inventory logs, and utilizing advanced software that is designed specifically for the marijuana industry.

SIGNAGE

Regarding the building advertising, ERBA Wellness will comply with Haw. Rev. Stat. §329D-7(o)(1) and Haw. Rev. Stat. §329D-7(o)(2). Neither marijuana, nor any marijuana product, nor any pictures or images of marijuana will be displayed in windows or within the view of the public. No signage for the building will be larger than 1,600 square inches and it will only contain the name "ERBA Wellness" in plain text, with no pictures or graphics.

PACKAGING AND LABELING

All packaging will be child-resistant and opaque so that the product cannot be seen from outside the package and will be in complete compliance with Haw. Rev. Stat. §329D-11, (2015), and H.A.R. §11-850-92(b)(8), (2015). All products available for sale at the retail dispensary will be pre-packaged at the production center in accordance with standard operating procedure (Attachment 10-1). This will prevent errors in dispensing and limit the risk of contamination that could affect product quality and safety. The label on the packaging will only use black letters on a white background, with no pictures, graphics or images, and will be clearly marked with all phrases and warnings required in H.A.R. §11-850-92(b)(7) and (8), (2015)

The label will also display the "use by" date, the name of the production center where the marijuana was produced as well as the date of production, a batch number, a barcode, instructions for use and the date the product was put into a package. Information detailing the

contents and potency of the product will also be provided on the label including levels of delta-9-tetrahydrocannabinol (THC), both total THC and levels of THCA, and of total cannabidiol (CBD). ERBA Wellness will sell manufactured marijuana products, and all such products will contain a listing of the equivalent physical weight of the marijuana used to manufacture the amount of the product that is within the packaging. Information on the type of extraction method and solvents used and the name of the testing lab will also be provided. No label of "organic" will be used unless permitted by the US Dept. of Ag. in accordance with the Organic Foods Production Act. Furthermore, since ERBA Wellness will sell capsules, lozenges, tinctures, and oral syringes, all of those products will be packaged in such a manner so that one dose contains no more than ten milligrams of THC and that one package does not contain more than a total of 100 milligrams of THC. ERBA will only use packaging that has a proven record of safe use in other industries such as pharmaceutical manufacturing and that are child resistant/ tamper evident in accordance with Title C.F.R. 1700 of the Poison Prevention Packaging Act.

CHAIN OF CUSTODY

Maintaining a thorough and responsible chain of custody is one of the most critical components in running a successful and fully-compliant marijuana business. The management of the inventory threads through the entire business and touches all the areas that are important to the business and to those that regulate it. Without good inventory management, via a comprehensive chain of custody, there are risks of security breaches, diversion, loss of quality, theft and lack of accountability by the staff. ERBA Wellness's inventory control plan is designed to ensure safekeeping of medical marijuana throughout the lifecycle of the product. This plan created by the executive team and Star Protection meets or exceeds all state regulations.

The chain of custody will be maintained and monitored in all stages from the production area, to the processing area and the retail dispensary. Employees working with inventory and chain of custody will work in pairs in order to prevent employee theft. In the production area, an authorized employee and a direct supervisor will maintain a manifest that includes the number of plants, what state the plant is in (either flowering or vegetative), and the location of the plant. Once the flower has been harvested from plants it will be sent to either the packaging area and then on to the dispensary, or it will be sent to the processing area, where it will be turned into a marijuana product. In the processing area, an authorized employee and a direct supervisor will maintain a manifest that tracks the amount of plant material on hand for processing, batches of work in progress product and finished product in inventory, packaging and labeling materials, ingredients and other disposable items used in the manufacturing process. In the packaging area, an authorized employee and a direct supervisor will maintain a manifest of how much unpackaged flower and finished marijuana products are in the area as well as the quantity of packaged flower and finished marijuana products waiting to be transported to the dispensary. A manifest will also be created anytime marijuana or marijuana product travel from one physical location to another within the production center itself and when transferring product to the retail dispensary. Managers at both facilities will coordinate with Star Protection and the security team.

A reconciliation of all inventory items, at every location, will be performed by a manager on a weekly basis and then reported to the VP of Compliance and the Chief Security Officer. Any discrepancy in physical item inventory versus last recorded item inventory is documented and reported to the Compliance Officer and as regulations require. After further investigation, any appropriate corrective measures are taken. Inventory that is stored in the safe for future use is inventoried weekly. Products on the dispensary floor are inventoried daily.

ATTACHMENTS

The following documents will serve as supplemental information to the Department of Health, for the review of the ERBA Wellness Dispensary Application. These documents are intended to show competency and preparedness of the ERBA Wellness team and to highlight areas of particular importance.

Attachment Summary:

10-1. Standard Operating Procedure – Product Packaging and Labeling Requirements

ATTACHMENT 10-1

Manufacturing Manual		
ERBA Wellness	Policy Name	**Product Packaging and Labeling Requirements**
	Policy Number	**TBD**
	Date this Version Effective	**TBD**
	Responsible for Content	**Vice President of Formulation**

I. Description

a. This protocol describes the method for the operation protocols pursuant to all laws, regulations, and company policies required for packaging and labeling.

II. Rationale/Purpose

a. This document is designed to provide a formal outline of the procedures the company shall follow to ensure the proper packaging and labeling protocols.
b. It is corporate policy to package all marijuana and marijuana products in child-resistant, tamper-proof/tamper-evident, opaque containers and fully document all packaging or labeling operations. Containers must protect the product from contamination and may not impart any toxic or harmful substance to the marijuana or marijuana product.

III. Responsibilities

a. It is the responsibility of assigned packaging and labeling personnel to follow all requirements of this Standard Operating Procedure
b. It is the responsibility of the Vice President of Formulation to ensure all packaging and labeling operations are performed in compliance with this Standard Operating Procedure.
c. It is the responsibility of the Vice President of Formulation to ensure all packaging and labeling operations are performed in compliance with all applicable federal, state, or local laws and regulations.
d. It is the responsibility of the Vice President of Compliance to confirm all selected packaging formats and packaging component specifications meet applicable requirements.
e. All company assurance employees will adhere to the policies and SOPs in this manual.

IV. Policy and Procedure

a. Policy
    i. Product containers and closures shall not be reactive, additive or absorptive so as to alter the safety, strength, quality or purity of the marijuana or marijuana product. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the product. Product containers and closures shall be clean and free from particular matter.
    ii. All labels must be black lettering on a white background with no pictures or graphics.

iii. No marijuana or marijuana product may be labeled as organic unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.
iv. Packaging must be child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act.
v. Packaging must be opaque so that product cannot be seen from the outside of the packaging.
vi. Each package cannot contain more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; provided that no manufactured marijuana product is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack of container.
vii. Any labeling or packaging materials meeting its written specifications will be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.
viii. Labels and other labeling materials for each different marijuana product, strength, dosage form or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel.
ix. Obsolete or outdated labels, labeling and other packaging materials shall be destroyed.
x. Gang-printed labeling for different products or different strengths or net contents of the same product is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size or shape.

b. Procedure
    i. Whenever possible, the packaging of marijuana and marijuana products will utilize roll labeling. If cut labeling is used for immediate container labels, individual unit cartons or multiunit cartons containing immediate containers that are not packaged in individual unit cartons; packaging and labeling operations shall include one of the following special controls:
        1. Dedication of labeling and packaging lines for each different strength of each different marijuana product
        2. Use of appropriate electronic or electromechanical equipment to conduct a 100 percent examination for correct labeling during or after completion of operations
        3. Use of visual inspection to conduct a 100 percent examination for correct labeling during or after completion of finishing operations for hand-applied labeling. Such examination shall be performed by one person and independently verified by a second person.
        4. Use of an automated technique, including differentiation by labeling size and shape, which physically prevents incorrect labeling from being processed by labeling and packaging equipment.

ii. Printing devices on or associated with packaging lines used to imprint labeling upon the product or case label, batch number or expiry date shall be monitored to assure that all imprinting conforms to the printing specified in the Packaging Batch Record.

iii. Strict control shall be exercised over labeling issued for use in product packaging including written descriptions in sufficient detail of the controls employed for issuance of labeling. Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the Packaging Batch Record.

iv. Procedures shall be used to reconcile the quantities of labeling issued, used or returned and shall require evaluation of any discrepancies found between the quantity of finished product and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Any such, discrepancies shall be investigated by production and approved by the Vice President of Formulation before a batch is released or distributed. Labeling reconciliation is waived for roll labeling if a 100 percent examination for correct labeling is performed in accordance with step 6 (see above).

v. All excess labeling bearing batch lot or control numbers shall be destroyed. Excess labeling that has not been imprinted with a batch number shall be returned to storage in a manner to prevent mix-ups and provide proper identification.

vi. Packaging and Labeling operations shall be designed to assure that correct packaging materials and labels and are used for each batch of marijuana or marijuana product. These shall incorporate the following features:

    1. Prevention of mix-ups and cross-contamination by physical or spatial separation of each product operation from other operations on different products or strengths.
    2. Identification of the marijuana or marijuana product with a batch lot or control number that permits determination of the history of the manufacture and control of the batch.
    3. Examination of packaging and labeling materials for suitability and correctness before packaging operations and documentation of such examination in the Packaging Batch Record.
    4. Inspection of the packaging and labeling facilities immediately before use to assure that all previous products have been removed from the packaging area. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent packaging operations have been removed. The results of these inspections shall be documented in the Packaging Batch Record.
    5. Identification and handling of filled marijuana and marijuana product containers that are set aside and held in unlabeled condition for future labeling operations (i.e. bright inventory) shall be adequate to preclude mislabeling of individual containers, product lots or portions of a product lot. Identification need not be

applied to each individual container but shall be sufficient to determine name, strength, quantity of contents and batch number of each container.

vii. Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the batch have the correct label. A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling. Results of these examinations shall be recorded in the Packaging Batch Record.

viii. Each packaged marijuana product shall be affixed with a product label. Product labels shall be applied at the manufacturing facility to be easily readable, and items 1-7 below must be firmly affixed while the remainder may appear on a package insert or on the package. Labels must include:

1. Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
    a. Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight or the marijuana used to produce the manufactured marijuana product;
    b. The concentration of tetrahydrocannabinol or Δ^9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and Cannabidiol;
2. The dispensary licensee's license number and name of the production center where marijuana in the product was produced;
3. The batch number and date of packaging;
4. Includes a computer tracking inventory identification number barcode generated by tracking software;
5. Date of harvest or manufacture and "Use by date";
6. Instructions for use;
7. The phrases "For medical use only" and "Not for resale or transfer to another person";
8. The following warnings:
    a. "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";
    b. "This product has intoxicating effects and may be habit forming";
    c. "Smoking is hazardous to your health";
    d. "There may be health risks associated with consumption of this product";
    e. "This product is not recommended for use by women who are pregnant or breast feeding";
    f. "Marijuana can impair concentration, coordination, and judgement. Do not operate a vehicle or machinery under the influence of this drug"; and

g. "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";

9. A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product;
10. The name of the laboratory that performed the testing;
11. Marijuana product type and brand;
12. Quantity included in the package; and
13. Proper storage conditions.

V. Review/Revision

Date	Description of the Revision	Approved

In accordance with the regulations, ERBA Wellness will destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the Department of Health or the Department of Public Safety Narcotics Enforcement Division Administrator. Procedures for waste disposal will ensure that all waste is secured and inaccessible by the public. Waste is produced through cultivation procedures, product manufacturing, as well as any expired or returned products at the retail dispensary.

ERBA Wellness' waste management plan (Attachment 11-1) operates with three streams of waste: compost, laboratory waste, and other waste. Plant waste will be composted on-site at the medical marijuana production center. All plant waste from dispensary operations will be securely stored and then transported to the production center to be composted. Laboratory waste consists of chemical waste, sanitizers, solvents, and any other waste from manufacturing operations, which will be disposed of by an approved hazardous waste company. Other waste includes waste created from business operations, such as paper products. Additional waste disposal provisions include detailed plans for liquid and solid waste disposal based on guidelines from the Department of Health. Pursuant to company policy and industry best practices, all waste will be stored and disposed of in a manner that: (1) minimizes the development of odors; (2) minimizes the potential for waste to attract, harbor, or become a breeding place for pests; (3) controls hazardous waste to prevent contamination of marijuana, contact surfaces, water supplies, and grounds surrounding the facility; (4) prevents diversion, theft, or loss of unusable marijuana product; and (5) provides traceability through documentation, reporting, and electronic tracking.

ERBA Wellness has a comprehensive system for systematically collecting and properly destroying all materials containing marijuana. The final material disposal will render both finished product and precursor materials completely unrecoverable and beyond reclamation. Any

packaging that can be salvaged without any risk of contamination or recycled shall be noted in the disposal record of the inventory management system.

COMPOST

ERBA Wellness will dispose of marijuana waste through grinding and composting techniques. The standard operating procedure for waste management contains further details on the procedure (Attachment 11-2). By composting solid marijuana waste, the cultivation facility will produce zero solid marijuana plant waste. A trained cultivation employee, under management supervision and in full view of surveillance cameras, will render solid marijuana waste unusable by grinding and incorporating plant material into the facility's compost pile. Marijuana plant waste will be ground with either compostable mixed waste, which includes food waste, yard waste, vegetable based grease or oils, or other approved compostable waste materials. Controlled waste materials for destruction may originate from several sources:

- Marijuana stems or other unusable plant materials generated at the manufacturing site are weighed, labeled and stored in a limited access area until they can be properly destroyed.
- All cannabinoid containing extracts, concentrates, in-process materials and bulk product that cannot be further processed into approvable packaged product.
- Product determined to not meet the minimum safety standards and specifications for brand consistency or otherwise rejected through quality assurance procedures.
- Packaged medical marijuana products at a dispensing facility that become damaged, short dated or were returned by a customer are securely stored at the dispensing facility.
- Any products that were subject to improper storage conditions, including but not limited to extremes in temperature, water damage, smoke damage, fires or equipment failure.

LABORATORY WASTE

The manufacturing department will utilize solvent recycling systems throughout the manufacturing process to minimize solvent waste, diminish environmental impact, and reduce cost of goods. Any solvents, as well as other waste streams that cannot be recycled, will be disposed of with a certified laboratory waste disposal company. To dispose of any leftover marijuana, marijuana extracts, or products that were not used in the sample analysis process or rendered into finished goods, staff will place raw marijuana, downstream products, and containers inside a secured waste disposal drum. The drum at time of disposal will generally contain about 70% liquid lab waste (flammable solvents, etc.) and about 30% solid waste (containers, vials, plates). However, it is the goal of ERBA Wellness to eliminate as much laboratory waste as possible.

All marijuana and manufactured marijuana products that are disposed of are rendered unrecognizable and unusable once inside the drum and saturated in solvent. The waste disposal company will be the last recipient in the chain of custody as drums are incinerated or disposed of in accordance with state and local laboratory waste disposal guidelines. ERBA Wellness will be aware of what is being disposed of and will also be aware of the hazards associated with the solvents that are inside the drum and follow all flammable/hazardous solvent disposal procedures as mandated by state regulations.

ERBA Wellness has elected to use carbon dioxide for its solvent extractions and the Waters supercritical fluid extraction bio-botanical extraction system to control the extraction parameters of the carbon dioxide during the extraction process. The recycling system is capable of reclaiming 90% of the carbon dioxide used during the process cycle. The remaining carbon dioxide will be purged from the extraction area using a fixed exhaust line plumbed to the outside.

In this manner the company will greatly reduce its consumption of carbon dioxide with only generating a minimal amount of waste which is carbon neutral.

OTHER WASTE

Pursuant to state and county regulations regarding wastewater, any wastewater will be disposed with environmentally sound procedures consistent with the Department of Health regulations and local laws. The production center will adhere to wastewater disposal standards and record and maintain all necessary information in the waste disposal log.

In accordance with local ordinances, ERBA Wellness will use refuse containers for all non-compostable waste including: paper, pasteboard boxes, glass, and other discarded materials not containing plant matter. Pursuant to company policy, the production center will properly recycle all acceptable materials by separating designated materials.

WASTE INVENTORY MANAGEMENT AND DIVERSION PREVENTION

All disposed waste will be recorded in the waste disposal log with the date of disposal, type and quantity of waste disposed, the manner of disposal, the name of the employee logging the waste, and the patient or caregiver who returned the waste, if applicable. All medical marijuana material or finished products awaiting disposal will be stored in a locked container, surveilled in a secure area, recorded in the log and inventory control system, and disposed of in accordance with ERBA Wellness' waste disposal policies and procedures.

Inventory records will include the quantity of marijuana materials and downstream products at the processing facility, including all in-process materials, on a daily basis as outlined in ERBA Wellness' inventory policies and procedures. Disposal records will include the disposal method used, the reason for disposal, and the employees responsible for disposal. The VP of Formulation will assign data entry tasks to qualified and trained employees. Required

manufacturing documentation may be recorded in ERBA Wellness' inventory control system or as determined by the VP of Formulation. All data maintained in the manufacturing management systems will be kept for at least six years after the batch has been distributed.

ERBA Wellness' inventory management system will track marijuana waste by weight and RFID or barcode throughout every phase of production, as well as returns and recalls in the retail phase. Upon destruction, the system will generate a destruction report. The system also allows for the electronic authentication of witnesses to the destruction through either a four-digit pin number or a biometric scan. The system evidences the lifecycle of every original plant RFID or barcode with an auditable trail to either retail sale or verified destruction. This software will automatically produce a quarterly report of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed in accordance with H.A.R. §11-850-38(b)(4) (2015).

ERBA Wellness will accept returns, unused, excess, or contaminated marijuana or manufactured marijuana products from qualified patients or caregivers, and will manage this waste according to the waste policies and procedures of ERBA Wellness (Attachment 11-2) while maintaining a written record in the waste disposal log (Attachment 11-3) and the inventory control system, which will include the name of the patient or caregiver.

Quarantined waste will be held in storage with full camera coverage until the waste is transferred for disposal. The secure waste container will be properly labeled for disposal and entered into ERBA Wellness' inventory control system with a disposed status. The Chief Managing Officer will ensure all waste container contents are entered in the waste log, properly recorded in the inventory control system as disposed, and that the entire container is removed for disposal as often as necessary.

ATTACHMENTS

The following documents will serve as supplemental information to the Department of Health, for the review of the ERBA Wellness Dispensary Application. These documents are intended to show competency and preparedness of the ERBA Wellness team and to highlight areas of particular importance.

Attachment Summary:

11-1. Waste Management Plan
11-2. Standard Operating Procedure – Medical Marijuana Waste Management
11-3. Sample Log – Waste Disposal Log

ATTACHMENT 11-1

WASTE MANAGEMENT PLAN

Procedures for marijuana waste disposal will ensure that all waste is secured and inaccessible by the public. The Chief Managing Officer and the Vice President of Compliance are responsible for developing and implementing procedures for waste disposal in all ERBA Wellness facilities that are in compliance with state and local law. ERBA Wellness' waste management plan operates with three streams of waste: compost, laboratory waste, and other waste. Plant waste will be composted on-site at the medical marijuana production center. All plant waste from dispensary operations will be securely stored and then transported to the production center to be composted. Laboratory waste consists of chemical waste, sanitizers, solvents, and any other waste from manufacturing operations, which will be disposed of by an approved hazardous waste company. Other waste includes waste created from business operations, such as paper products. Additional waste disposal provisions include detailed plans for liquid and solid waste disposal based on guidelines from the Department of Health.

The company's medical marijuana production center intends to produce a minimal amount of marijuana waste, however, the waste produced during operations and contaminated products will need to be disposed of properly. All waste composed of or containing finished marijuana and marijuana products, will be stored, secured, and managed in accordance with all applicable ordinances and regulations. The company will compost waste on-site at the medical marijuana production center.

Laboratory waste consists of chemical waste, sanitizers, solvents, and any other waste from extraction operations. Medical waste relates to any finished extracted product that has been deemed as waste by an appropriate supervisor and cannot be composted, which will be then be hauled by the same hazardous waste company that will also dispose of all laboratory waste.

All disposed waste will be recorded in the Waste Disposal Log with details pertaining to the date of disposal, type and quantity of waste, and the manner of disposal. Additional waste disposal provisions include detailed plans for excess product disposal, liquid and solid waste disposal based on guidelines from the Department of Health, and the disposal of expired, contaminated, or otherwise unusable marijuana products. The Chief Managing Officer will also investigate any verifiable incident of unauthorized destruction of marijuana.

MARIJUANA WASTE MANAGEMENT SUMMARY

The company's waste management policies detail the operational procedures for marijuana waste disposal. The Chief Managing Officer and Vice President of Compliance are assigned responsibility for enforcing policies and procedures relating to marijuana waste management. Pursuant to regulations, all waste, including waste composed of, or containing, finished marijuana and marijuana products, will be stored, secured, and managed in accordance with applicable statutes, regulations, and ordinances. The company's waste disposal procedures are detailed in the standard operating procedure.

ATTACHMENT 11-1

The medical marijuana production center and dispensary will log and secure waste onsite. All waste at the dispensary will be manifested and returned to the medical marijuana production center for disposal. All disposed waste will be recorded in the waste disposal log with the following details at a minimum:

- The date of disposal,
- Type and quantity of waste disposed,
- The manner of disposal,
- The name of the cultivation employee logging the waste, and
- The patient or caregiver who returned the waste if applicable.

Additional waste disposal provisions include detailed plans for excess product disposal, liquid and solid waste disposal based on guidelines from environmental agencies, composting practices, and the disposal of expired, contaminated, or otherwise unusable marijuana products.

All supervisors are responsible for ensuring the quality and safety of marijuana products in their inventory on a daily basis. The Chief Cultivation Officer, Vice President of Formulation, and Vice President of Dispensary will ensure that expired, contaminated, or otherwise unusable marijuana products in their respective departments are transported to the proper area for disposal in accordance with the company's waste management policies and properly recorded in the inventory management or point of sale systems.

Pursuant to state and county regulations regarding wastewater, any wastewater will be disposed with environmentally sound procedures consistent with the Department of Health regulations and local laws. The medical marijuana production center will adhere to all local wastewater disposal standards and record and maintain all necessary information regarding wastewater in the waste disposal log. Unlike hydroponic systems, the medical marijuana production center's soil based media will not result in any liquid waste runoff.

In accordance with local ordinances, the company will comply with the county's preferred methods of waste disposal, recordkeeping requirements, and all Federal, State, and local laws for all types of waste produced during cultivation operations. Pursuant to company policy and industry best practices, all cultivation waste will be stored and disposed of in a manner that:

- Minimizes the development of odors;
- Minimizes the potential for waste to attract, harbor, or become a breeding place for pests;
- Protects against contamination of marijuana, contact surfaces, water supplies, and grounds surrounding the facility;
- Controls hazardous waste to prevent contamination of marijuana, contact surfaces, water supplies, and grounds surrounding the facility;
- Prevents diversion, theft, or loss of unusable marijuana product; and
- Provides traceability through documentation, reporting, and electronic tracking.

ATTACHMENT 11-1

The company has decided to dispose of marijuana waste through grinding and composting techniques. By composting solid marijuana waste, the medical marijuana production center will produce zero solid marijuana plant waste. The Chief Cultivation Officer will ensure that all pre-disposal reporting and recordkeeping requirements are satisfied. A trained cultivation employee, under management supervision, will render solid marijuana waste unusable by grinding and incorporating marijuana plant material into the facility's compost pile. Marijuana plant waste will be ground with either compostable mixed waste, which includes food waste, yard waste, vegetable based grease or oils, or other approved compostable waste materials.

In accordance with local ordinances, the company will use refuse containers for all non-compostable waste including: paper, pasteboard boxes, glass, and all other trash or discarded materials not containing plant matter. Pursuant to company policy, the medical marijuana production center will properly recycle all acceptable materials by first separating designated materials and making them available for recycling. The company will properly dispose of all non-compostable solid waste in accordance to the county's policies. Additionally:

- All facilities will properly utilize refuse containers for recyclable materials, which will be clearly separated from solid waste containers.
- The company will provide for the source-separation of any metals and packaging materials.
- A designated employee will be responsible for the breakdown of packaging materials before placing them in waste containers so as to not take up unnecessary space.
- The company will provide for proper recycling either by entering into an agreement with a permit holder or certified recycler.
- The company will establish a recycling program that is convenient and accessible to all employees for recycling of designated materials.

The supervisors are responsible for ensuring the quality and safety of marijuana and marijuana products in their inventory on a daily basis. Each facility will ensure that any unusable marijuana and marijuana products remain properly stored for disposal in accordance with the company's waste management policies and properly recorded in the inventory management or point of sale systems.

The dispensary will receive prepackaged marijuana flower and marijuana products from the medical marijuana production center. Patients will be encouraged to return any unused medical marijuana products to the retail dispensing facility to ensure appropriate waste management. The retail dispensing facility will have in place a standard operating procedure related to the intake of this material, separation from products that are for sale, and return to the medical marijuana production center for proper disposal.

WASTE RELATED DIVERSION PREVENTION

Storage of Expired and Disposed Medical Marijuana Products

All medical marijuana material awaiting disposal will be:

- Stored in a locked container,
- Monitored in a secure area,
- Recorded in the log and inventory control system, if necessary, and
- Disposed of in accordance with the company's waste disposal policies and procedures.

Regular Audits Required

The performance of audits and inventory counts in accordance with the company's policies and procedures for inventory management and waste disposal ensure a quick resolution of discrepancies and errors. The Chief Security Officer will perform a periodic review of system administrators and responsible personnel to prevent diversion opportunities.

- Audit procedures will ensure a full inventory of marijuana waste at each ERBA Wellness facility, as a minimum requirement.
- Any inventory discrepancies discovered by any employee must be reported to the Chief Cultivation Officer, Vice President of Formulation, or Vice President of Dispensary upon discovery. Any discrepancies discovered during a shift must be resolved before the end of the shift. If they are unable to be resolved, the Chief Security Officer will be notified immediately.
- The Chief Security Officer will report all unresolved inventory discrepancies to the Department of Health and law enforcement authorities as necessary.
- The Chief Security Officer will monitor unresolved inventory discrepancies on a daily basis and will gain approve from the Chief Managing Officer and Vice President of Compliance for the reconciliation entry of any inventory discrepancy.

Damaged Marijuana Products

The Chief Cultivation Officer, Vice President of Formulation, and Vice President of Dispensary in coordination with the Quality Assurance Officer will ensure that marijuana materials or products that have been subjected to improper storage conditions, (due to natural disasters, fires, accidents or equipment failures), are not salvaged and distributed and are disposed of in accordance with the company's waste disposal policies. Improper storage conditions include, but are not limited to, conditions that expose products to:

- Extremes in temperature,
- Humidity,
- Smoke,
- Fumes,
- Pressure,
- Age, or
- Radiation.

The Vice President of Formulation may conduct salvaging operations only if approved by the Quality Assurance Officer and there is documentation including:

- Evidence from laboratory tests and assays that the marijuana or marijuana products meet all applicable standards of identity, strength, quality and purity; and
- Evidence from inspection of the premises that the marijuana or marijuana products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident, if any.

INVENTORY CONTROL SYSTEM

The Chief Security Officer and the Inventory Manager are responsible for developing and implementing operational procedures for inventory management and waste disposal that are in compliance with local regulations and state laws. The Chief Managing Officer will ensure the inventory control system is accurate and capable of producing, upon request, reports on all marijuana and marijuana products stored including waste inventory. All waste, including waste composed of or containing marijuana, will be stored, secured, and managed in accordance with applicable state and local laws and regulations. Additional waste disposal provisions include detailed plans for excess product disposal, liquid, and solid waste disposal based on local ordinance, composting practices, and the disposal of expired, contaminated, or otherwise unusable marijuana and marijuana products.

Discrepancies identified during inventory, including diversion, theft, loss, or criminal activity related to waste will be reported to the Vice President of Compliance, the Chief Security Officer, the Department of Health, and law enforcement as necessary. The Chief Managing Officer will also report any verifiable incident of unauthorized destruction of marijuana and marijuana products internally and externally as needed.

The Chief Managing Officer will ensure the inventory control system is accurate and capable of producing, upon request, reports on all marijuana products stored including waste inventory. The medical marijuana production center will secure all marijuana waste until hauled away by a licensed hazardous waste company. All waste will be recorded in the waste management log and the inventory control system as a disposal. Discrepancies identified during inventory, including diversion, theft, loss, or criminal activity related to waste will be reported to the Vice President of Compliance, the Chief Security Officer, the Department of Health, and law enforcement as necessary.

Inventory records will include the quantity of marijuana materials at each ERBA Wellness facility, including all in-process materials, on a daily basis as outlined in the company’s inventory policies and procedures. Disposal records will include the disposal method used for any marijuana products. All data maintained in the manufacturing management systems will be kept for at least six years after the batch has been distributed. The Quality Assurance Officer will oversee the accuracy and maintenance of all records.

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Inventory Control System

The company's inventory management system will track unusable marijuana (e.g., outdated, damaged, deteriorated, mislabeled, or contaminated) and marijuana waste by weight and RFID or barcode throughout every phase of marijuana production, as well as returns and recalls in the retail phase. Upon destruction, the system will generate a destruction report. The system evidences the lifecycle of every original plant RFID or barcode with an auditable trail to either retail sale or verified destruction.

Recordkeeping

All waste disposed of must be recorded in the waste disposal log including:

- The date of disposal;
- The type and quantity disposed of;
- The manner of disposal; and
- The name of the employee, patient, or caregiver who supplied the waste if applicable.

Excess Product Disposal

Any marijuana material that is not needed for normal, efficient operation in order to serve the projected needs of qualifying patients, or in excess of authorized quantities will be disposed in accordance with waste disposal policies and procedures. The Inventory Manager, in coordination with the Chief Managing Officer, will determine and document the need for excess inventory disposal.

Quality Control of Waste Disposal

The Vice President of Dispensary, in coordination with the Quality Assurance Officer, is responsible for ensuring the quality and safety of marijuana and marijuana products in the dispensing facility's inventory on a daily basis. The Vice President of Dispensary will ensure that expired, contaminated, or otherwise unusable marijuana materials are disposed of in accordance with waste disposal policies and procedures and properly recorded in the inventory control system.

Waste Received from Patients and Caregivers

The company will accept returns, unused, excess, or contaminated marijuana or marijuana products from qualified patients or caregivers, and will manage this waste according to the waste policies and procedures of the company while maintaining a written record in the waste disposal log and the inventory control system, which will include the name of the patient or caregiver, if applicable.

Unauthorized Destruction of Marijuana

The Chief Managing Officer will report any verifiable incident of unauthorized destruction of marijuana to law enforcement as needed. All company employees must report the unauthorized destruction of marijuana to the appropriate supervisor immediately. Unauthorized disposal of marijuana may be cause for termination.

ATTACHMENT 11-1

WASTE DISPOSAL PROCEDURES

Sources

The company has a comprehensive system for systematically collecting and properly destroying all materials containing marijuana. The final material disposal will render both finished product and precursor materials completely unrecoverable beyond reclamation. Routine disposal procedures will include company employees from retail dispensary facilities to securely transport all materials designated for destruction to the medical marijuana production center for compost or medical waste disposal. Controlled waste materials for destruction may originate from several sources:

- Marijuana stems or other unusable plant materials generated at the medical marijuana production center are weighed, labeled and stored in a limited access area until they can be properly destroyed.
- All cannabinoid-containing extracts, concentrates, in-process materials and bulk product that cannot be further processed into approvable packaged product are labeled and held under quarantine in a secure storage area until they can be properly destroyed.
- Packaged product determined to not meet the minimum safety standards and specifications for brand consistency or otherwise rejected by Quality Assurance are held under quarantine in a secure storage area separate from any released products until they can be properly destroyed.
- Packaged medical marijuana products at the retail dispensing facility that become damaged, short dated or were returned by a customer are securely stored at the retail dispensing facility until they can be properly transported to the manufacturing site and securely stored until they can be properly destroyed.
- Any products that were subjected to improper storage conditions including but not limited to extremes in temperature, water damage or smoke due to natural disasters, fires or equipment failures are held under quarantine and securely stored until they can be properly destroyed.

Chain of Custody

A rigorous chain of custody will be maintained to ensure that medical marijuana and marijuana products that have been scheduled for disposal are not released for distribution in compliance with all company policies and procedures. All products waiting for disposal are held in secured quarantine.

Product Security and Recordkeeping

Quarantined waste will be held in storage with full camera coverage until the waste is transferred for disposal. The secure waste container will be properly labeled for disposal and entered into the company's inventory control system with a disposed status. The Chief Cultivation Officer, Vice President of Formulation, and Vice President of Dispensary must ensure all waste container contents are entered in the waste log, properly recorded in the inventory control system as disposed, and the entire container is removed for disposal as often as necessary.

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Disposal Method

All disposed materials will be treated in a manner that renders the medical marijuana material unrecoverable. The company will recycle packaging whenever possible and will salvage any packaging that does not pose any risk of contamination. Once such marijuana waste has been rendered unusable, it may be:

- Disposed of with an appropriately licensed solid waste management facility approved by the Chief Executive Officer; or
- If the material mixed with the marijuana waste is organic material, the mixture may be composted.

All disposed materials will be treated in a manner that renders the medical marijuana product unrecoverable by the medical marijuana production center it is transferred to. The company will recycle packaging whenever possible and will salvage any packaging that does not pose any risk of contamination. Once such marijuana waste has been rendered unusable it may be disposed of with an appropriately licensed hazardous waste management facility approved by the Chief Executive Officer.

Laboratory Waste

The laboratory will dispose of flammable solvents as well as other waste streams with a certified laboratory waste disposal company. To dispose of any leftover marijuana that was not used in the sample analysis process the lab staff will place that marijuana, products, and containers inside a waste disposal drum. The drum at time of disposal will generally contain about 70% liquid lab waste (flammable solvents, etc.) and about 30% solid waste (containers, vials, plates).

All marijuana and marijuana products that are disposed of are rendered unrecognizable and unusable once inside the drum and saturated in solvent. The waste disposal company will be the last person in the chain of custody as drums are incinerated or disposed of in accordance with state and local laboratory waste disposal guidelines.

The company will be aware of what is being disposed of and will also be aware of the hazards associated with the solvents that are inside the drum and follow all flammable/hazardous solvent disposal procedures as mandated by state regulations.

Solvent Waste

ERBA Wellness has elected to use carbon dioxide for its solvent extractions and the Waters supercritical fluid extraction bio-botanical extraction system to control the extraction parameters of the carbon dioxide during the extraction process. The recycling system is capable of reclaiming 90% of the carbon dioxide used during the process cycle. The remaining carbon dioxide will be purged from the extraction area using a fixed exhaust line plumbed to the outside. In this manner the company will greatly reduce

its consumption of carbon dioxide with only generating a minimal amount of waste which is carbon neutral.

Liquid Waste

Liquid waste containing nutrient residues, marijuana, or by-products of marijuana processing shall be disposed of in compliance with requirements for discharge into surface water, groundwater, and sewers, or disposed of in an industrial wastewater holding tank.

Storage and Transport

All marijuana products for disposal will be held under secured quarantine and stored until they can be properly destroyed. All of the marijuana materials and cannabinoid containing products will be transported in a locked and secure storage compartment via a transporting vehicle. All shipments of material designated for destruction shall travel from the retail dispensing facility to the medical marijuana production center for disposal. All transport vehicles will be staffed or accompanied by a minimum of two company employees and at least one employee will remain with the vehicle at all times until all marijuana materials are safely removed from the vehicle.

The company will utilize the services of an environmental waste hauler for laboratory and medical waste, and will compost marijuana plant materials on-site. All waste materials will be consolidated at the medical marijuana production center. The Chief Managing Officer and Vice President of Compliance are responsible for the company's hazardous and controlled substance waste policies and procedures.

WASTE DISPOSAL POLICY

Quality Assurance of Cultivation Waste Material

The Chief Cultivation Officer is responsible for ensuring the quality and safety of marijuana and marijuana products in the medical marijuana production center's inventory on a daily basis. Two or more trained cultivation employees will be responsible for inspection of all crops for any visible foreign matter and sub-standard material. These employees will also perform a visual microscopic and naked-eye inspection of each crop processed to determine:

- Organoleptic characteristics (color, texture and odor);
- Presentation of the material (raw, cut, crushed, compressed);
- The presence of admixtures, foreign matter (sand, glass particles, dirt), mold, or signs of decay;
- The presence of insects; and
- The presence of foreign material originating from poor or degraded containers.

Damaged and/or degraded plant material will be removed and disposed of with Chief Cultivation Officer approval and in accordance with waste disposal policies and procedures. All marijuana waste from cultivation operations will be disposed of in accordance with waste disposal policies and procedures. All other cultivation waste will be stored and disposed of as to:

- Minimize the development of odors;
- Minimize the potential for waste to attract, harbor, or become a breeding place for pests;
- Protect against contamination of marijuana, contact surfaces, water supplies, and grounds surrounding the facility; and
- Control hazardous waste to prevent contamination of marijuana, contact surfaces, water supplies, and grounds surrounding the facility.

Best Management Practices

Best Management Practices are methods or techniques found to be the most effective and practical means in achieving an objective while making the optimum use of the company's resources. The collection of management practices used by the company including USDA Standards, American Pharmacists Association's Good Cultivation Practice, Good Agriculture Practice, and Good Handling Practice are part of the BMP plan. The Chief Cultivation Officer is responsible for the implementation and supervision of BMP protocols regarding energy and waste management including:

1. The Chief Cultivation Officer will establish input-output plans for energy, nutrients, and agrochemicals to ensure efficient use and safe disposal.
2. Energy saving practices, buildings, and machinery will be implemented throughout the operations.
3. The company will recycle organic wastes and inorganic material as allowed by law.
4. The operation will minimize non-usable wastes.
5. All fertilizers and agrochemicals will be securely stored.
6. The company will maintain records of energy use, storage, and disposal.

Design and Operating Procedures to Minimize Waste Odors

During operational times when large quantities of marijuana waste are added to the compost site, the company may include additional odor neutralizing materials including enzymatic catalysts that can be used to degrade odorous compounds. These are normally applied to the surface of the compost windrow or sprayed in the airspace above it. The Chief Managing Officer will verify the effectiveness of the odor neutralizing material added. In addition, oxidizing chemicals such as hydrogen peroxide and potassium permanganate can be used to chemically oxidize anaerobic odors. These chemicals can be effective if incorporated evenly in the windrows and in low concentrations to prevent accidental kill of the aerobic microorganisms.

ATTACHMENT 11-2

Operations Manual		
ERBA Wellness	Policy Name	**Medical Marijuana Waste Management**
	Policy Number	**TBD**
	Date this Version Effective	**TBD**
	Responsible for Content	**Chief Managing Officer**

a. Description

a. This protocol describes the method for the disposing of medical marijuana and medical marijuana products at all ERBA Wellness facilities.

b. Rationale/Purpose

a. This document is designed to provide a formal outline of the procedures ERBA Wellness shall follow to ensure appropriate disposal of medical marijuana and medical marijuana products.

c. Responsibilities

a. It is the responsibility of all employees to follow the requirements of this standard operating procedure
b. It is the responsibility of the Chief Managing Officer to ensure all product is disposed of in compliance with this standard operating procedure.

d. Policy and Procedure

a. Policy
    i. Whenever possible, medical marijuana should be returned to the medical marijuana production center for disposal through composting.
    ii. All product awaiting disposal that cannot be sent to the medical marijuana production center will be disposed of in the dispensary.
    iii. Disposal procedures require two employees to perform all disposal in plain view of surveillance cameras. Any employee found to be improperly disposing of medical marijuana is subject to termination.
b. Procedure
    i. Any cannabis waste must be labeled as such with a brightly colored waste label to ensure it is immediately recognizable as waste. When the marijuana or marijuana product is labeled as waste it must be updated in the inventory management system to indicate it is awaiting disposal.
    ii. Waste is stored in a segregated section of the secure storage vault to ensure it does not contaminate any other product. The vault has an attached Waste Disposal Log which must be updated each time a product is added to indicate the product awaiting disposal, the person who added the waste, the reason for disposing of the product, and the date and time it was added to waste storage.
    iii. If waste is stored at the dispensary, it must be transported to the medical marijuana production center for disposal. Two agents must remove and catalog all product in the waste storage section and prepare the waste for shipment.

1. Shipping
    a. Physically count the inventory and compare to the Waste Disposal Log. Any discrepancies must be immediately reported to security.
    b. Update inventory to indicate the product is in transit and create a shipping manifest.
    c. Package the waste for transportation and schedule the delivery.
2. Receiving
    a. Once the shipment arrives at the medical marijuana production center, two agents must accept custody of the shipment and compare the contents to the shipping manifest. If there is any discrepancy security must be notified immediately.
    b. If all products are accounted for, the inventory management system is updated to reflect the current location of the product.
    c. This waste is then stored in the secure storage vault at the medical marijuana production center until it is ready for destruction.

iv. Two dispensary agents must remove the product from the secure storage vault and update the products removal in the inventory management system.
v. All medical marijuana must be ground and then mixed with composting material which makes the marijuana unusable beyond recovery.
vi. The destroyed waste is then placed in the compost bin which is locked to prevent unauthorized access.
vii. The Waste Disposal Log and the inventory management system is updated with information regarding each product disposed of, the reason for disposal, agents performing the disposal, and the date and time the action was performed.

e. Review/Revision

Date	Description of the Revision	Approved

ATTACHMENT 11-3

ERBA WELLNESS WASTE DISPOSAL LOG

Facility:	**Vault Number:**
Dates:	**Responsible Manager:**

Adding or Removing?	Product Type	Batch	Quantity	Method of Disposal	Reason for Disposal	Date/Time	Name and Title of Agents

All cultivation and manufacturing operations will comply with state and county health, safety, and sanitation regulations to ensure the highest quality product for patients. This includes establishing procedures for the adequate maintenance and sanitization of all equipment and utensils used in the cultivation and manufacture of marijuana products, as well as the development of quality control and quality assurance plans that include: plans to detect, identify and prevent dispensing errors; policies and procedures to document and investigate approved medical marijuana finished product returns, complaints (Attachment 12-1) and adverse events (Attachment 12-2), and to provide for proactive, rapid voluntary or involuntary recalls (Attachment 12-3) of any lot of medical marijuana finished product where recall is indicated. These policies and procedures shall include: a plan for any retesting of returned approved medical marijuana finished products, a plan for storage and disposal of medical marijuana and any manufactured medical marijuana-infused products not passing requirements, and a plan that ensures that all adverse events and total recalls are reported to the Department within twenty-four (24) hours of their occurrence; and a plan to track contamination incidents and document the investigated source of such incidents, as well as the appropriate corrective action(s) taken. Additionally, the company will exclusively utilize supercritical fluid extraction via carbon dioxide to minimize the potential health and safety risks associated with the use of hazardous solvents, like hydrocarbons, in the manufacturing process and exposure of these solvents to employees and facility, but most importantly to minimize the potential health and safety risks to patients. Supercritical fluid extraction and simple refinement techniques in conjunction with the company's maintenance, sanitization, quality control and quality assurance procedures will allow the company to quickly become operational, ensuring ERBA Wellness can effectively meet

Oahu's anticipated medical marijuana patient demand, while also minimizing exposure to hazardous chemicals, as well as other contaminants, and maximizing product safety.

In order to ensure the safety of patients, all packaging has been carefully selected to protect the marijuana or marijuana product from contamination without imparting any toxic or harmful substance to the product. This includes child resistant, opaque packaging that meets all labeling requirements outlined in Haw. Rev. Stat. § 329D-11 (2015) as well as packaging that has a proven track record of safety in pharmaceutical manufacturing. In the case of manufactured products, all products will be packaged with a 10 mg THC dose per serving and a maximum of 100 mg THC per package so as to protect patient safety and prevent potential overconsumption.

LABORATORY TESTING

Prior to any dried marijuana flower or manufactured marijuana product being released for sale, the batch must be held in quarantine until a certificate of analysis demonstrating compliance with regulatory testing limits is obtained from a certified laboratory. This certificate must include all tests required by H.A.R. §11-850-85 (2015). Any marijuana or marijuana product that does not meet regulatory requirements and internal quality control requirements will be removed from inventory and destroyed according to the company's disposal SOPs.

Product which passes testing will be released from quarantine and made available for sale. All test results will be imported into the inventory management system, BioTrackTHC, where they will be available for review by patients, caregivers, dispensary staff, and the Department. ERBA Wellness believes this transparency will allow patients to make informed decisions about their medicine and help protect patient safety. Test results will be retained indefinitely with quarterly reports being sent to the Department in accordance with regulations.

POLICIES AND PROCEDURES

ERBA Wellness will develop detailed written quality assurance and quality control policies and procedures for all aspects of the handling and production of marijuana in order to ensure the product is safe and free of contamination. This includes detailed employee training programs, along with annual training on health, safety, and sanitation standards, as well as procedures for how to safely and appropriately store and dispose of marijuana and constituent materials at all stages of production and sale. Employees must be trained on the safe use of each piece of equipment needed to perform job functions prior to beginning work.

Employees are trained to maintain strict personal hygiene in order to ensure the cleanliness and safety of products similar to protocols suggested by OSHA and the FDA. This includes frequent hand washing, and not reporting to work when sick or infected with any condition that may affect product quality, such as open lesions including boils, sores, or infected wounds. Any supervisor who notices/suspects an employee is ill must send the employee home immediately with instructions not to return to work until they have fully recovered. Similarly, employees must ensure that only authorized members of staff physically handle marijuana and marijuana products. Patients and caregivers may not touch any marijuana until the purchase is finalized. Additionally, no animals other than service animals are allowed inside the dispensary facility. This policy will ensure product remains contaminant free and is safe for patient use.

The retail dispensary and all fixtures will be kept clean and in good repair with adequate lighting. All toxic cleaning compounds, sanitizing agents, and pest control measures such as bait traps, will be used in a way that protects against contamination of marijuana or products in a manner that is in accordance with any applicable local, state or federal law, rule, regulation or ordinance. The dispensary will have adequate screening or other protection against the entry of

pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.

Recall Procedures

The CEO will determine the need to execute a withdrawal or recall of any marijuana, marijuana product, paraphernalia, or other product distributed by the company in order to protect patient health from products that present a risk of injury or gross deception, or otherwise are defective. There are two levels of product recall: recall and withdrawal. A recall is generally undertaken to protect customer health and safety. A withdrawal, however, is generally conducted for quality purposes or as a precautionary measure before an official recall is implemented. In the event of a recall, the company will notify the Department immediately and the Chief Managing Officer (CMO) will determine if a press release will be issued.

The following examples would constitute an incident requiring a withdrawal or recall:

1. Product found with a pesticide residue from an illegal/restricted chemical.
2. Product found with a level of pesticide residue that exceeds permitted legal limits.
3. Known, assumed or suspected product contamination by chemical, physical or microbiological hazards.
    a. E.g. - Microbiological hazard is blood contamination or microbial growth.
    b. E.g. - Physical contaminants include plastic, glass, wood, metal and pests.
4. Incorrect labeling, which constitutea a breach in food safety, quality or legality standards.
5. Notification from a supplier that any of the above had occurred to constituents prior to supply.
6. Widespread failure of a paraphernalia product.
7. Malicious contamination.

The CEO will assign a withdrawal or recall event to one of the following classes:

Class 1: A situation involving removal from of products in which the consequences of use or exposure are life threatening or involve a serious adverse health consequence;

Class 2: A situation in which the use of, or exposure to, a contaminated product will cause temporary adverse health consequences or where the probability of serious adverse health consequence is remote or

Class 3: A situation in which the use of, or exposure to, the product is not likely to cause adverse health consequences (for example a non-hazardous labeling violation).

Execution of a Withdrawal or Recall

If the CEO determines the product complaint is valid, the following steps will be taken:

1. Stop distribution of the affected product;
2. Effectively notify all employees, management personnel, and the Department;
3. Remove the affected product from the market as efficiently as possible;
4. Remove the affected product from all storage, processing and sales areas;
5. Dispose of the affected product in accordance with waste management SOPs; and
6. Conduct a root cause analysis.

Mock withdrawal and recall drills required

Mock recalls are used to determine whether the withdrawal and recall procedure is capable of identifying and quickly controlling a batch of potentially affected product and reconciling the quantities produced, quantities in inventory, and quantities distributed. A mock withdrawal or recall will identify potential problems and allow employees to become familiar with recall procedures. If problems are identified in the procedures, they will be corrected by the department directors and employees will be retrained on new procedures.

ATTACHMENTS

The following documents will serve as supplemental information to the Department of Health, for the review of the ERBA Wellness Dispensary Application. These documents are intended to show competency and preparedness of the ERBA Wellness team and to highlight areas of particular importance.

Attachment Summary:

12-1. Standard Operating Procedure – Investigation of Marijuana Product Adverse Events
12-2. Standard Operating Procedure – Investigation of Marijuana Product Complaints
12-3. Standard Operating Procedure – Complaints and Recall Plan

ATTACHMENT 12-1

Dispensary Manual		
ERBA Wellness	Policy Name	**Investigation of Marijuana Product Adverse Events**
	Policy Number	**TBD**
	Date this Version Effective	**TBD**
	Responsible for Content	**Chief Medical Officer**

I. Description

a. This Standard Operating Procedure describes the investigation procedures for marijuana product adverse events.

II. Rationale/Purpose

a. It is corporate policy to thoroughly investigate all marijuana product adverse medical events and promptly report all required adverse events to the Department of Health within the timelines specified by department regulations.

III. Responsibilities

a. The Chief Medical Officer will oversee policy compliance for personnel under his or her supervision.
b. All company employees will adhere to the policies and SOPs in this manual.
c. It is the responsibility of the Chief Medical Officer to accurately document and submit all reportable incidents as specified in this Standard Operating Procedure.
d. It is the responsibility of the Chief Compliance Officer to assure the timely submission of adverse medical events and any other required information to the Department of Health.

IV. Definitions

a. Adverse medical experience - any adverse event associated with the use of a marijuana product, whether or not considered marijuana related, including events occurring during routine product usage, including product abuse, overdose, withdrawal or any failure of expected pharmacological action.
b. Disability - substantial disruption of a person's ability to conduct normal life functions.
c. Life-threatening adverse medical experience - any adverse medical experience that places the patient, at immediate risk of death from the adverse medical experience as it occurs.
d. Serious adverse medical experience - any adverse experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse medical experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly (birth defect).
e. Unexpected adverse medical experience - any adverse medical experience not listed in the current labeling or patient insert for the marijuana product. This

includes events that may be symptomatically related to a listed event, but differs from the event because of greater severity or specificity.

V. Policy and Procedure

a. Policy
   i. The Chief Medical Officer shall promptly investigate all Adverse Medical Experiences and shall submit a report to the Department of Health as soon as possible.
   ii. Product investigations of Adverse Medical Experiences shall utilize sound scientific principles based upon the nature of the medical experience and whenever appropriate include retesting of any suspect product
   iii. The above reports submitted to the Department of Health should maintain patient privacy thus not disclosing patient names or addresses. These reports should include the name of the reporter from whom the information was received.
   iv. The Chief Medical Officer shall maintain for six (6) years all records involving adverse medical experiences including any reports, correspondence and follow-up required by this Standard Operating Procedure. Copies shall be made available to the Department of Health upon request.

b. Procedure
   i. Customer complaints involving an adverse medical experience may be received in writing, via mail, E-mail or over the telephone. All complaints are immediately forwarded to the Chief Medical Officer.
   ii. All customer complaints for marijuana products will be evaluated to determine if they meet the preceding definition for an Adverse Medical Experience (#1).
   iii. Every effort should be made to obtain any remaining portion of the original complaint product involving an adverse medical experience for examination. Any available original complaint product should be returned to the dispensing facility and subsequently forwarded to the manufacturing site for evaluation and testing.
   iv. Product Marijuana product complaints involving either a Serious (#4) or Unexpected (#5) Adverse Medical Experience, see previous definitions, must be reported to the Department of Health within 24 hours of their occurrence and receipt of the complaint.

VI. Review/Revision

Date	Description of the Revision	Approved

ATTACHMENT 12-2

Dispensary Manual		
ERBA Wellness	Policy Name	**Investigation of Marijuana Product Complaints**
	Policy Number	**TBD**
	Date this Version Effective	**TBD**
	Responsible for Content	**Vice President of Dispensary**

I. Description

a. This Standard Operating Procedure describes the investigative procedure for marijuana product complaints.

II. Rationale/Purpose

a. It is corporate policy to handle all product complaints by patients, their designated caregivers, physicians or other medical personnel in a prompt, courteous and professional manner.

III. Responsibilities

a. The Vice President of Dispensary will oversee policy compliance for personnel under his or her supervision.
b. All company employees will adhere to the policies and SOPs in this manual.
c. It is the responsibility of all company employees to report any product complaints they become aware of and forward all potential complaints to the Vice President of Dispensary for appropriate follow up and investigation.
d. It is the responsibility of the Vice President of Dispensary to accurately document all aspects of each individual product complaint, appropriately investigate and report these incidents.
e. It is the responsibility of the Chief Medical Officer to oversee the complaint investigation requirements of this Standard Operating Procedure and to assure the timely reporting of any adverse medical events to the Department of Health.

IV. Policy and Procedure

a. Policy
    i. Personal protective equipment including safety glasses, lab coats, and gloves should be used.
    ii. Product complaints may be received in writing (via mail or Email) and over the telephone. Upon receipt, all written complaints will be immediately forwarded to the Vice President of Dispensary. Company employees receiving a product complaint via the telephone shall either forward the call to the Vice President of Dispensary or record the customer's name, address, phone number, product name, lot number (if available), product complaint and then inform the customer that the responsible individual will be calling them to address this situation. Customer service employees will record this complaint information using a Product Complaint Record (see attachment 1) and immediately forward it to the Vice President of Dispensary.

iii. The Vice President of Dispensary shall assign a sequential complaint number to all product complaints upon receipt and enter the complaint in the annual Product Complaint Log.
iv. All product complaints shall be acknowledged by the Vice President of Dispensary within 1 working day of receipt and promptly investigated.

b. Procedure
   i. All product complaint investigations will, at a minimum, include the following information:
      1. The date the complaint was received
      2. Whether it was received by phone call or written
      3. The original customer complaint correspondence (if received in writing)
      4. The name, address and phone number or email address of the complainant
      5. The product's name, strength and lot number (if available)
      6. The nature of the complaint
      7. The name of the individual who received and documented the complaint.
      8. The sequential number assigned by the Vice President of Dispensary for each complaint
      9. Appropriate complaint investigation and follow-up
      10. The manner in which the complaint was resolved with the name and date of the company representative making that determination.
   ii. Based upon the nature of the complaint and individual product characteristics the Vice President of Dispensary's investigation of these reported incidents shall include:
      1. Examination of retained samples from the same product and lot number.
      2. The utilization of sound scientific principles based upon the nature of the product complaint and where appropriate include retesting product according to its written finished product or packaging specifications.
      3. Obtaining the original complaint product back from the customer for examination.
      4. If available and necessary for a thorough investigation, any remaining complaint product should be returned to the dispensing facility and subsequently forwarded to the manufacturing site for evaluation or testing.
      5. Review of the product manufacturing records with production to identify possible cause(s) of the product complaint and potential Corrective or Preventive Actions (CAPA) by production to minimize the possibility of future product defects.

iii. All interim contacts or correspondence with the complainant and product manufacturing reviews will be noted on the Product Complaint Record or an attachment.
iv. Upon completion of this investigation or other resolution of the complaint, the complainant will be notified in writing.
v. A written evaluation on all complaints will be completed at least once per year. This evaluation will include a per lot tabulation of the frequency of complaints for each product and a comparison to the previous year. Adverse trends in the frequency of product complaints will be evaluated for potential Corrective or Preventive Action (CAPA).
vi. All files regarding product complaints shall be maintained by the Vice President of Dispensary department for a minimum of six (6) years after the date that the complaint was received. Copies shall be made available to the Department of Health upon request.

V. Review/Revision

Date	Description of the Revision	Approved

ATTACHMENT 12-2

PRODUCT COMPLAINT RECORD

DATE:_____ □ Written □ Phone Call

Customer Name: _____

Address: _____

_____

Phone No. _____

Product Name/Strength: _____

Lot No. _____(if available)

Complaint: _____

_____

Complaint Taken By: _____

COMPLAINT INVESTIGATION #_____

RESOLUTION OR DISPOSITION

Completed By:

ATTACHMENT 12-3

COMPLAINTS, DISPENSING ERRORS AND RECALLS

Procedures for handling all complaints are detailed in this Complaint and Product Recall Plan. Basic protocols for dispensing errors and near misses are outlined. The complaint procedures section covers complaint classifications, management responsibilities, and steps for investigation and resolution. Voluntary and mandatory recalls of marijuana are detailed with procedures for addressing customer complaints and incidents requiring product withdrawal or recall. Following the incident classification scheme and the associated definitions, the term "recall" will only be used when the situation mandates. Examples of incidents to be addressed with recall or withdrawal procedures are provided, and measures for required mock withdrawal and recall drills are detailed.

Provisions include plans for tracking affected products in the event of contamination and for the establishment of a Withdrawal and Recall Team, which will be responsible for executing and coordinating all aspects of a withdrawal or product recall. The Withdrawal and Recall Team contact sheet must be established and will be maintained and updated quarterly by the Chief Executive Officer. In the instance of a product recall, the Department of Health of Health will be notified immediately.

COMPLAINT PROCEDURES

COMPLAINT CLASSIFICATION

All complaints must be categorized by the department manager as a product complaint or other complaint. Other complaints may include, but are not limited to neighborhood related issues, service related issues, employee-related issues or other operational related issues. The department manager must respond to any complainant relating any issue other than product related issues within twenty-four hours. If the department manager cannot fully resolve the issue, the Chief Managing Officer must be notified, and the Chief Managing Officer shall determine the appropriate course of action. It is ERBA Wellness policy to make a good faith effort to resolve any complaint, whether legitimate or frivolous whenever possible.

COMPLAINT HANDLING

All employees are responsible for documenting any complaint received from another employee, another dispensary, a patient or caregiver or any other party. An employee may receive a complaint in person, by phone or email. The employee receiving the complaint must notify the appropriate department manager immediately. All employees will be trained by their department manager to handle complaints including verbal de-escalation techniques and investigative questioning.

INVESTIGATION OF A PRODUCT COMPLAINT

Once notification of a product complaint has been received, it is the responsibility of the department manager in coordination with the Chief Managing Officer to begin accurate and detailed documentation and product tracking. The Chief Managing Officer must:

1. Gather information from complainant about the nature of the dispensing error or product complaint.
2. Assemble the personnel or experts needed to conduct a product complaint investigation.
3. Conduct a thorough investigation into the complaint.
4. Determine the nature and potential causes of the problem.
5. Determine any other product(s) that may potentially be affected.
6. Determine the appropriate action and document all actions taken:

a. Product Recall: Food Safety or Health Risk due to physical, chemical, biological or immunological.
b. Product Withdrawal: a quality related issue with the affected product(s).
c. No Corrective Actions: an isolated incident with the affected product(s).

CLASSIFICATION OF A WITHDRAWAL OR RECALL EVENT

CLASSIFICATION OF A WITHDRAWAL OR RECALL

The classification of a recall typically involves the presence of bacteria or a substance that may cause a potential allergic reaction. The term "recall" can have legal significance, insurance, and liability implications. The term should be used carefully and only when regulations mandate. Otherwise, the term withdrawal should be used.

DETERMINING THE NEED FOR A RECALL OR WITHDRAWAL

The Chief Managing Officer is responsible for determining the need for a product withdrawal or recall after investigation of the complaint.

1. There are two levels of product recall: recall and withdrawal. A recall is generally undertaken to protect customer health and safety. A withdrawal, however, is generally conducted for quality purposes or as a precautionary measure before an official recall is implemented.
2. In the event of a recall, ERBA Wellness must notify the Department of Health immediately and the Chief Executive Officer will determine if a press release should be issued. In some cases, a press release and Department of Health notification may not be warranted in the event of a withdrawal (i.e. a defective paraphernalia recall).
3. The Chief Managing Officer must begin execution of a withdrawal or recall immediately upon determination of need or in the event of a request or mandate from any regulatory body with authority to do so.
4. The Chief Managing Officer must determine the need to execute a withdrawal or recall of any marijuana, marijuana product, or other product distributed by the ERBA Wellness in order to protect patient health from products that present a risk of injury or gross deception, or otherwise are defective.
5. If the Chief Managing Officer is unsure of the need for withdrawal or recall or of the correct event classification, the Chief Executive Officer must be contacted immediately for a decision. The Chief Executive Officer may engage the services of an expert to assist the process.
6. The Chief Managing Officer must notify the insurance company and determine if any coverage for the incident is available. If the event is covered, the Chief Managing Officer must file all documentation necessary after the completion of withdrawal or recall activities.
7. The Chief Managing Officer must notify legal counsel and maintain communication with counsel throughout the withdrawal or recall procedures. Any recommendations by counsel for alternative procedures must be approved by the Chief Executive Officer.

VERIFICATION REQUIRED FOR RECALL PROCEDURES

Any determination by the Chief Managing Officer to implement recall procedures must be supported by test results or other scientific documentation or expert opinion. An assessment should be done to determine the procedures to implement. The following points must be considered:

1. Whether or not any disease or injuries have already occurred from the use of the product.

2. Assessment of hazard to various segments of the population, e.g., immune compromised customers, surgical customers etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
3. Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.
4. Assessment of the likelihood of occurrence of hazard.

CLASS OF WITHDRAWAL OR RECALL EVENT

The Chief Managing Officer must assign a withdrawal or recall event to one of the following classes:

1. Class 1: When there is an emergency situation involving removal from the market of products in which the consequences of use or exposure to the product are life threatening or involve a serious adverse health consequence;
2. Class 2: When there is a situation in which the use of, or exposure to, a contaminated product may cause temporary adverse health consequences or where the probability of serious adverse health consequence is remote (for example, pathogenic bacterial population, exclusive of C. botulinum, adequate to cause food poisoning); or
3. Class 3: When there is a situation in which the use of, or exposure to, the product is not likely to cause adverse health consequences (for example a non-hazardous labeling violation).

EXECUTING A WITHDRAWAL OR RECALL EVENT

EXECUTING A WITHDRAWAL OR PRODUCT RECALL

If the Chief Managing Officer determines the product complaint is valid, the following steps must be taken immediately:

1. Stop distribution of the affected product;
2. Effectively notify all employees, management, patients, caregivers, and the Department of Health of the withdrawal or recall;
3. Remove the affected product from the market as efficiently as possible;
4. Remove the affected product from all storage, processing and sales areas;
5. Dispose of the affected product in accordance with waste management policies;
6. Conduct a root cause analysis and report the effectiveness and outcome of the withdrawal or recall; and
7. Conduct a post recall meeting with all necessary parties for evaluation.

WITHDRAWAL AND RECALL PROCEDURES

1. Gather all information collected in the tracking process.
2. Detain and segregate all products to be withdrawn or recalled which are in the control of ERBA Wellness.
3. Adhere a “DO NOT DISTRIBUTE” sign and complete the Withdrawal and Recall Log component of the Incident Log.
4. Send a Notification of Recall to the affected parties.
5. Notify the Department of Health immediately.
6. Ensure the following information is accurately documented:
    a. Name and batch number of the withdraw/recalled product(s).

   b. Production date(s) of the withdraw/recalled product(s).
   c. Reason for the withdrawal/recall.
   d. Quantity of withdraw/recalled product(s) distributed.
   e. Quantity of withdraw/recalled product(s) in inventory.
   f. Area(s) of distribution and customers affected.
7. Coordinate and monitor the recovery of all affected product(s).
8. Conduct a reconciliation of the total quantity of recalled product and affected product in inventory against the total quantity produced.
9. Randomly remove and submit samples of recalled product(s) to an independent laboratory for testing as appropriate.
10. Collect testing results and discuss the results and corrective actions that may be required with the Department of Health.
11. The Chief Managing Officer must prepare a Withdrawal and Recall Report.

WITHDRAWAL AND RECALL TRAINING AND PLANNING

TRAINING AND MOCK WITHDRAWAL AND RECALL DRILLS REQUIRED

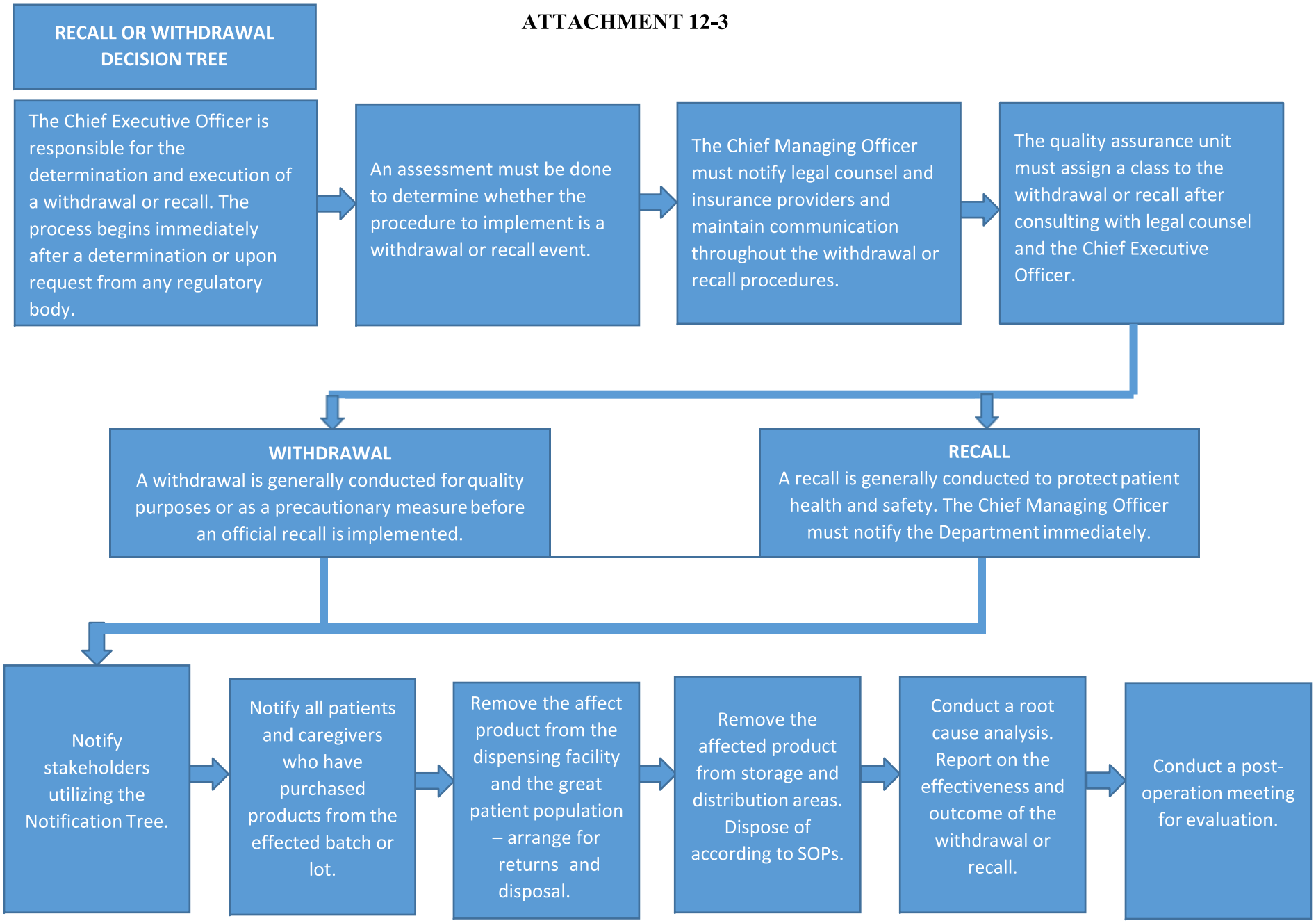
The Chief Managing Officer must implement all necessary withdrawal and recall training for all employees including mock recalls. Mock recalls are used to determine whether the withdrawal and recall procedure is capable of identifying and quickly controlling a batch of potentially affected product and reconciling the quantities produced, quantities in inventory, and quantities distributed. A mock withdrawal or recall will identify potential problems and allow employees to become familiar with recall procedures. If problems are identified in the procedures, they must be corrected by the Chief Managing Officer and employees must be retrained on new procedures.

DRILL PROCEDURES

The Chief Managing Officer must carry out mock withdrawal or recall procedures at least annually by randomly selecting at least two items including marijuana, marijuana products or other accessory products.

1. The mock procedures should follow all regular procedures; however, no product should be retrieved from patients or caregivers or removed from inventory or storage.
2. All parties involved in a mock withdrawal must be notified immediately that it is a mock procedure.
3. The mock recall file should include the name, address, and telephone number of clients for the lot tested, production records and the processing, inventory and distribution history of each lot involved.
4. All recommended corrective actions and deficiencies must be documented in a mock withdrawal and recall report to be submitted to the Chief Executive Officer.
5. Any corrective actions or deficiencies must be corrected by the Chief Managing Officer and all employees must be re-trained on new procedure.

ATTACHMENT 12-3



None of the ERBA Wellness' owners have any history of having a business or professional license revoked. ERBA Wellness is majority owned by the individuals outlined below. Through their cumulative businesses, the owners have held multiple licenses ranging from liquor licenses issued by the State of Hawaii to professional licenses issued by the Federal Government.

Dave Ung is a Founder of the District Nightclub & Lounge and serves as the company President. He is responsible for analyzing liquor laws to maintain compliance, development of inventory control, and directing the budget and financials. This business is in good standing, still in operation, and holds an active liquor license. Ung was also a Founder of Vice Inferno Brewery as well as President. In addition to the budgetary and liquor law compliance responsibilities noted above, this required accurate reporting for Federal and State brewery licenses with the Alcohol and Tobacco Tax and Trade Bureau as well as the Honolulu Liquor Commission. The Brewery licenses have much stricter requirements for compliance than liquor licenses and are still held by Ung in good standing with no licenses ever revoked.

Dr. Mel Chiogioji (RADM, USN (ret)) is the Founder of MELE Associates, a private multi-specialty contracting firm with over 150 employees and offices in Maryland, Virginia, Washington D.C., and Hawaii. This business is in good standing and still in operation with no licenses ever revoked.

Fred Lau has forty years' experience owning and operating nurseries and agricultural centers in the State of Hawaii. He currently owns or operates four companies in Hawaii; Hawaiian Landscape Co. Inc., Hawaii Landscape Maintenance Co. LLC, Makakilo Nursery LLC, and Mari's Gardens LLC, with over 100 employees. The nurseries are a combined 195 acres that provide wholesale and retail plants. All of these businesses are in good standing and have never had any license revoked.

Robert King has been the Founder and President of Pacific Biodiesel Technologies, LLC as well as two subsidiaries, for the previous 21 years. He also manages two additional biodiesel refinery companies in Oregon and Texas. He has owned his own businesses for over 35 years, none of which has ever had a business license revoked.

Mark Wu founded Bridge International LLC, which offers product distribution, sales brokering, marketing and consultation services. This business is in good standing and still in operation and has never had a license revoked.

Kazuya Lathrop founded La-Yama LLC, which manages online retail sales, consignment and wholesale of consumer electronics. This business is in good standing and still in operation and has never had a license revoked.

Brendon Lau currently owns a Mini-Mart with 6 employees. This business has held a liquor license for 3 years and is in compliance. This business has never had a license revoked.

Daniel Chong is currently employed as a Realtor® where he assists in negotiations, drafts contracts, and prepares statements, deeds and leases. He has had a realtor's license for three years and it is in good standing and has never been revoked.

In summary, no member of the ERBA Wellness team has ever had a business or professional license revoked and all of the current business and professional licenses are in good standing.