

August 20, 2009

Greeting:

It is with solemn respect that I address this court in Japan. I am fully aware of the longstanding ban on the use of cannabis in Japan since American General Douglas MacArthur and his colleagues rewrote the Japanese constitution in 1948. It was then that the many thousands of years of history of the Japanese use of cannabis came to a close – Taima Torishimaru Ho, the Cannabis Control Act was enacted. Sadly, the foundation of General MacArthur's ban on cannabis was based upon flawed information. In reality the use of cannabis in the United States of America had been with great medical benefit to the American society for 60 years. Park Davis, Eli Lilly, Sharp and Dohme, and Wyeth were among the drug companies all making prescription cannabis pharmaceuticals that were effective treatments for a wide variety of ailments at that time. In 1937 in a well orchestrated vilification of cannabis, then dubbed "marijuana" by Harry J. Anslinger, Assistant Prohibition Commissioner in the Bureau of Prohibition, before being appointed as the first Commissioner of the Treasury Department's Federal Bureau of Narcotics on 08-12-30, along with the Hearst Newspaper Company making unfounded claims of violence and insanity associated with "marijuana" use, the Stamp Act was passed rendering cannabis unavailable despite the objections of the American Medical Association. In the United States by the federal Bureau of Narcotics later to become the Drug Enforcement Agency, as in Japan, by the US occupying forces after World War II, most the use of cannabis in the culture was suppressed and banned so that most Japanese may not realize that "marijuana" is the same plant as cannabis, which was once a prominent and revered part of Japanese culture.

My experience in addressing the court comes from my over 40 years studying cannabis and the English language cannabis research and literature beginning before I entered the Brown University Program in Medicine in 1970. I am a graduate of the University of California, Berkeley, Bachelor of Arts program in 1970, and a graduate of the Brown University Program in Medicine in 1975. I began in the general practice of medicine in 1976 after completing an internship at the University of South Carolina in Spartanburg, South Carolina from 1975-1976. A year later I became a rural general practitioner of medicine in Tennessee where I provided medical care to the residents of a small community and a neighboring Amish religious community. I also began regular work in a regional medical center in central Tennessee at the Maury County Hospital. In the next 5 years of medical practice, I was mentored by John O. Williams, MD, then President of the Tennessee Academy of Family Physicians.

I have referenced these early years of my practice as it was a unique time and experience in America. Under the Nixon administration the U.S. had recently developed the Controlled Substances Act of 1970 that effectively banned the use of herbal cannabis in the United States. Cannabis was however a folk medicine frequently used in the rural Tennessee communities where I lived, despite the government prohibition. I became aware of the many uses of cannabis by the uses described by my patients. I was in a position to observe the use of cannabis, and, come to my own conclusions about the risks and benefits of cannabis use.

In 1982 I brought my family to California to be closer to my aging parents and relatives. I continued as an emergency physician in California from 1982 until 2002, along with a general practice of medicine. In 1996 the State of California passed what was titled the Compassionate Use Act of 1996, a law that allowed Californians to use cannabis. The law was designed to allow people with serious medical problems the opportunity to use cannabis when approved by

their physician. This law came into effect in 1996 by an overwhelming vote by the people of California, despite the ongoing Federal ban on the use of cannabis. From this time on I was legally able to use my clinical expertise in the uses of cannabis within the legal framework of California law. I made a transition from a practice of emergency medicine to a practice of cannabis consultations for people with serious illnesses.

For the past 10 years I have been in the medical practice of evaluating and treating these people with serious medical conditions with cannabis. This is not to the exclusion of conventional medical therapy but as an adjunct to existing therapy. Despite a challenge from the executive branch of the federal government to stop this practice in California, the United States Supreme Court allowed a lower court decision to stand allowing the California physicians the right to speak freely to their patients about the use of cannabis and further to recommend cannabis for these serious medical conditions.

This medical practice of cannabis consulting has lead my medical career into a deeper understanding of cannabis therapeutics based in the evolving field of cannabinoid science. In addition to my ongoing clinical experiences in the use of herbal cannabis for a wide variety of medical conditions I have augmented my training with membership in several scientific organizations. I am a member of the International Cannabinoid Research Society, the ICRS, to which I have presented papers since 2002 about the use of cannabis in clinical practice. The ICRS is a scientific organization that has been meeting for 19 years to reveal the latest discoveries in cannabinoid science. The Society is primarily made up of research scientists from the University based laboratories, representatives from the U.S. National Institutes of Health, (NIH), the National Institute of Drug Abuse, (NIDA), and many pharmaceutical companies from all around the world, Japan included. Typically, 100-150 research laboratories from about 25 nations around the world attend these annual conferences to reveal their new findings of the physiology, pharmacology, and pathology of the cannabinoid system. One could project that the goal of research by the pharmaceutical scientists is to develop single molecule drugs, in a western model of therapy, that would replace herbal cannabis as the therapeutic agent for the many conditions that are benefited by cannabis. To date there is only synthetic THC, tetrahydrocannabinol, available in the United States, and it does not enjoy acceptance by the cannabis using patients as a satisfactory substitute for the natural plant.

I am also a member of the International Association for Cannabis as Medicine, IACM, based in Germany. At this Association conference in 2005 at the Leiden University in the Netherlands, I presented my pilot study on the effect of cannabis in Crohn's disease. Collaborating with a larger group of physicians I have nearly completed a larger study of Crohn's disease and ulcerative colitis patients that I will be publishing later this year. A third organization that I belong to is the National Clinical Conference on Cannabis Therapeutics, commonly called the Patients Out of Time Conference. This organization holds a biennial conference in the United States sponsored by the University of California San Francisco School of Medicine for continuing medical education credits for attending physicians and nurses. I also presented my Crohn's disease pilot study findings to this conference in 2006.

In an effort to inform and educate physicians about the role of the human endocannabinoid system and the clinical applications of cannabis, I have participated as a founding member of and now president of the California Cannabis Research Medical Group, or the CCRMG. Founded in 1999 this society of physicians and health care providers collaborates on clinical research projects. One of the primary missions of this medical group is to organize presentations at schools and hospitals in an effort to provide up-to-date information to physicians and the public about the clinical applications of cannabis. Because of the fact that the federal government refuses to recognize the medicinal value of cannabis it has been very helpful to the doctors and the public to understand the legal boundaries in which cannabis can be utilized for medicinal use in the United States. Scores of physicians are

members of the California Cannabis Research Medical Group – they have approved the use of cannabis for numerous serious medical conditions in approximately 70,000 patients in California. Several of these CCRMG physicians have participated in my Crohn's disease project by bringing their own patients into the study.

In the United States at this time the medicinal use of cannabis is legal in 13 states, and it has been accepted as a defense when deemed to be a medical necessity in the State of Maryland. The states where it has been legalized include California, Hawaii, Alaska, Washington, Oregon, Nevada, New Mexico, Colorado, Montana, Michigan, Vermont, Maine, and Rhode Island. In all of these states the laws have been changed to allow for the use, possession and cultivation of varying numbers of cannabis plants and quantities of dried flowering tops of the female cannabis plant. Each state has a slightly different set of qualifying conditions, five of which explicitly name Crohn's Disease as a qualifying condition, and one, California, implicitly includes Crohn's Disease. Cannabis has been decriminalized in several other states, and legislation is pending in many states at this time to legalize either the adult use or the medicinal use of cannabis.

The first state to approve the medicinal use of cannabis was California on 11-06-96. The ballot initiative removed state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess a "written or oral recommendation" from their physician that he or she "would benefit from medical marijuana." Patients diagnosed with any debilitating illness where the medical use of marijuana has been "deemed appropriate and has been recommended by a physician" are afforded legal protection under this act. Conditions typically covered by the law include but are not limited to: arthritis; cachexia; cancer; chronic pain; HIV or AIDS; epilepsy; migraine; and multiple sclerosis. No set limits regarding the amount of marijuana patients may possess and/or cultivate were provided by this act, though the California Legislature adopted guidelines in 2003.

The second state to approve the medicinal use of cannabis was Washington on 11-03-98. Illnesses afforded legal protection under this act are: cachexia; cancer; HIV or AIDS; epilepsy; glaucoma; intractable pain (defined as pain unrelieved by standard treatment or medications); and multiple sclerosis. Taking effect on 11-02-08 was another Washington bill allowing patients to cultivate up to 15 plants and/or possess up to 24 ounces of usable marijuana. Patients who possess larger quantities of cannabis than those approved by the Department will continue to receive legal protection under the law if they present evidence indication that they require such amounts to adequately treat their qualifying medical condition. Washington State Senate Bill 6032 also affirmed changes previously recommended by the state's Medical Quality Assurance Commission to expand the state's list of qualifying conditions to include Crohn's disease, hepatitis C, and any "diseases, including anorexia, which results in nausea, vomiting, wasting, appetite loss, cramping, seizures, muscle spasms, and/or spasticity, when these symptoms are unrelieved by standard treatments or medications."

The third state to approve the medicinal use of cannabis was Oregon on 12-03-98. The law removed state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess a signed recommendation from their physician stating that marijuana "may mitigate" his or her debilitating symptoms. Patients diagnosed with the following illnesses are afforded legal protection under this act: cachexia; cancer; chronic pain; epilepsy and other disorders characterized by seizures; glaucoma; HIV or AIDS; multiple sclerosis and other disorders characterized by muscle spasticity; and nausea. Other conditions are subject to approval by the Health Division of the Oregon Department of Human Resources. Oregon State Senate Bill 1085, which took effect on January 1, 2006, raises the quantity of cannabis that authorized patients may possess from seven plants (with no more than three mature) and three ounces of cannabis to six mature cannabis plants, 18 immature seedlings, and 24 ounces of usable cannabis.

The fourth state to approve the medicinal use of cannabis was Alaska on 03-04-99. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess written documentation from their physician advising that they "might benefit from the

medical use of marijuana." Patients diagnosed with the following illnesses are afforded legal protection under this act: cachexia; cancer; chronic pain; epilepsy and other disorders characterized by seizures; glaucoma; HIV or AIDS; multiple sclerosis and other disorders characterized by muscle spasticity; and nausea. Other conditions are subject to approval by the Alaska Department of Health and Social Services. Patients (or their primary caregivers) may legally possess no more than one ounce of usable marijuana, and may cultivate no more than six marijuana plants, of which no more than three may be mature.

The fifth state to approve the medicinal use of cannabis was Maine on 12-22-99. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess an oral or written "professional opinion" from their physician that he or she "might benefit from the medical use of marijuana." Patients diagnosed with the following illnesses are afforded legal protection under this act: epilepsy and other disorders characterized by seizures; glaucoma; multiple sclerosis and other disorders characterized by muscle spasticity; and nausea or vomiting as a result of AIDS or cancer chemotherapy. Patients (or their primary caregivers) may legally possess no more than one and one-quarter ounces of usable marijuana, and may cultivate no more than six marijuana plants, of which no more than three may be mature.

The sixth state to approve the medicinal use of cannabis was Hawaii on 12-28-00. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess a signed statement from their physician affirming that he or she suffers from a debilitating condition and that the "potential benefits of medical use of marijuana would likely outweigh the health risks." Patients diagnosed with the following illnesses are afforded legal protection under this act: cachexia; cancer; chronic pain; Crohn's disease; epilepsy and other disorders characterized by seizures; glaucoma; HIV or AIDS; multiple sclerosis and other disorders characterized by muscle spasticity; and nausea. Other conditions are subject to approval by the Hawaii Department of Health. Patients (or their primary caregivers) may legally possess up to 3 ounces of usable marijuana, and may cultivate no more than seven marijuana plants, of which no more than three may be mature.

The seventh state to approve the medicinal use of cannabis was Colorado of 06-01-01. The Colorado law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess written documentation from their physician affirming that he or she suffers from a debilitating condition and advising that they "might benefit from the medical use of marijuana." (Patients must possess this documentation prior to an arrest.) Patients diagnosed with the following illnesses are afforded legal protection under this act: cachexia; cancer; chronic pain; chronic nervous system disorders; epilepsy and other disorders characterized by seizures; glaucoma; HIV or AIDS; multiple sclerosis and other disorders characterized by muscle spasticity; and nausea. Other conditions are subject to approval by the Colorado Board of Health. Patients (or their primary caregivers) may legally possess no more than two ounces of usable marijuana, and may cultivate no more than six marijuana plants.

The eighth state to approve the medicinal use of cannabis was Nevada. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who have "written documentation" from their physician that marijuana may alleviate his or her condition. Patients diagnosed with the following illnesses are afforded legal protection under this act: AIDS; cancer; glaucoma; and any medical condition or treatment to a medical condition that produces cachexia, persistent muscle spasms or seizures, severe nausea or pain. Other conditions are subject to approval by the health division of the state Department of Human Resources. Patients (or their primary caregivers) may legally possess no more than one ounce of usable marijuana, and may cultivate no more than seven marijuana plants, of which no more than three may be mature.

The ninth state to approve the medicinal use of cannabis was Maryland. Maryland's legislature passed a medical marijuana affirmative defense law in 2003. This law requires the court to consider a

defendant's use of medical marijuana to be a mitigating factor in marijuana-related state prosecution. If the patient, post-arrest, successfully makes the case at trial that his or her use of marijuana is one of medical necessity, then the maximum penalty allowed by law would be a \$100 fine.

The tenth state to approve the medicinal use of cannabis was Vermont. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients diagnosed with a "debilitating medical condition." Patients diagnosed with the following illnesses are afforded legal protection under this act: HIV or AIDS, cancer, and Multiple Sclerosis. Patients (or their primary caregiver) may legally possess no more than two ounces of usable marijuana, and may cultivate no more than three marijuana plants, of which no more than one may be mature. A subsequent Senate Bill 7, which took effect on 07-01-07, expands the definition of "debilitating medical condition" to include: "(A) cancer, multiple sclerosis, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, or the treatment of these conditions, if the disease or the treatment results in severe, persistent, and intractable symptoms; or (B) a disease, medical condition, or its treatment that is chronic, debilitating, and produces severe, persistent, and one or more of the following intractable symptoms: cachexia or wasting syndrome; severe pain; severe nausea; or seizures." The measure also raises the quantity of medical cannabis patients may legally possess under state law from one mature and/or two immature plants to two mature and/or seven immature plants. Senate Bill 7 also amends state law so that licensed physicians in neighboring states can legally recommend cannabis to Vermont patients.

The eleventh state to approve the medicinal use of cannabis was Montana on 11-02-04. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess written documentation from their physicians authorizing the medical use of marijuana. Patients diagnosed with the following illnesses are afforded legal protection under this act: cachexia or wasting syndrome; severe or chronic pain; severe nausea; seizures, including but not limited to seizures caused by epilepsy; or severe or persistent muscle spasms, including but not limited to spasms caused by multiple sclerosis or Crohn's disease. Patients (or their primary caregivers) may possess no more than six marijuana plants.

The twelfth state to approve the medicinal use of cannabis was Rhode Island. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess "written certification" from their physician stating, "In the practitioner's professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks for the qualifying patient." Patients diagnosed with the following illnesses are afforded legal protection under this act: cachexia; cancer; glaucoma; Hepatitis C; severe, debilitating, chronic pain; severe nausea; seizures, including but not limited to, those characteristic of epilepsy; or severe and persistent muscle spasms, including but not limited to, those characteristic of multiple sclerosis or Crohn's Disease; or agitation of Alzheimer's Disease. Other conditions are subject to approval by the Rhode Island Department of Health. Patients (and/or their primary caregivers) may legally possess 2.5 ounces of cannabis and/or 12 plants, and their cannabis must be stored in an indoor facility.

The thirteenth state to approve the medicinal use of cannabis was New Mexico. The law mandates the state Department of Health by 10-01-07, to promulgate rules governing the use and distribution of medical cannabis to state-authorized patients. These rules shall address the creation of state-licensed "cannabis production facilities," the development of a confidential patient registry and a state-authorized marijuana distribution system, and "define the amount of cannabis that is necessary to constitute an adequate supply" for qualified patients. In January 2009, the New Mexico Department of Health finalized rules governing the production, distribution, and use of medicinal cannabis under state law. Patients registered with the state Department of Health and who are diagnosed with the following illnesses are afforded legal protection under these rules: Severe chronic pain, Painful peripheral neuropathy, Intractable nausea/vomiting, Severe anorexia/cachexia, Hepatitis C infection currently receiving antiviral

treatment, Crohn's disease, Post-traumatic Stress Disorder, Amyotrophic Lateral Sclerosis (Lou Gehrig's disease), Cancer, Glaucoma, Multiple sclerosis, Damage to the nervous tissue of the spinal cord with intractable spasticity, Epilepsy, HIV/AIDS, Hospice patients, Other conditions are subject to approval by the Department of Health. Patients may legally possess six ounces of medical cannabis (or more if authorized by their physician) and/or 16 plants (four mature, 12 immature) under this act.

The fourteenth state to approve the medicinal use of cannabis was Michigan on 12-04-08. The law removes state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess written documentation from their physicians authorizing the medical use of marijuana. Patients diagnosed with the following illnesses are afforded legal protection under this act: Cancer, glaucoma, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, hepatitis C, amyotrophic lateral sclerosis, Crohn's disease, agitation of Alzheimer's disease, nail patella (arthritic disease), or the treatment of these conditions. Patients are also offered legal protection if they have a chronic or debilitating disease or medical condition or treatment of said condition that produces 1 or more of the following: cachexia or wasting syndrome; severe and chronic pain; severe nausea; seizures, including but not limited to those characteristic of epilepsy; or severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis. Patients (or their primary caregivers) may possess no more than 12 marijuana plants kept in an enclosed, locked facility or 2.5 ounces of usable marijuana.

It is notable that Hawaii, Montana, Rhode Island, New Mexico, and Michigan have specifically named Crohn's disease as an approved or qualifying condition for the use of cannabis. In California it is not a named condition but falls under the umbrella of "any illness for which marijuana provides relief".

When my medical practice began in California I was not aware of the utility of cannabis for Crohn's disease. It was not until Crohn's disease patients came to me to report their improvement using cannabis that I began to look into the matter. Questioning other physicians in the California Cannabis Research Medical Group, CCRMG, I found that other physicians had similar experiences in hearing testimonies that cannabis significantly improved many symptoms of Crohn's disease, reduced the number of bowel movements per day, reduced the number and severity of flare-ups of the disease, reduced the quantity and need for conventional medications, and helped in weight gain for the patient. Crohn's disease became one of the conditions studied by a group of physicians in the CCRMG.

A Crohn's Questionnaire with 34 questions was developed to evaluate the experience of the Crohn's patient with cannabis use. In the pilot study of 10 patients with Crohn's disease and two patients with another inflammatory bowel disease, ulcerative colitis, the questionnaire looked at paired responses of symptom changes with and without cannabis use. In all areas of inquiry the patients described statistically significant improvement on pain, anorexia (loss of appetite), nausea, vomiting, fatigue, depressed mood, and activity level. Additionally, there were statistically significant reductions in stools per day, and weight gain with the use of cannabis. Statistically significant reductions in the frequency of flare-ups and severity of flare-ups were also observed in all patients questioned. As noted above, a larger group of patients with Crohn's disease and ulcerative colitis have now been collected. The findings of this study will be presented for publication in the next few months.

Without going into great detail, a brief scientific outline of the way that cannabis interacts with the human body will help to understand the efficacy and safety of herbal cannabis in relationship to Crohn's disease and the seemingly disparate medical conditions that all respond to cannabis. The biology of the cannabinoids has only been identified within the past 20 years during which time an explosion of knowledge has occurred.

There are over 400 chemical compounds in the cannabis plant – about 70 are known as the cannabinoids, molecules that are unique to the cannabis plant. The cannabinoids interact with cannabinoid receptors that are found in specific locations in the human body. These cannabinoid receptors are found in all of the animals in the animal kingdom except insects. Molecules within the body that naturally activate the cannabinoid receptors are known as the endocannabinoids. The activation of these receptors occurs with both the endocannabinoids and the cannabis plant cannabinoids, or “phytocannabinoids”. The receptors have been divided into two classes, the CB1 and CB2 receptors. The CB1 receptors are found in the brain and nerve cells. The CB1 receptors control appetite, immune function, muscle control, pain, intraocular pressure, cognition, emesis, neuroexcitability, reward mechanisms, and thermoregulation. In general cannabinoid activation of the CB1 receptors down regulate these natural processes. The CB2 receptors are located in immune system, especially the spleen, and various circulating white blood cells associated with the immune response. Activation of the CB2 receptors control immune function, cell proliferation, inflammation and pain.

The function of the endogenous cannabinoid system in the body is becoming more appreciated through advances in cannabinoid pharmacology. The identification of the cannabinoid receptors has lead to a host of agonists and antagonists (stimulants and blockers) being synthesized. Utilizing these tools, investigators are discovering that the system is likely to be important in the modulation of pain and appetite, suckling in the newborn and the complexities of memory. In addition to being utilized to learn more about the natural function of the endocannabinoid system, a number of these cannabinoid receptor agonists and antagonists are being developed as potential pharmaceutical therapies. In the meantime, dronabinol (Marinol®), nabilone (Cesamet®, a synthetic cannabinoid) and cannabis are the currently available cannabinoid therapies in the United States. As yet unavailable in the United States is a whole cannabis extract (Sativex®) delivered as an oro-mucosal spray with approximately a 50:50 ratio of THC and cannabidiol, a non-psychoactive cannabinoid. It is available in Canada and undergoing late phase testing in the US and other countries. Patients who have tried the synthetic single molecule pharmaceuticals consistently report that they are less effective and have unpleasant side effects, compared to natural cannabis.

There is no surprise among physicians in the practice of cannabis therapeutics, who being students of cannabinoid science appreciate the efficacy of cannabis in Crohn’s disease. The human bowel wall is found to have both classes of cannabinoid receptors, CB1 and CB2, which when activated reduce pain, muscular spasms, inflammation and promote healing. In Crohn’s disease, these normal functions of the cannabinoid receptors can be activated by herbal cannabis to exert these desired effects.

In the August 2005 issue of the journal, *Gastroenterology*, Karen Wright PhD and her research team at the University of Bath, England, Department of Pharmacy and Pharmacology found that human tissues from the gastrointestinal lining of patients with Crohn’s disease were found to contain large quantities of cannabinoid receptors. Activation of these receptors promoted healing of the gastrointestinal membrane. The researchers concluded that a pharmacologic strategy for treatment of patients suffering from inflammatory disorders such as Crohn's disease and ulcerative colitis could be achieved by increasing the activation of these receptors. The study's findings were "the first [clinical] evidence that very selective cannabis-derived treatments may be useful as future therapeutic strategies in the treatment" of inflammatory bowel disease, said lead author Karen Wright.

Crohn’s disease is a condition recognized to be very difficult to treat. It tends to require repeated surgeries to remove sections of diseased bowel only to have the disease recur in a new location. It is complicated by fistulae (tunneling to other organs), obstructions, chronic infections, and bleeding. Historically, patients with Crohn’s disease have their life shortened by

the disease and its complications. Current conventional medical therapies include immune system modulating drugs (azathioprine, Imuran®, Azasan®, 6 mercaptopurine, and methotrexate), anti-inflammatory drugs (mesalamine, Asacol®, Pentasa®, Rowasa®, Colazal®, Canasa®), antibiotics (Flagyl®, Cipro®), steroids (prednisone, Endocort®), and injectable inflammatory pathway blockers, (infliximab, etanercept, Remicade®, Humira®, Enbrel®) as the primary treatment modalities. In addition to these pharmaceuticals most patients have also been prescribed anti-diarrheals, (Imodium®, Lomotil®), and antispasmodics, (Bentyl®) in the normal course of management. Only a rare patient has used none of these conventional medications. Most patients have used at least one and commonly several of these medications.

There is also a large group of adjunctive medications that are prescribed to deal with pain, depression, anxiety, insomnia, anorexia, muscle spasms, and diarrhea. They include antidepressants, opioid pain relievers, sleep aids, stimulants, sedatives, antimicrobials, and muscle relaxants. For the Crohn's patient nearly all of these additional problems may be treated with cannabis alone.

Existing therapies for Crohn's disease are usually expensive and inadequate in controlling the disease process. They are inconvenient in that they typically require multiple daily doses, sometimes by enemas, sometimes by injections with needle and syringe, and they are associated with long lists of adverse effects. Despite regular use of conventional medications patients often report that it is difficult to leave home for more than a couple hours because frequent stools and pain make travel very problematic. Mostly patients describe that the existing therapies are simply ineffective.

Cannabis, like any other medication, may not be effective for all Crohn's disease patients. For a majority of cannabis treated patients there are reports that the use of cannabis has significantly reduced the quantity and frequency of existing therapy and in many cases conventional medications have been discontinued altogether when using cannabis on a regular basis. Patients report that their use of cannabis provides some relief with once daily administration, and reaches an optimal level with 2-4 times daily administration of smoked or vaporized cannabis. Some patients experiment with ingested cannabis, (tinctures, oils, capsules, teas, and baked goods), but most prefer smoking or vaporizing for its rapid onset of action, (about 5 minutes), and its ease of self titrating the dose. Measured quantities of cannabis use are complicated by many variables, including the quality of cannabis, the method of administration, and the tolerance developed to regular use. A mean quantity of use in our pilot study on Crohn's disease was between 2-3 grams of dried, trimmed, flowering tops per day.

Difficulties in smoked cannabis use include mild pulmonary airway irritation, often resolved by changing from smoking to vaporizing cannabis. In other cases changing over to ingested forms of cannabis can be corrective. The other difficulties in the use of cannabis are more social and economic in nature. Patients prefer to keep their use of cannabis private, avoiding detection by their employer and their community. Even though a National Survey poll in 2001 showed that 75% of Americans and 75% of American physicians believe that Americans should have access to cannabis for medicinal purposes, there is an unresolved stigma against cannabis use. This negative stigma is promulgated by well funded anti-cannabis campaigns that continue to come from the federal government, (ONDCP - Office of National Drug Control Policy), without recognition of the therapeutic value of cannabis. These campaigns include grossly misleading misinformation about the risks of cannabis use, while completely ignoring favorable cannabis research. The National Institute of Drug Abuse, NIDA, funds research directed toward cannabis as a drug of abuse and never as a therapeutic medication. Access to reasonably priced, organically grown cannabis remains a problem for many people who wish to use cannabis for medicinal purposes.

The Institute of Medicine published Marijuana and Medicine Assessing the Science Base, in 1999. The Institute of Medicine is aware that the development and acceptance of smokeless marijuana delivery systems” may take years to develop; in the meantime there are patients with debilitating symptoms for whom smoked marijuana may provide relief.” The Institute of Medicine report makes the following general conclusions about the biology of cannabis and cannabinoids. Cannabinoids have an extremely favorable drug safety profile. Unlike opioid receptors, cannabinoid receptors are not located in brainstem areas controlling respiration, so lethal overdoses due to respiratory suppression do not occur. The LD50 (a lethal dose in 50% of the subjects) has been estimated to be 1500 pounds smoked in 15 minutes as extrapolated from animal studies,,, This represents death by CO, carbon monoxide poisoning, and not from cannabinoid overdose.

The Medical Board of California advised physicians in a July 2004 Action Report that “The intent of the board at this time is to reassure physicians that if they use the same proper care in recommending medical marijuana to their patients as they would any other medication or treatment, their activity will be viewed by the Medical Board just as any other appropriate medical intervention...If physicians use the same care in recommending medical marijuana to patients as they would recommending or approving any other medication or prescription drug treatment, they have nothing to fear from the Medical Board.” The Board recommends following the accepted standards that would be used in recommending any medication. A history and physical examination should be documented. The provider should ascertain that medical marijuana use is not masking an acute or treatable progressive condition. A treatment plan should be formulated. A patient need not have failed all standard interventions before marijuana can be recommended. The physician may have little guidelines in actually recommending a concrete dose for the patient to use. As there are so many variables associated with effect, the physician and patient should develop an individual self-titration dosing plan that allows the patient to achieve the maximum benefit with tolerable side effects. Discussion of potential side effects and obtaining verbal informed consent are desirable. Periodic review of the treatment efficacy should be documented. Consultation should be obtained when necessary. Proper record keeping that supports the decision to recommend the use of medical marijuana is advised. Despite all these guidelines, the California Medical Board still reminds physicians that making a written recommendation “could trigger a federal action.”

The American Psychiatric Association recently approved a strongly worded statement supporting legal protection for patients using medical marijuana with their doctor’s recommendation. The APA action paper reiterates that “the threat of arrest by federal agents, however, still exists. Seriously ill patients living in these states with medical marijuana recommendations from their doctors should not be subjected to the threat of punitive federal prosecution for merely attempting to alleviate the chronic pain, side effects, or symptoms associated with their conditions or resulting from their overall treatment regimens...[We] support protection for patients and physicians participating in state approved medical marijuana programs. “ Subsequently, the 124,000 member American College of Physicians, ACP, issued a position paper supporting research into the therapeutic role of marijuana and urging protection for both physician who participate in discussions regarding the use of medical cannabis and their patients who seek to use it.

I have had an opportunity to interview Kenichi Narita initially on a telephone visit in May 2009 and subsequently on a few internet video conferences since then. Mr. Narita was able to share with me several documents from his medical record including colonoscopy photographs, and pathology reports of his condition. These are the tools of the medical trade - the colonoscopy and the biopsy. The colonoscopy is the direct visualization of the colon and the distal small bowel, and the biopsy is a sampling of a small amounts of tissue for microscopic

analysis. The pathology report is prepared from the gross and microscopic evaluation of the tissue specimen. This is ultimately the basis of the diagnosis in conjunction with the clinical history and physical examination.

Since I completed my medical school training in 1975, I have never seen a “light” case of Crohn’s disease. Though Mr. Narita may appear young and relatively healthy at this time of his life, it does not diminish the gravity of his disease. Unfortunately for Mr. Narita the diagnosis of Crohn’s disease is a very serious condition that he will need to battle for the rest of his life. Mr. Narita has shared with me the fact that he has a complication of Crohn’s disease known as a fistula. He has tried the latest conventional therapy but it has not provided a significant benefit in resolving this complication. Often the best outcome from treatment is to keep the disease from progressing rather than expecting the disease to resolve.

There is no question in my mind that Kenichi Narita’s symptoms and the course of his medical condition are consistent with the diagnosis of Crohn’s disease. Mr. Narita has reported to me that he has his best results in easing the pain, cramping, and abnormal stools with the use of cannabis. I believe that this is at least as good as any therapy available at this time. I would not discourage him from trying other existing therapies that he has not already tried before, but cannabis is exceptional in being non-toxic, well tolerated, and unique in its combination of analgesic, anti-inflammatory, anti-spasmodic, and immune modulating properties. It provides mental ease and a refreshing outlook in an otherwise dismal situation. I truly see his cannabis use as a medical necessity.

Mr. Kenichi Narita, as with other patients with Crohn’s disease, has a number of symptoms that are responsive to cannabinoid therapy. Even more, I have observed that the course of this disease is significantly improved with cannabis therapy. As a patient he is faced with the choice of utilizing a medication that he has found to be effective despite the governmental ban on this age-old herbal medication. I, as a physician knowing the effects of cannabis use in Crohn’s disease, would recommend it to him even when his government and mine frown upon it. There may be a time in the future when cannabinoid based medications are developed that exceed the benefits of the natural plant, but for now this is not the case. At this time his best treatment comes at least in part from the medicinal use of the cannabis plant to alleviate his pain and suffering.

Your compassion and understanding is greatly appreciated.

Thank you for allowing me to address the court.

Sincerely,

Jeffrey Hergenrather, MD