No. 00-151

IN THE

# Supreme Court of the United States

UNITED STATES OF AMERICA,
*Petitioner,*

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND
JEFFREY JONES,
*Respondents.*

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

**Brief *Amici Curiae* of the American Public Health Association, California Nurses' Association, Lymphoma Foundation of American, Irvin Henry Rosenfeld *et al.*, in Support of Respondents**
**[additional *Amici* listed on inside of front cover]**

*DANIEL N. ABRAHAMSON
JUDITH K. APPEL
The Lindesmith Center
1095 Market Street, Suite 505
San Francisco, CA 94103
Telephone: (415) 554-1900

Attorneys for *Amici Curiae*
*(Counsel of Record)

## ADDITIONAL *AMICI*

Barbara M. Douglass
Elvy Musikka
George Lee McMahon
American Medical Women's Association
Colorado Nurses' Association
AIDS Treatment Initiatives
AIDS Resource Center of Wisconsin
AIDS Project Arizona
Mothers Against Misuse and Abuse
Marin County Medical Society of California
Gay and Lesbian Medical Association

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## I. INTEREST OF THE AMICI*

*Amici Curiae* are health care and medical organizations – including the American Public Health Association, the world's largest public health organization – whose memberships are comprised of physicians, nurses, public health officers, researchers and care providers, as well as individuals suffering from serious and debilitating illnesses and their families. *Amici* also include four persons who have received herbal cannabis from the federal government for more than a decade to help treat their serious illnesses.[1]

*Amici* have different experiences, expertise, and perspectives on medical, scientific and public health issues, but are united in their knowledge that there is a small but significant percentage of seriously ill patients who do not respond to or cannot tolerate conventional therapies. For these individuals, the art of medicine – the ability of treatment providers to work closely with a patient to fashion or modify a treatment regimen tailored to the patient's unique needs at a particular moment in time, even in the absence of a clear scientific roadmap – assumes heightened importance.

*Amici* join together in this brief to underscore the efficacy and legitimacy of cannabis as medicine – a sometimes necessary medicine – and to refute the disingenuous claims to the contrary of the non-medical groups who have weighed in on behalf of the federal government in this case. In supporting the doctrine of

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* No entity or counsel apart from those whose names appear on this Brief have contributed monetarily or substantively to its production. Sup. Ct. R. 37.6.

[1] Descriptions of *Amici Curiae* are set forth in the Appendix to this brief.

medical necessity and providing this Court with a review of recent literature describing the therapeutic properties of cannabis and the plight of patients who derive relief from it, *Amici* do not take a position on whether cannabis should be removed from Schedule I of the Controlled Substances Act. But *Amici* do take issue with the assertions of the government's *Amici* that the medical use of cannabis is simply a stalking horse for marijuana legalization, Br. *Amicus Curiae* of Drug Free America Foundation at 3, 8-9, is part of a "homosexual" agenda, Br. *Amicus Curiae* of Family Research Council at 18, that the therapeutic qualities of herbal cannabis lack scientific grounding, id. at 13-15, or that there are conventional therapies that always work better than cannabis for seriously ill patients, id. at 2. Medical literature and the documented experiences of a diverse body of patients belie these claims.

Each party has given its consent, in writing, to the filing of this Brief.

## II. PRELIMINARY STATEMENT

This case raises a very narrow issue. It asks only whether federal courts may consider the plight of suffering patients when exercising equitable powers in response to a request for injunctive relief, when not clearly deprived of that power by a federal statutory scheme.[2] How this narrow

[2] This case does not raise the validity vel non of California's Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5, or of similar laws enacted in states that together comprise the majority of the country's populace. Such laws have a far broader scope than the doctrine of medical necessity articulated by the Court of Appeals. The Compassionate Use Act, for example, authorizes a patient to use medicinal cannabis for any medical condition, so long as the patient and his or her physician have determined that cannabis might provide relief. "Medical necessity" patients comprise a small subset of those covered by

question is answered, though, can affect the health and well-being of seriously ill persons for whom cannabis provide the only effective relief. We urge this Court to take its cue from the United States' Institute of Medicine ("IOM") and answer that question in the affirmative.

As Dr. John Benson, Jr., Dean of the Oregon Health Sciences University School of Medicine and principal investigator for the IOM, stated in the release of the IOM Report, MARIJUANA AND MEDICINE, ASSESSING THE SCIENCE BASE (1999) [hereinafter "IOM Report"]:

> [P]hysicians frequently encounter patients who do not respond well to standard medications, or for whom adjunct therapies are needed. For these patients, we found that cannabinoids appear to hold potential for treating pain, chemotherapy-induced nausea and vomiting, and the poor appetite and wasting caused by AIDS or advanced cancer. . . . We do not recommend smoking marijuana for *long-term* medical use . . . [and] see little future in smoked marijuana as a medicine. That said, **we conclude**[] **that there are some limited circumstances in which we recommend smoking marijuana for medical uses.**

Opening Statement of J. Benson, IOM News Conference March 17, 1999 (emphases added).

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such state laws. This case raises only issues of federal statutory and common law and the power of the federal courts, and could easily have arisen in a state that has yet to decriminalize the medicinal use of cannabis.

This statement is not an isolated opinion, but confirms the conclusions of numerous credentialed clinicians and researchers. *Amici* for Petitioner ignore the findings of the IOM Report that support Respondents, citing instead only those portions of the very balanced Report that point to the potential difficulties of cannabis use. As usual, the truth lies somewhere between the claims of the most extreme anti-cannabis and pro-cannabis advocates. This Court should be guided by the full range of facts, not selective characterizations. On balance, the facts support Respondents.

## III. SUMMARY OF ARGUMENT

A small but significant number of seriously ill patients who suffer from cancer, HIV/AIDS, multiple sclerosis, epilepsy, or other conditions do not benefit from, or cannot tolerate, the leading or conventional therapies available in the medical armamentarium. Some of these patients, together with their physicians, have found cannabis to be effective at alleviating symptoms of their condition or side effects of their treatment. The experiences of patients, the observations of their physicians, the conclusions of medical researchers, and the recent findings of blue-ribbon government panels undeniably demonstrate that cannabis has therapeutic properties, which, for some people, can mean the difference between life and death or relative health and severe harm.

What is more, the side effects of cannabis are typically less severe than those caused by conventional medications used to treat debilitating illnesses and conditions. Indeed, first-line therapies for cancer and HIV/AIDS, for example, can induce acute or chronic nausea or anorexia for which cannabis provides the only relief for some patients.

Nor is the prescribable component of cannabis, synthetic THC (Marinol), an adequate alternative for those patients for whom cannabis provides the only relief. Marinol has several shortcomings, including slow uptake, inability to titrate, and difficulty to swallow. In addition, Marinol does not contain CBD, another component of cannabis that, unlike THC, has been shown to be neuroprotective, anti-inflammatory, and anti-convulsant.

Lastly, to the extent the government acknowledges that the constituent components of cannabis, together or in isolation, can provide important therapeutic benefits, it is clear that the medical needs of seriously ill patients for whom cannabis provides the only relief will not have their needs met anytime soon by the federal government or private sector.

Accordingly, the judgement below should be affirmed.

## IV. ARGUMENT

### A. Abundant Scientific Evidence Demonstrates That Cannabis Has Important Therapeutic Benefits.

As any health care professional can attest, no therapy is effective 100% of the time for all patients. And although almost all ailments can be treated with more than one medication, a small but significant percentage of patients suffering from debilitating or life-threatening illnesses do not benefit from any conventional therapies currently offered by modern medicine. See Declaration of Dr. Marcus Conant,

J.A. at 99. Clear illustrations of this are seen in some people who suffer from acute or chronic pain, nausea, wasting, muscle spasms and seizure disorders.

While Petitioner, and especially the *Amici* for Petitioner, take strong issue with the therapeutic role of herbal cannabis, the scientific literature – and the highly respected research panels from the United States and Great Britain – make clear that there is widespread agreement that cannabis is effective in alleviating the symptoms of many patients who have not obtained relief from conventional treatments.[3]

### 1. The U.S. Institute of Medicine and the British House of Lords Independently Confirm that Cannabis is Medically Appropriate for Some Patients.

Leading researchers and governmental institutions in the United States and Britain have independently affirmed that herbal cannabis is a crucial medical option for a small class of seriously ill patients who do not benefit from conventional therapies. Specifically, over the last four years, the federal Institute of Medicine[4] and Britain's House of Lords each undertook an extensive scientific review of cannabis and its constituent cannabinoids to assess the

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[3] The term "herbal cannabis" or simply "cannabis" refers to the unrefined plant, in keeping with the terminology of most scientific literature. The term "crude marijuana" used by *Amici* for Petitioner is inaccurate as a scientific term for Cannabis sativa L.

[4] The Institute of Medicine was chartered in 1970 by the National Academy of Sciences (NAS) to bring professionals in different disciplines together to examine policy matters pertaining to the health of the nation. The IOM furthers NAS' responsibility to advise the federal government on such issues pursuant to an 1863 Congressional charter.

medical and public health benefits and risks posed by this plant. Among their key findings, both institutions reached the following conclusions: 1) there are several medical conditions for which a significant minority of patients do not respond to the standard leading therapies; 2) for some of these patients, herbal cannabis provides important relief from life-threatening or seriously debilitating symptoms; and 3) the side effects of herbal cannabis treatment are no worse, and often much less harsh, than those caused by conventional medications and therapies.

### a. The Institute of Medicine

In 1997, largely in response to the passage of California's Compassionate Use Act and the subsequent decision of a federal district court to enjoin the federal government from threatening California physicians with sanctions if they discussed the medical benefits of cannabis with their patients, Conant v. McCaffrey, 172 F.R.D. 681 (N.D. Cal. 1997), the White House Office of National Drug Control Policy commissioned the national Institute of Medicine to undertake an extensive review of the scientific evidence of the therapeutic applications of cannabis. The IOM's report, "Marijuana and Medicine: Assessing the Science Base," was published in the spring of 1999.

The IOM assessed a wide array of evidence and testimony. It arrived at six recommendations. Those recommendations primarily emphasize the desirability of further research into the effects of cannabinoids and the development of alternative delivery systems by which patients could ingest cannabis or its constituent elements through methods other than smoking. Critically, however, the IOM Report recognized that there are a number of medical conditions for which currently available therapies

fail to serve a significant minority of patients but for which cannabis has a demonstrated medical benefit.

The IOM's findings regarding the medical efficacy of herbal cannabis to treat acute nausea and vomiting, wasting, and muscle spasticity are discussed in more detail below. But a principal conclusion reached by the IOM – a conclusion that the government's *Amici* omit from their briefs – is that the use of herbal cannabis is medically appropriate for certain patients suffering from debilitating conditions who have unsuccessfully tried all government-approved therapies to treat their conditions, and who are under the care and monitoring of a physician.[5] IOM Report at 179.

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[5] Specifically, the IOM Report suggested that:

> Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms . . . must meet the following conditions: Failure of all approved medications to provide relief has been documented; [t]he symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs; [s]uch treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and; [i]nvolves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

IOM Report at 179. While the IOM's statement ostensibly would limit the use of cannabis to six months' duration, in the context of the full report it is apparent that the IOM does not urge the automatic termination of treatment at an arbitrary date, but rather recommends that patients' cannabis use be reevaluated on at least a biannual basis. The authors' reluctance to approve the longer-term use of cannabis was based primarily on their concern about the possible pulmonary risks posed by cannabis.

### b. The House of Lords

While the IOM was conducting its evaluation, Britain's House of Lords was questioning and taking testimony from leading researchers, clinicians and patients regarding the medical benefits and drawbacks of cannabis. The House of Lords' report was issued in November 1998. Select Committee on Science and Technology, House of Lords, Sess. 1997-98, 9th Report, Cannabis: The Scientific and Medical Evidence: Report (hereinafter "Lords Report").

The findings and recommendations of the Lords Report closely parallel those of the IOM. Like the IOM, the House of Lords determined that cannabis holds important medical benefits for certain seriously ill patients for whom conventional therapies are ineffective.

The House of Lords, however, went a step further than the IOM. On the basis of its assessment of the medical benefits of cannabis, the House of Lords recommended that the government of Britain:

> transfer cannabis and cannabis resin from Schedule I of the Misuse of Drugs Regulations to Schedule 2, so as to allow doctors to prescribe an appropriate preparation of cannabis, albeit as an unlicensed medicine[6] and on the named-

[6] The United Kingdom, unlike the U.S., allows physicians to prescribe an unapproved medicine to a particular patient, so long as the physician provides the patient's name to the manufacturer. The Lords Report points out that a physician who prescribes cannabis on these terms must be aware of conditions for which cannabis might be contraindicated and inform patients of the possible effects on driving and cognitive function. Lords Report at § 8.16

patient basis, and to allow doctors and pharmacists to supply the drug prescribed.

Lords Report at § 8.23 (iii).

### 2. Cannabis Provides Essential Relief from Pain, Nausea, Anorexia, Muscle Spasticity and Seizures.

**Pain:** Neuropathic pain is a symptom commonly associated with a variety of illnesses or conditions, including metastic cancer, HIV/AIDS, multiple sclerosis (MS) and diabetes, and can also be a side effect of the recommended treatments for various conditions. Over 30% of patients with HIV/AIDS suffer from excruciating pain in the nerve endings (polyneuropathies), many in response to the antiretroviral therapies that constitute the first line of treatment for HIV/AIDS. Yet there is no approved treatment for such pain that is satisfactory for a majority of patients.[7] As a result, some patients must reduce or discontinue their HIV/AIDS therapy because they can neither tolerate nor eliminate the debilitating side effects of their first-line medications.

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[7] See, e.g., D. Simpson et al., Selected Neurologic Manifestations of HIV Infection: Dementia and Peripheral Neuropathy, Improving the Management of HIV Disease Vol. 7, Dec. 1999; N. Quang-Cantagrel et al., Opioid Substitution to Improve the Effectiveness of Chronic Noncancer Pain Control: a Chart Review, 90 Anesthesia and Analgesia 933 (2000) (reporting opioid analgesics are effective for only 36% of patients, ineffective for 34%, and intolerable for 30% of patients); Neurologic AIDS Research Consortium, Peripheral Neuropathy, http://www.neuro.wustl.edu/narc/peri-neuropathy.html ("Treatment of neuropathic pain...is notoriously difficult...[e]ven narcotics may not fully relieve [it].")

Patients with various pain syndromes, particularly neuropathic pain, claim significant relief from cannabis. See, e.g., Lords Report at §§ 5.26-5.30; L. Grinspoon & J. Bakalar, MARIJUANA: THE FORBIDDEN MEDICINE 109-26 (1997) [hereinafter "FORBIDDEN MEDICINE"]. The validity of their experiences is corroborated by studies in which cannabinoids have been shown to be effective analgesics in animal pain models. See, e.g., W. Martin, Basic Mechanisms of Cannabinoid-Induced Analgesia, International Association for the Study of Pain Newsletter (Summer 1999) ("There is now unequivocal evidence that cannabinoids are antinociceptive in animal models of acute pain").

**Nausea, Anorexia and Wasting:** Nausea, anorexia, and wasting are common symptoms of many cancers and AIDS.[8] They are also the common adverse side effects of chemotherapy and other aggressive therapies used to treat those diseases and associated pain.[9] Certain individuals, though, do not respond to currently available antiemetics. See, e.g., Declaration of Dr. Marcus Conant, J.A. at 101 (conventional drugs fail to relieve severe nausea and vomiting for some patients); Declaration of Dr. Howard Maccabee, J.A. at 110 (same); Declaration of Dr. Lester Grinspoon, J.A. at 127-128 (about half of patients treated with anticancer drugs suffer from severe nausea and vomiting; many of these patients find little or no relief in conventional antiemetics); IOM Report at 157 ("[f]ew

[8] See, e.g., IOM Report at 151 (observing that patients receiving aggressive chemotherapy have "a 20-30 percent likelihood of experiencing acute emesis.")

[9] The nausea-inducing properties of opioid analgesics used to treat pain are uncontroverted. See, e.g., American Medical Ass'n, ENCYCLOPEDIA OF MEDICINE 98 (C. Clayman ed., 1989) ("Nausea [and] vomiting . . . may occur with narcotic analgesic drugs."); THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 1223 (R. Berkow ed., 16th ed. 1992) (same).

therapies have proven successful in the treatment of the AIDS wasting syndrome.")

Herbal cannabis has been proven to provide critical relief for persons suffering from acute or chronic nausea and vomiting, but who do not respond to conventional therapies. Cancer patients undergoing chemotherapy, persons with HIV/AIDS taking antiretroviral drugs, and patients in severe pain who are prescribed nausea-inducing opioid analgesics comprise many members of this class. As the Institute of Medicine explains, "[t]he critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but rather whether there is a group of patients who might obtain added or better relief from marijuana or cannabinoid drugs." IOM Report at 153. The IOM unequivocally answers this question in the affirmative:

> . . . It is possible that the harmful effects of smoking marijuana for a limited time might be outweighed by the antiemetic benefits of marijuana, at least for, patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis. Such patients should be evaluated on a case by case basis and treated under close medical supervision.

Id. at 154. See also Lords Report at § 5.12 (finding cannabis effective in alleviating acute nausea and vomiting).

The IOM's conclusion is supported by a significant body of clinical research and experience. In 1988, a New York State-sponsored study examined the effects of herbal cannabis on cancer chemotherapy patients who were unresponsive to standard antiemetics. Seventy-eight percent responded positively to cannabis. V. Vinciguerra et al., Peer

Reviewed Results of New York State-Sponsored Cancer/Marijuana Studies, 88 New York State J. of Med. 525 (1988). Several other states have undertaken similar trials with similar results. See generally R. Musty and R. Rossi, Effects of Smoked Cannabis and Oral Delta-9-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials, 1 J. of Cannabis Therapeutics 29 (2001).[10] A 1991 survey of 2000 oncologists reported that 40% of the respondents considered cannabis to be therapeutically useful and would prescribe it if it were lawful to do so. R. Doblin and M. Kleiman, Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes, 14 J. of Addictive Diseases 5 (1991). See also Declaration of Dr. Howard Maccabee, J.A. at 110; FORBIDDEN MEDICINE at 23-45.

Similarly, cannabis affords essential relief to patients suffering from anorexia and wasting syndromes for whom no other medications have worked. See IOM Report at 157 ("[Cannabinoids] could . . . be beneficial for a variety of effects, such as increased appetite, while reducing the nausea and vomiting caused by protease inhibitors and the pain and anxiety associated with AIDS."); Lords Report at § 5.15 (noting cannabis can counteract anorexia and wasting); Dec. of Dr. Marcus Conant, J.A. at 100-101 (same); FORBIDDEN MEDICINE at 100-09. See also Conant v. McCaffrey, 2000 U.S. Dist. LEXIS 13024, *12-13 (N.D. Cal. 2000) (describing AIDS patient suffering from life-threatening wasting syndrome who needs herbal cannabis to stimulate appetite).

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[10] These studies took place before the introduction of current, more powerful, antiemetic drugs, such ondansetron (Zofran) and granisetron (Kytril). However, as noted in the IOM Report, a significant percentage of patients still do not respond to these newest drugs. IOM Report at 151.

**Muscle Spasticity:** As the IOM Report notes, current treatments for painful muscle spasms, commonly associated with multiple sclerosis and spinal cord injuries, have only limited effectiveness and their use is complicated by various adverse side effects. Id. at 164. A growing body of clinical and preclinical literature demonstrates that cannabinboids are effective in controlling the debilitating symptoms of multiple sclerosis ("MS"). See D. Baker et al., Cannabinoids Control Spasticity and Tremor in a Multiple Sclerosis Model, 404 Nature 117 (Mar. 2, 2000); Lords Report at §§ 5.19-5.23. For example, while conventional treatments have limited effectiveness for bladder dysfunction and pain associated with MS, see IOM, MULTIPLE SCLEROSIS: CURRENT STATUS AND STRATEGIES FOR THE FUTURE (2000) at 149, 171, cannabis has been shown to be effective in alleviating these problems. Lords Evidence at 31-43. In addition, a survey of British and American MS patients reports that after ingesting herbal cannabis a significant majority experienced substantial improvements in controlling muscle spasticity and pain.[11] In one case study, herbal cannabis provided relief from both muscle spasms and ataxia (loss of coordination), a multiple benefit not achieved by any currently available medications.[12] Many MS patients also report that the relief afforded by cannabis has allowed them to discontinue many of the conventional medications that caused debilitating side effects. See FORBIDDEN MEDICINE at 80-94.

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[11] P. Consroe et al., The Perceived Effects of Smoked Cannabis on Patients With Multiple Sclerosis, 38 European Neurology 44 (1997) (reporting 91-98% of respondents experienced lessened nighttime spasticity and muscle pain, and 71-74% of respondents reported decreased night leg pain, depression, tremor, anxiety, spasms on walking, leg weakness, trunk numbness, and facial pain).

[12] H. Meinck et al., Effect of Cannabinoids on Spasticity and Ataxia in Multiple Sclerosis, 236 J. of Neurology 120 (1989).

**Seizures:** Clinical experience and emerging research further indicate that cannabis can help control epileptic seizures. Lords Report at § 5.31; FORBIDDEN MEDICINE at 66-80. Cannabidiol (CBD), one of the primary (and non-psychoactive) cannabinoids present in the cannabis plant, appears to be of particular benefit, allowing patients who ingest it in the auric phase of a seizure to avoid seizure activity. Some epileptics who cannot tolerate conventional anti-seizure medications have been able to use cannabis to successfully control their seizures, absent debilitating side effects. See J. Cunha, Chronic Administration of Cannabidiol to Healthy Volunteers and Epileptic Patients, 21 Pharmacology 175 (1980); Declaration of Dr. Lester Grinspoon, at 76-79. See also Regina v. Parker [2000] 75 C.R.R. (2d) 233 (holding that epileptic who suffered "frequent serious and potentially life-threatening seizures" and for whom surgery and conventional medications were unsuccessful is entitled to take herbal cannabis to control seizures notwithstanding the prohibition of medicinal cannabis use under Canadian drug control statutes).

As these studies and reports demonstrate, where conventional therapies are unsatisfactory for seriously ill patients, herbal cannabis can provide a restorative, sometimes life-saving alternative. In such instances, it is both ethical and legitimate for physicians to recommend and patients to choose such treatment.

### B. The Side Effects of Medicinal Cannabis are Often Less Severe Than Those of Conventional Medications.

As an initial matter, it is important to note that this case concerns the narrow class of people who meet the

definition of medical necessity, meaning that they have no other alternative to relieve their pain and suffering. Further, as the warnings that accompany numerous over-the-counter and prescription medications make clear, the Food and Drug Administration approves, and physicians order, medications that can cause debilitating, even fatal reactions in persons who ingest them. Against this backdrop, there is significant evidence that cannabis "is safer, with fewer serious side effects than most prescription medicines, and far less addictive or subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics." Declaration of Dr. Lester Grinspoon, J.A. at 136.

The Institute of Medicine examined the various potential harms associated with the medical use of cannabis and determined that "the adverse effects of cannabis are within the range tolerated for other medications." IOM Report at 127-28. Indeed, cannabis is considered to have a very wide margin of safety, see Regina v. Parker, 75 C.R.R. (2d) at *48-49 (noting wide margin of safety of, and no evidence of overdose fatality from cannabis), whereas even the most commonly used synthetic analgesics – aspirin, acetaminophen (Tylenol), and nonsteroidal anti-inflammatory drugs like ibuprofen – are attributed with causing as many as 76,000 hospitalizations and more than 7,600 deaths annually. FORBIDDEN MEDICINE at 109.

**Immune system:** Of particular import to individuals with HIV/AIDS, cannabis shows no indication of having an immuno-suppressant effect. See IOM Report at 110. A recent study by Dr. Donald Abrams at the University of California San Francisco confirms that the use of cannabis does not adversely affect the immune system of HIV patients taking antiretroviral therapies. See D. Abrams, Short Term Effects of Cannabinoids on HIV-1 Viral Load, presented at

the 13th International AIDS Conference at Durban, South Africa (July 2000).[13]

**Cardiovascular system:** The ingestion of cannabis raises the heart rate, but there is no evidence that this increase poses a risk of cardiac arrest in patients who do not have pre-existing heart problems. See IOM Report at 121.

**Pulmonary system:** As for pulmonary effects, smoked herbal cannabis unquestionably causes tars to be introduced into the respiratory tract. Like for smokers of tobacco, studies have suggested that cannabis smokers have a greater number of cellular and molecular abnormalities in the bronchial epithelium cells than nonsmokers, and that these changes are associated with an increased cancer risk. S. Barsky et al., Histopathologic and Molecular Alterations in Bronchial Epithelium in Habitual Smokers of Marijuana, Cocaine, and/or Tobacco, 90 J. of the National Cancer Institute 1198 (1998). On the other hand, "[t]here is conflicting evidence on whether regular marijuana use harms the small airways of the lungs." IOM Report at 115. Thus, it is uncertain whether smoking cannabis, particularly for patients who may only consume enough to mitigate their symptoms, can actually cause pulmonary harm, such as chronic obstructive pulmonary disease (COPD) or lung cancer. See L. Zimmer and J. Morgan, MARIJUANA MYTHS, MARIJUANA FACTS 113-15 (1997); S. Sidney et al., Marijuana Use and Cancer Incidence, 8 Cancer Cause and Control 722 (1997).

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[13] Cannabis can contain viable fungal spores, which can pose a hazard for patients with compromised immune systems. However, cannabis can be easily sterilized in a home oven at 300 degrees Fahrenheit, for five minutes to kill spores without degrading or vaporizing the THC. J. McPartland and P. Pruitt, Medical Marijuana and Its Use by the Immunocompromised, 3 Alternative Therapies 39, 43 (1997).

**Psychological effects:** *Amici* for the government would like this Court to believe that this case is about letting more people get "high." Nothing could be further from the truth. In fact, for seriously ill patients, who are quite debilitated by disease, the euphoric effect sought by recreational users of cannabis is generally undesirable. Accordingly, they will seek a dose that is adequate to alleviate their symptoms but not so large as to cause mental impairment. IOM Report at 84. Indeed, researchers who study the therapeutic properties of cannabis regard a patient's "high" to be an indication of excessive intake. See Lorris Evidence at 178.

**Dependence:** Patients who use cannabis on a chronic basis may develop mild physiological dependence and experience withdrawal symptoms, particularly if their cannabis use is discontinued abruptly. But these symptoms are "subtle, compared with the profound physical syndrome of alcohol or heroin withdrawal." IOM Report at 90.[14] And compared to tobacco and alcohol, dependence on cannabis is relatively rare. Id. at 94. To put the matter in perspective:

> Tolerance and dependence are normal physiological adaptations to repeated use of any drug. The correct use of prescribed medications for pain, anxiety, and even hypertension commonly produces tolerance and some measure of physiological dependence.

[14] These symptoms include restlessness, irritability, mild agitation, insomnia, sleep EEG disturbance, nausea, and cramping. Id. at 90. The IOM Report stressed that this syndrome "has only been reported in a group of adolescents in treatment for substance abuse problems or in a research setting where subjects were given marijuana or THC on a daily basis [and then precipitously withdrawn from it]." Id. at 91 (citations omitted).

Id. at 84-86. In short, the medical use of cannabis, particularly by patients who meet the stringent criteria of the medical necessity defense, does not raise serious concerns of drug dependence.

### C. For Many Seriously-Ill Patients, Marinol Does Not Offer a Satisfactory Treatment Alternative.

The federal government contends that Marinol, the brand name of dronabinol and a synthetic isomer of THC, offers "[o]ne method of delivery of cannabinoids." Brief of Petitioner at 41, n.18. Marinol, however, is not a satisfactory treatment alternative for many patients with serious and otherwise intractable conditions.

First, Marinol is composed of only a single compound, THC. By contrast, cannabis is a complex botanical substance, containing over 400 constituents and approximately 66 cannabinoids, which fall into 10 groups of closely related cannabinoids. The main cannabinoids include delta9-THC, delta8-THC, cannabidiol (CBD), cannabinol, cannabichromeme, and cannabigerol. IOM Report at 24-25. Several of these cannabinoids – not just THC – have therapeutic applications, either alone or in combination with others:

> Herbal cannabis contains a mixture of active compounds. It is too early to be certain if the therapeutic action is limited to one compound. . . . Cannabis may contain a synergistic mixture of active compounds. This is particularly likely now that we know

> there are at least two receptor specified loci of action.

Lords Evidence at 32. See also J. McPartland, Side Effects of Pharmaceuticals Not Elicited by Comparable Herbal Medicines: The Case of Tetrahydrocannabinol and Marijuana, 5 Alternative Therapies 57, 60 (July 1999). For example, CBD, which is not psychoactive, has been shown to have potential neuroprotective and anti-inflammatory uses. See A. Hampson et al., Cannabidiol and (-) Delta-9-tetrahydrocannabinol are Neuroprotective Antioxidants, 95 Proceedings of the National Academy of Science 8268 (1998) (neuroprotection); A. M. Malfait et al., The Nonpsychoactive Cannabis Constituent Cannabidiol is an Oral Anti-Arthritic Therapeutic in Murine Collagen-Induced Arthritis, 17 Proceedings of the National Academy of Science 9561 (Aug. 2000) (anti-inflammatory/anti-arthritic effect).

Second, Marinol's onset of action is gradual and prolonged. Peak blood levels only are achieved 2-3 hours after ingestion. Indeed, Marinol's delayed onset is a primary reason that the government considers Marinol to have a low abuse potential. See 63 Fed. Reg. 59,751 (Nov. 5, 1998) (Notice of Proposed Rulemaking). As a result, patients in need of immediate relief must often suffer an extended period of time before Marinol takes effect. By contrast, smoking herbal cannabis – though by no means an ideal route of ingestion – is a more efficient delivery mechanism that provides the blood stream with the therapeutic properties of cannabis almost instantaneously resulting in prompt relief for patients. In the words of one of the principal investigators for the IOM Report, "[s]moking . . . delivers rapid drug effect, whereas the THC capsule takes effect slowly and its results are variable. There are many symptoms for which a quick-acting drug is ideal, such as

pain, nausea, and vomiting." Opening Statement of Stanley J. Watson, Jr., IOM News Conference March 17, 1999.

Third, smoking herbal cannabis, despite significant drawbacks, can be a more effective and less debilitating route of ingestion than swallowing a Marinol capsule. After being swallowed, Marinol is delivered first to the stomach and then to the liver where it is metabolized into 11-hydroxy-delta 9-THC. This metabolite is 3-4 times more psychoactive than THC delivered to the lungs by smoked cannabis. IOM Report at 36. Therefore, not only do patients on Marinol suffer a prolonged wait for relief, but also often experience harsh psychoactive side effects from ingesting a full-dose of THC that they are unable to mitigate. By contrast, patients who smoke herbal cannabis can regulate their dose of THC, achieving the desired therapeutic effect without experiencing a "high."

> Many patients report relief of symptoms at a dose short of those producing psychedelic effects. This is reminiscent of the treatment of cancer pain and post-operative pain with narcotics by PCA (patient controlled analgesia) where the patient titrates their pain down to a bearable level while still thinking clearly.

Lords Evidence at 31. As Dr. Roger Pertwee, a cannabinoid researcher states:

> [S]moking . . . is actually a very good route of administration, in some ways; it is very effective, there is a very rapid absorption, and the patients have a great deal of control over how much they take. They learn to titrate.

Lords Evidence at 73.[15]

Finally, Marinol has been approved for treatment of only two indications: nausea/vomiting associated with cancer chemotherapy in patients who have failed to respond adequately for conventional antiemetic agents and AIDS-related anorexia. 64 Fed. Reg 35,928 (1999). Because Marinol must be swallowed, however, it is exceedingly difficult for some severely nauseated patients to get or keep the capsules down. See Declaration of Dr. Howard Maccabee, J.A. at 110-111. Therefore, the "choice" of Marinol is in fact illusory for some of the most seriously ill patients.

### D. Patients Cannot Obtain Meaningful Access to Cannabis Treatment Through "Alternative Options."

The federal government avers that desperate patients who seek to obtain relief from cannabis have abundant "options," other than obtaining cannabis privately after receiving the advice and approval of their physicians. The government suggests that such patients should 1) participate in a clinical trial; 2) wait until cannabis has been rescheduled; or 3) wait until a pharmaceutical-quality, nonsmoked cannabinoid product is available. For most suffering patients, these alternatives are meaningless.

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[15] As an alternative to smoking, the therapeutic components of the cannabis plant can be inhaled using vaporizer devices. Vaporizers heat cannabis to 150-200 degrees Centigrade, evaporating the cannabinoids and other volatile oils. This temperature is below the burning point of combustible plant material, so smoke is not generated. This technology has been available for over 20 years. McPartland and Pruitt, supra, at 43.

### 1. Few Patients Will be Able to Participate in Controlled Clinical Trials Involving Herbal Cannabis.

Controlled, double-blind clinical trials of new drugs are expensive to conduct. Therefore, researchers will pursue such studies only if they can obtain independent funding from a commercial sponsor, such as a pharmaceutical company, or from a grant-making entity, such as the government. But neither of these options is likely with respect to cannabis. As both the IOM and House of Lords reports note, pharmaceutical companies are unwilling to invest in clinical trials for smoked cannabis because the herbal plant would never be approved as a prescribable medicine:

> The market outlook in the U.S. is distinctly unfavorable for the marijuana plant and for cannabinoids found in the plant. Commercial interest in bringing them to market appears nonexistent.

IOM Report at 219. It is also unlikely that the government will support an adequate number of such trials. Despite the widespread interest in the subject, the National Institute of Health has funded only one clinical trial involving herbal cannabis in the last decade, and that study investigated the safety, rather than the efficacy, of its use.[16] Even for less controversial treatments, the chance of receiving NIH funding is small.[17] Only one state, California, has earmarked

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[16]See D. Abrams, Medical Marijuana: Tribulations and Trials, 30 Journal of Psychoactive Drugs 163 (1998).

[17] As the IOM Report states: "Research grant approvals are handled through the conventional NIH peer review process for extramural research, a highly competitive process with success rates in 1997 of 32%

funds to research the therapeutic effects of cannabis[18], and some of those funds may be spent on animal or *in vitro* studies. Only one county in the United States, San Mateo, California, has provided some funding for clinical research with medicinal cannabis, but that funding cannot support extensive ongoing.[19]

Even if there were an unlikely increase in the number of clinical trials of herbal cannabis, a very limited number of patients would be able to participate in these trials due to geographical restrictions or disease or symptom specificity of the research. Further, even if several trials secured government or private funding, it is not clear that the federal government – the sole lawful source in the United States for herbal cannabis – would be willing or able to provide researchers with a sufficient supply of the cannabis plant. The University of Mississippi, under exclusive contract with the National Institute on Drug Abuse (NIDA), produces all herbal cannabis for U.S. research trials. IOM Report at 213. The stocks have historically been primarily allocated to research investigating herbal cannabis as a drug of abuse and only incidentally to research investigating its therapeutic

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of approved NIDA grants. . . . In 1998, less than 25% of **all** first time investigator-initiated grant applications . . . to the NIH were funded." IOM Report at p. 214.

[18] In 1999, SB 847 codified at Health & Safety Code § 11362.9, established, but did not fund, a three-year cannabis research program to be housed within the University of California. In 2000 the legislature appropriated and the governor approved $3 million for the program's first year. Funding for future years is uncertain.

[19] The $350,000 will fund a single 12 week study involving 60 patients. Local Pot Study Sought, San Jose Mercury News, Dec. 26, 1999.

efficacy. See, e.g., http://www.nih.gov/grants/award/award.htm.[20]

### 2. The Federal Government Refuses to Provide Herbal Cannabis for Controlled Clinical Trials Involving Single Patients.

Patients who would qualify under a medical necessity defense for the use of herbal cannabis may not be eligible to participate in standard clinical trials involving herbal cannabis. Their medical conditions may be too rare or idiosyncratic to warrant even a small-scale clinical trial. Or they may live too far from the location of the nearest trial to make the frequent trips to the clinic or hospital required by many protocols. Alternatively, they may not be able to leave their families or jobs and remain sequestered in a hospital for the duration required by other clinical protocols.

Such patients nevertheless may be good candidates for "n-of-1" trials; that is, trials involving the efficacy of the drug as to a single individual. The validity and usefulness of n-of-1 trials is well documented.[21] Like larger-scale studies, n-of-1 studies are subject to the requirements of randomization and double-blinding, but each patient serves as his or her own control. This research design allows

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[20] The first researcher who attempted to obtain cannabis for research purposes under NIDA's revised cannabis access policy was denied access to the material notwithstanding the fact that his research proposal had been approved by the FDA. Letter from Dr. Steven Gust, Special Assistant to the Director (NIDA) to Dr. Ethan Russo of 2/1/00.

[21] See, e.g., E.B. Larson et al., Randomized clinical trials in single patients during a 2-year period, 270 J. of the Am. Med. Ass'n 2708 (1993); D. Cook, Randomized Trials in Single Subjects: the N of 1 Study, 32 Psychopharmacology Bull. 363 (1996).

investigators to examine a particular experimental therapy with an eye to fashioning larger-scale trials.[22] In addition, n-of-1 studies enable physicians to better respond to case-specific circumstances of patients by modifying treatment regimens.[23]

For these reasons, the IOM Report advocates n-of-1 trials for this patient population:

> Until a non-smoked, rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that **there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana**, such as pain or AIDS wasting. One possible approach is to treat patients as n-of-1 clinical trials, in which patients are fully informed of their status as experimental subjects using a harmful drug delivery system, and in which their condition is closely monitored and documented under medical supervision, thereby increasing the knowledge base of the risks and benefits of marijuana use under such conditions. **We recommend these "n-of-1" clinical trials** .

IOM Report at 179-80 (emphases added).

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[22] See, e.g., R. Van Reekum et al., N of 1 Study: Amantadine for the Amotivational Syndrome in a Patient With Traumatic Brain Injury, 9 Brain Inj. 49 (1995).

[23] See e.g., E. Wiebe, N of 1 Trials: Managing Patients With Chronic Fatigue Syndrome: Two Case Reports, 42 Can. Fam. Physician 2214 (1996).

Yet despite the support for n-of-1 studies in the scientific literature and the recommendation of the IOM, the U.S. Department of Health and Human Services ("HHS") rejected this design for studies involving herbal medicinal cannabis. On May 21, 1999, HHS published an "Announcement of the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research."[24] In the Department's words, "the single-patient IND [investigative new drug] process would not produce useful scientific information, and we do not foresee that they would be supported under this program." Id. The rejection by HHS of n-of-1 studies deprives many patients of access to medicinal cannabis within a bona fide research project.

### 3. Pharmaceutical-Quality, Nonsmoked Cannabis Medicines Are Years Away from Development and Marketing.

The IOM Report describes the obstacles that any pharmaceutical company would face when undertaking the kind of research and development program with herbal cannabis that would be required for FDA approval. The costs of development are substantial, and the uncertainty of rescheduling a product developed from the plant creates a deterrent to investment. By contrast, Marinol was developed and marketed with substantial support from the federal

[24] According to HHS policy, cannabis would be made available to only approved research projects. However, the policy establishes an additional hurdle for independently-funded researchers, who must have their clinical protocols approved not only by the FDA, but also by an ad hoc panel of the Public Health Service, which employs separate approval criteria. Normally, an independent researcher must only have his or her protocol approved by the FDA.

government.[25] It is extremely unlikely that an herbal cannabis product would receive the extensive governmental assistance conferred upon Marinol. As an additional obstacle, potential patent protection for materials derived from naturally-occurring plants may be quite limited. Thus, the lack of commercial interest is not surprising. The IOM Report concludes:

> . . . the development of the marijuana plant is beset by significant scientific, regulatory, and commercial obstacles and uncertainties. The prospects of its development as a new drug are unfavorable, unless return on investment is not a driving force. It is noteworthy that no pharmaceutical firm has sought to bring it to market in the U.S.

Id. at 219.

Even if a pharmaceutical company were to begin developing a pharmaceutical-quality cannabis medicine administered through a rapid-onset alternative (i.e., nonsmoked) delivery mechanism, it would take several years to obtain marketing approval in the U.S.[26] Depending on the delivery mechanism used, the product might require approval

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[25] Preclinical and clinical research on Marinol were largely supported by the National Cancer Institute. The scheduling of Marinol was expedited by the DEA, which scheduled the drug before the FDA approved it for marketing. IOM Report at 202-03. Moreover, the FDA did not require the manufacturer to perform costly abuse liability studies, id., thus dramatically reducing the time and cost of bringing Marinol to market. Id. at 218.

[26] Only one small British pharmaceutical company, GW Pharmaceuticals Ltd., has begun to develop cannabis-based medicines derived from the whole plant. See www.medicinal-cannabis.org. This company has not yet begun a formal development program in the U.S.

under both the new drug and device processes set out in federal law. See 21 C.F.R. Part 3 (combination products). In short, any suitable pharmaceutical alternative to herbal cannabis will not come to market for several years, if at all.

**4. The Prospect of the Rescheduling of Herbal Cannabis is Remote and Uncertain.**

The federal government also suggests that suffering and dying patients have the option of waiting until herbal cannabis is removed from Schedule I of the CSA. To date, however, such rescheduling efforts have encountered years of delay in proceeding through the administrative gauntlet. In 1972, the National Organization for the Reform of Marijuana Laws sought to reschedule cannabis. After 22 years of litigation, that effort failed. Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C.Cir. 1994).

In July 1995, Jon Gettman filed a petition seeking the rescheduling of cannabis based on new developments in scientific knowledge. After five and one-half years, that petition has still not emerged from the Department of Health and Human Services. Even if HHS were to recommend that herbal cannabis should be rescheduled, its recommendation would not be binding on the Drug Enforcement Administration, which would undertake its own evaluation based on factors set forth in 21 USC § 811. Even if successful, these processes would not be completed in time to bring relief to the clients of the Oakland Cannabis Buyers' Cooperative who currently meet the stringent medical necessity criteria for herbal cannabis.

## V. CONCLUSION

For the foregoing reasons, the judgment of the United States Court of Appeals for the Ninth Circuit should be affirmed.

Respectfully submitted,

*DANIEL N. ABRAHAMSON
JUDITH K. APPEL
The Lindesmith Center
1095 Market Street, Suite 505
San Francisco, CA 94103
Telephone: (415) 554-1900

Attorneys for *Amici Curiae*

*(Counsel of Record)

## APPENDIX

*Amicus Curiae* American Public Health Association ("APHA"), founded in 1872, is the largest public health organization in the world, representing over 50,000 public health professionals. A national organization, APHA is devoted to the promotion and protection of personal and environmental health. It represents all disciplines and specialties in public health, including maternal and child health and substance abuse. APHA strives to improve public health for everyone by proposing solutions based on research, helping to set public health practice standards, and working closely with national and international health agencies

*Amicus Curiae* California Nurses' Association ("CNA") is the largest organization of Registered Nurses in California, representing 31,000 members in more than 100 hospitals, clinics, and home health agencies. Over the past decade CNA has been one of the fastest growing health care unions in the nation, earning a national reputation for its efforts in the field of regulatory reform and patient advocacy. It is in light of the experiences of its constituent members, who work daily on the front lines not only with seriously ill patients but also with the latest medicines and medical technologies, that CNA endorses medical cannabis as a legitimate treatment option for certain seriously ill patients.

*Amicus Curiae* Lymphoma Foundation of America is a national nonprofit organization devoted to helping lymphoma patients and their families. An estimated 62,000 new cases of lymphoma (cancers of the lymph system) will be diagnosed this year. It is the Lymphoma Foundation's experience, over many years, with thousands of patients, that marijuana is an efficacious and at times necessary treatment

for nausea, vomiting, and lack of appetite – serious, sometimes life-threatening symptoms that afflict many lymphoma patients undergoing chemotherapy and radiation.

*Amicus Curiae* Irvin Henry Rosenfeld was diagnosed at age 10 with multiple congenital cartilogenous exostosis, a disease causing the continuous growth of bone tumors, and the generation of new tumors, on ends of most of the long bones in his body. He was told he would not survive into adulthood. In an attempt to treat the painful symptoms of this disease, he was prescribed high doses of opioid analgesics, muscle relaxants and anti-inflammatory medications which he took on a daily basis, but which had minimal efficacy and produced debilitating side effects. In 1971, Mr. Rosenfeld began using smoked herbal cannabis with the approval and under the supervision of a team of physicians. Mr. Rosenfeld found the cannabis highly efficacious in alleviating pain, reducing swelling, relaxing muscles and veins that surround the bone tumors, and preventing hemorrhaging. In 1982, the United States government, operating under the Compassionate Care IND Program, at the request of his physicians, began supplying Mr. Rosenfeld with herbal cannabis to treat his condition. For the past 19 years, the government has consistently provided him with a 75-day supply of herbal cannabis, totaling 33 ounces per shipment. Mr. Rosenfeld smokes 12 marijuana cigarettes a day to control the symptoms of his disease. In the 30 years that Mr. Rosenfeld has used herbal cannabis as a medicine, he has experienced no adverse side effects (including no "high"), has been able to discontinue his prescription medications, and has worked successfully for the past 13 years as a stockbroker handling multi-million dollar accounts. Mr. Rosenfeld and his physicians believe that but for herbal cannabis, Mr. Rosenfeld might not be alive, or, at the very least would be bed-ridden.

*Amicus Curiae* Barbara M. Douglass was diagnosed with Multiple Sclerosis in 1988 at the age of 22. In 1991, Ms. Douglass began receiving herbal cannabis from the United States government upon the advice and assistance of her physician. Prior to this date, Ms. Douglass had never tried cannabis. Each month, the government provides her physician with one can containing three hundred cannabis cigarettes, each weighing 7/10 oz. Ms. Douglass and her physician report that herbal cannabis provides relief from pain, spasms, and stimulates her appetite to counteract the effects of wasting syndrome from which she suffered prior to using cannabis. Ms. Douglass has never experienced any adverse side effects from marijuana. Without cannabis, Ms. Douglass believes she would not be alive today.

*Amicus Curiae* Elvy Musikka was diagnosed with glaucoma in 1975 at the age of 36. She tried conventional medications to treat her condition, but could not tolerate them. Reluctantly, in 1976, she decided to try herbal cannabis at the advise of her physician. The cannabis provided her immediate relief, substantially lowering her intraocular pressure as no other medication had, and with few side effects. Ms. Musikka ingests cannabis by smoking it, as well as eating it in baked goods and olive oil. Fearful of the legal consequences of smoking cannabis, Ms. Musikka underwent several risky surgeries in an attempt to correct her condition, but they were unsuccessful and left her blind in one eye. In 1988 Ms. Musikka was arrested in Florida and charged with cannabis possession. She challenged her conviction in the Florida Supreme Court where she prevailed, becoming the first person in that state to establish a medical necessity defense for cannabis. Shortly thereafter, the federal government enrolled Ms. Musikka in its medical cannabis program and has provided her with one and one-half pounds of herbal cannabis on a quarterly basis ever since. Mrs.

Mussika and her physician believe that if she were deprived of cannabis she would go blind.

*Amicus Curiae* George Lee McMahon was born July 22, 1950 with Nail Patella Syndrome, a rare genetic disorder that causes severe pain, nausea and muscle spasms. Mr. McMahon tried conventional medications to treat his symptoms, but found the side effects of these medications to be intolerable. In the early 1980's Mr. McMahon discovered that herbal cannabis alleviated his pain, nausea and spasms, stimulated his appetite and allowed him to sleep through the night. In 1988 Mr. McMahon informed his physician that he was successfully self-medicating with cannabis. His physician ordered him to cease his cannabis use and return to prescription medications. Over the following six months, Mr. McMahon's health progressively degenerated. Mr. McMahon's physician then helped Mr. McMahon apply to the federal government's Compassionate Care IND Program. In March 1990, Mr. McMahon was accepted into the program and for the past decade has received 300 cannabis cigarettes each month from the United States government. Mr. McMahon and his physician believe that without cannabis Mr. McMahon would not be alive today.

*Amicus Curiae* American Medical Women's Association ("AMWA") is a national, non-profit organization of over 10,000 women physicians and physicians-in-training representing every medical specialty. Founded in 1915, AMWA is dedicated to promoting women in medicine and advocating for improved women's health policy.

*Amicus Curiae* Colorado Nurses' Association ("CNA") is a professional organization of registered nurses in Colorado and is a constituent of the American Nurses' Association. The primary purpose of this association for the past 90 years has been to provide direction and a voice for the profession

of nursing and nurses as leaders in health care, and to work for the improvement of health standards and the availability of health care services for all people.

*Amicus Curiae* AIDS Treatment Initiatives ("ATI") is a nonprofit organization devoted to enhancing the quality of life and extend long-term survival for people living with HIV disease through treatment education, treatment advocacy, and access to complementary therapies. ATI accomplishes this mission through nutrition and adherence counseling services, symptom and side effect management, and adjunct consulting services to primary care physicians. ATI was incorporated in 1991 and supports an active client caseload of 1,200 client members. ATI's primary geographic focus is the Southeastern United States but nationally serves client members located throughout the United States.

*Amicus Curiae* AIDS Resource Center of Wisconsin ("ARCW"), through its Legal Services Program, provides direct legal representation to hundreds of persons living with HIV and AIDS throughout the entire state of Wisconsin at no charge to the clients. In addition handling a variety of legal matters including HIV confidentiality, social security benefits, employment matters and estate planning, ARCW pursues impact litigation and public advocacy projects.

*Amicus Curiae* AIDS Project Arizona is an organization dedicated to stopping the transmission of HIV, empowering infected persons to live longer, healthier lives and providing an innovative, comprehensive continuum of services for individuals and families affected by the disease.

*Amicus Curiae* Mothers Against Misuse and Abuse (MAMA) is a non-profit organization founded in 1982, which provides an educational approach to the many aspects of substance use. In today's society, in addition to problems

with illegal drugs, there are high levels of alcohol abuse, prescription drug misuse and abuse, and great harm caused by excessive consumption of nicotine, caffeine and over-the counter drugs. MAMA offers guidelines for evaluating a drug's benefits and risks, including both health risks and legal risks. MAMA's goals are to promote better communication; to provide current, scientific drug education to all ages of society; and to advocate for appropriate treatment, including the use of medical marijuana for seriously ill patients.

*Amicus Curiae* Marin County Medical Society of California is an organization representing 400 members and whose purpose is to promote and develop the science and art of medicine and the care and well-being of patients; to conserve and protect the health of the public; to promote the betterment of the medical profession; to cooperate with groups of like purposes and to unite with similar organizations in the formation and activities of the California Medical Association.

*Amicus Curiae* The Gay and Lesbian Medical Association (GLMA) is a tax-exempt 501(c)3 non-profit organization working to end homophobia in healthcare. Our membership of 2,000 medical professionals represents the interests of more than 70,000 lesbian, gay, bisexual, and transgender (LGBT) physicians and medical students, as well as millions of LGBT patients throughout North America who seek equality in healthcare access and delivery. GLMA promotes quality health care for LGBT and HIV-positive people, including access to medical marijuana for seriously ill patients.