No. 00-17222

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MARCUS CONANT, *et al.*,

Plaintiffs-Appellees,

v.

EDWARD JURITH, Acting Director of the Office of National Drug Control Policy, *et al.*,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

BRIEF OF AMICI AMERICAN PUBLIC HEALTH ASSOCIATION, AMERICAN MEDICAL STUDENT ASSOCIATION, CALIFORNIA NURSES ASSOCIATION, LYMPHOMA FOUNDATION OF AMERICA, BARBARA M. DOUGLASS, GEORGE LEE McMAHON, ELVY MUSIKKA and IRVIN HENRY ROSENFELD ON BEHALF OF THE APPELLEES SUPPORTING AFFIRMANCE

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I. IDENTITY OF THE AMICI CURIAE

Amici Curiae are highly respected health care and medical organizations, including the American Public Health Association, the California Nurses Association, and the Lymphoma Foundation of America, and four individuals who have found marijuana uniquely effective in treating their particular conditions and who, under a physician's supervision, are receiving federally supplied medical marijuana, Barbara M. Douglass, George Lee McMahon, Elvy Musikka, and Irvin Henry Rosenfeld.[1]

Amici represent both sides of the health care equation who together, through firsthand experience and reliance on scientific studies, believe that physicians should be able to discuss and, when appropriate, recommend the use of marijuana. On one side of the equation are health care professionals who have regular contact with persons in need of relief from debilitating symptoms of serious illnesses. The other side of the equation is represented by patients who suffer from serious illnesses, who have found relief from smoking marijuana when authorized prescription drugs have failed to alleviate their symptoms. Indeed, four of the Amici are seriously ill persons whose physicians not only recommended medical marijuana but who also successfully sought permission from the federal government for their patients to obtain and use medical marijuana.

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[1] A more detailed description of each *Amicus* is provided at Appendix 1 to this brief.

Amici, as a result of their scientific training and personal experiences, are uniquely qualified to discuss the medical evidence supporting the use of marijuana to treat certain illnesses. By providing the Court with a review of the scientific evidence supporting medical marijuana's efficacy, *Amici* herein illustrate that recommendations and discussions concerning marijuana are grounded in legitimate science.

Amici have received the consent of all parties for the filing of this brief. This brief supports the affirmance of the permanent injunction preventing the federal government from (a) revoking a physician's Drug Enforcement Administration ("DEA") registration merely because the doctor recommends medical marijuana to a patient based on a sincere medical judgment and (b) from initiating any investigation solely on that ground. ER 283.

II. SUMMARY OF ARGUMENT

This case involves the federal government's continued attempts to interfere with vital, medically sound, and necessary communications between doctors and their severely ill patients. A small but significant number of seriously ill patients who suffer from cancer, HIV/AIDS, multiple sclerosis, epilepsy, or other serious medical conditions do not benefit from, or cannot tolerate, the currently available conventional therapies available in the medical armamentarium. Many of these patients, together with their physicians, have found that marijuana effectively alleviates symptoms of their conditions and side effects caused by their primary treatments.

The experiences of patients and the observations of their physicians are in accord with the conclusions of medical researchers, and recent government-sponsored commissions that have concluded that marijuana has therapeutic properties not replicated by other currently available medications. In fact, for affected persons, the medical use of marijuana can literally mean the difference between life and death. At a minimum, marijuana provides some seriously ill patients the gift of relative health and the ability to function as productive members of society. Moreover, the side effects of marijuana are typically less severe than side effects associated with currently authorized medications.

In choosing how to manage their illnesses, patients are entitled to complete and candid discussions and, where appropriate, recommendations concerning marijuana (as well as other bona fide medical options) as a possible therapy for certain conditions, particularly when conventional therapies fail to provide adequate relief. How a patient decides to use the information received from his or her physician is a personal decision solely within the control of the patient.[2] The key, however, is that each and every patient is entitled to be fully informed.[3]

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[2] For example, a particular patient may choose to participate in research projects using federally supplied marijuana. *See* Bill Workman, *Pot study in spotlight: San Mateo County's clinical trial is a first in U.S.*, S.F. Chron., July 25, 2001 (noting that a $500,000, 1 ½year study investigating the efficacy of marijuana on selected HIV/AIDS patients received federal approval and is obtaining federally harvested marijuana), *available at* http://www.sfgate.com/wais/search/arch-pro.shtml; *see also* University of California Center for Medicinal Cannabis Research Web Site (listing 11 approved studies that will utilize federally supplied marijuana,

Despite convincing evidence that marijuana can be an effective anti-inflammatory, analgesic, appetite-stimulating, antiemetic, and antispasmodic agent, the government seeks to prohibit doctors from "recommending"—but not "discussing"—these beneficial uses of medical marijuana. The government's attempt to differentiate between "recommending" and "discussing" is simply meaningless when applied to the clinical world of a physician.[4]

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including the previously mentioned San Mateo County study being conducted by Dr. Israelski) *available at* http://www.cmcr.ucsd.edu/geninfo/research.htm.

[3] The government erroneously tries to bring this case within the scope of the Supreme Court's recent opinion in *United States v. Oakland Cannabis Buyers' Coop.*, 121 S. Ct. 1711 (U.S. 2001). In *Oakland Cannabis Buyers' Coop.*, the Supreme Court held that "medical necessity is not a defense to manufacturing and distributing marijuana" in violation of the federal Controlled Substances Act, 21 U.S.C. § 841. *Id.* at 1719. The issue before this Court does **not** involve the distribution or manufacture of marijuana, nor does it involve a compassionate use exception for individuals, an issue expressly left open by the Court in *Oakland Cannabis Buyers' Coop*. *Id.* at 1724 (Stevens, J. concurring).

[4] In granting the plaintiffs' request for a permanent injunction, the district court succinctly identified the fallacy of the government's attempt to distinguish between "discuss" and "recommend":

> The government's test is wholly unworkable. The government would define "recommend" as "to present as worthy of confidence, acceptance, use, etc." or "to suggest." It would be impossible to discuss even the pros and cons without, at least in some cases, the patient concluding that the doctor is suggesting marijuana or "presenting it as worthy of acceptance." This would be so even if the doctor never used the term "recommend" or "suggest."

Amici firmly and reasonably believe that if the District Court's ruling is not upheld, their physician members will not be able to fulfill their ethical duties as clinicians and health professionals. Thus, contrary to the government's position that medical marijuana is contrary to the public interest, it is the government's threats and a scenario of unfounded and arbitrary prohibitions on a doctor's ability to freely exercise medical judgment that is "inconsistent with the public interest."[5]

ER 281.

[5] The Controlled Substance Act permits the Attorney General to suspend or revoke a physician's permit to prescribe controlled substances if the physician "has committed such acts as would render his registration under section 303 [21 U.S.C. § 823] inconsistent with the pubic interest." 21 U.S.C. § 824(a)(4). According to the government's position in this case, notwithstanding its own role as a producer and supplier of medical marijuana, a doctor's recommendation of marijuana—a drug with demonstrated effectiveness for some patients and for which there is no presently available authorized substitute—is contrary to the "public interest" in all states, including the eight states that have passed laws permitting medical marijuana.

Since 1996, at least 6 states, Alaska, California, Maine, Nevada, Oregon, and Washington, have passed laws based on voter initiatives. *See* Alaska Stat. Ann. §§ 11.71.090, 17.37.010 to .080 (2000); Cal. Health & Safety Code § 11362.5 (2001); Me. Rev. Stat. Ann. tit. 22, § 2383-B5 (2000); Nev. Const., art. 4, § 38; Or. Rev. Stat. §§ 475.300 to .346 (1999); Wash. Rev. Code §§ 69.51A.005 to .902 (1997 & Supp. 2000-01). Hawaii has enacted similar measures through its legislature. Haw. Rev. Stat. §§ 329-121 to -128 (Supp. 2000).

III. RELIABLE SCIENCE AND FIRSTHAND CLINICAL EXPERIENCE PROVIDE A SOUND BASIS FOR DOCTORS TO RECOMMEND MARIJUANA TO CERTAIN SERIOUSLY ILL PATIENTS.

Clinical experience and a growing body of medical research confirm that for a small but significant number of patients, marijuana serves as the **only** effective medicine for suppressing nausea, stimulating appetite, or relieving pain.

Numerous studies by blue-ribbon government panels and federally funded, peer-reviewed scientific studies have consistently found that marijuana is effective for treating certain symptoms. Additionally, scientific studies establish that marijuana's side effects are often less severe than those of drugs currently approved for treating the same ailments. Moreover, the personal experiences of doctors and patients who have firsthand experience with the efficacy of marijuana is in accord with the conclusions of the scientific studies.

A. BLUE-RIBBON GOVERNMENT PANELS HAVE CONCLUDED THAT MARIJUANA IS EFFECTIVE AND MEDICALLY BENEFICIAL.

1. A U.S. commissioned study concluded that cannabinoid drugs are of potential therapeutic value.

In 1997, largely in response to the passage of California's Compassionate Use Act[6] and the preliminary injunction issued by the federal district court in this

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[6] Cal. Health & Safety Code § 11362.5 (West Supp. 2001) (available online at http://www.leginfo.ca.gov/calaw.html).

action,[7] the White House Office of National Drug Control Policy commissioned the National Institute of Medicine of the National Academy of Sciences ("IOM")[8] to undertake an extensive review of the scientific evidence of the therapeutic applications of cannabis. *Institute of Medicine Marijuana and Medicine: Assessing the Science Base*, (Janet E. Joy, et al., eds., National Academy Press 1999) ("IOM Report").[9] The IOM was tasked with assessing the current scientific findings concerning medical marijuana. In accomplishing its task, the IOM reviewed the scientific bases identifying the active ingredients of marijuana, how those ingredients act on human and animal physiology, and clinical experiments evaluating the efficacy of marijuana and several of its active agents. IOM Report at 9.

After an exhaustive year-long study that included scientific workshops, analysis of relevant scientific literature, and extensive consultation with biomedical

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[7] ER 50-92 (enjoining the government from threatening California physicians with sanctions if they discussed the medical benefits of cannabis with their patients).

[8] The IOM 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's responsibility to advise the federal government on such issues pursuant to an 1863 congressional charter.

[9] The complete IOM report is available at http://www.nap.edu/books/0309071550/html.

and social scientists, the IOM's 250-plus-page report concluded that "[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation." IOM Report at 15, 179.

The IOM acknowledged that marijuana currently provides the only alternative for certain people for whom approved medicines are ineffective and emphasized the desirability of further research into the effects of cannabinoids and the development of delivery systems by which the active ingredients of marijuana can be delivered to patients in a dose-controlled, smoke-free manner. IOM Report at 10-11, 179. As a result, it is not surprising that the IOM conditionally endorsed medical marijuana.[10]

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[10] 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, the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs, such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and involves 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 marijuana 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' marijuana use be reevaluated on at least a semiannual basis. The authors' reluctance to approve the longer-term use of

Examples of specific findings and studies relied on by the IOM are identified in Section C below.

2. An administrative law judge concluded that marijuana has accepted medical uses.

In the late 1980's, as part of the response to petitions to remove marijuana from the list of Schedule I substances,[11] the United States Department of Justice referred the matter to an Administrative Law Judge for evidentiary hearings and an advisory opinion. In September 1988, after more than two years of proceedings, Administrative Law Judge Francis L. Young, pursuant to the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, released an *Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge in the Matter of Marijuana Rescheduling Petition*, Docket No. 86-22 (Dep't Justice D.E.A., Sept. 6, 1988) (hereinafter, "ALJ Opinion").[12] ALJ Young found that the facts established that marijuana has an "accepted medical use" for

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cannabis was based primarily on their concern about the possible pulmonary risks posed by smoking marijuana.

[11] *See* 21 U.S.C. § 812.

[12] The complete text of ALJ Young's option is available at http://www.druglibrary.org/schaffer/library/studies/YOUNG/index.html.

treatment of (a) nausea resulting from chemotherapy, (b) spasticity resulting from multiple sclerosis and other causes, and (c) hyperparathyroidism.[13]

Additionally, the ALJ Opinion held that "there is accepted safety for use of marijuana under medical supervision." ALJ Opinion at 66. In particular, ALJ Young noted that "[t]here was no record in the extensive medical literature describing a proven, documented cannabis-induced fatality," and that marijuana has an estimated LD-50 rating[14] of between 1:20,0000 and 1:40,0000. ALJ Opinion at 56-57. In lay terms, a smoker would have to consume 20,000 to 40,000 times as much marijuana as contained in one marijuana cigarette (approximately 1,500 pounds) in fifteen minutes to induce a lethal response.[15] ALJ Opinion at 57.

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[13] Hyperparathyroidism is a condition causing increased calcium in the blood. Symptoms include nausea, vomiting, abdominal pain, skeletal pain, and weakened skeletal structure. *See* http://www.familydoctor.org, American Academy of Family Physicians, 2000.

[14] An LD-50 or LD_{50} value is the amount of material that it takes to kill 50% of a test group in one dose. LD-50's are extrapolated for human dosage from animal studies.

[15] In contrast, aspirin causes hundreds of deaths each year and has a therapeutic ratio of 1:20. *See* ALJ Opinion at 58. A therapeutic ratio "defines the difference between a therapeutically effective dose and a dose which is capable of inducing adverse effects." *Id.* For example, two aspirins is the generally recommended dose for adults, and forty aspirins may "cause a lethal reaction in some patients and will almost certainly cause gross injury to the digestive system, including extensive internal bleeding." *Id.* "[M]arijuana's therapeutic ratio, like its LD-50 rating, is impossible to quantify because it is so high." *Id.*

ALJ Young concluded:

> [t]he evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA [the Drug Enforcement Administration] to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.

ALJ Opinion at 68. In response, the Administrator of the DEA rejected the findings and recommendations of ALJ Young, asserting that there was no scientific evidence showing that marijuana was better than other approved drugs for any specific medical condition *See* 54 Fed. Reg. 53767 (Dec. 29, 1989). It was through the DEA's statement not ALJ Young's findings and recommendation that were without support.

Indeed, in the intervening years since ALJ Young's opinion, additional evidence has come to light that reinforces ALJ Young's findings. For example, the DEA stated, without citation, that "[t]he oncological community does not consider marijuana to have currently accepted medical use . . . for the treatment of emesis [vomiting] caused by cancer chemotherapy." *Id.* (Finding of Fact No. 47). But, a random-sample, anonymous survey of the members of the American Society of Clinical Oncology conducted in 1990 found that more than 44% of respondents reported recommending the use of marijuana for the control of emesis to at least

one cancer chemotherapy patient, and 48% would prescribe marijuana to some of their patients if it were legal.[16]

The DEA also criticized ALJ Young for failing to "acknowledge the position of . . . the American Medical Association." But the AMA's Council on Scientific Affairs, since at least 1997, has cautiously acknowledged the potential medical efficacy of marijuana and called for additional

> adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.[17]

In both of its 1997 and 2001 policy statements, the AMA also stated that "effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions."[18]

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[16] *See* SER 30-35, Richard E. Doblin & Mark A.R. Kleiman; *Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes*, 9 J. Clin. Oncol. 1314-1319 (1991).

[17] Report 10 of the Council on Scientific Affairs (I-97), *Medical Marijuana 28, available at* http://www.ama-assn.org/ama/pub/article/2036-4299.html. The recommendation for additional research was affirmed at the AMA's 2001 Annual Meeting. Report 6 of the Council on Scientific Affairs (A-01), *Medical Marijuana, available at* http://www.ama-assn.org/ama/pub/article2036-4971.html.

[18] Report 10 (I-97) at 28; Report 6 (A-01) at 2.

3. Great Britain has concluded that marijuana holds unique medical benefits for certain seriously ill patients.

While the IOM was conducting its evaluation, Great Britain's House of Lords was also conducting hearings and taking testimony from leading researchers, clinicians and patients regarding the medical benefits and drawbacks of cannabis.[19] The findings and recommendations of the Lords Report parallel those of the IOM. The House of Lords concluded that "cannabis almost certainly does have genuine medical applications, especially in treating the painful muscular spasms and other symptoms of MS and in the control of other forms of pain."[20]

Given the state of current medical knowledge and anecdotal evidence attesting to the efficacy of marijuana, the House of Lords concluded that the

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[19] Select Committee on Science and Technology, House of Lords, Sess. 1997-98, 9th Report, *Cannabis: The Scientific and Medical Evidence: Report* (Nov. 4, 1998), *available at* http://www.publications.parliament.uk/pa/ld199798/ldselect/ldsctech/151/15101.htm ("Lords Report").

[20] Lords Report § 8.2, at 41. The House of Lords called for additional scientific studies into marijuana's medical value as well as identifying alternative modes of administration which would retain the benefit of rapid absorption offered by smoking, without the adverse effects. Lords Report §§ 8.1-8.4, at 41.

government should act immediately "to allow doctors to prescribe an appropriate preparation of cannabis, albeit as an unlicensed medicine."[21]

4. Canada recently passed a medical marijuana law after evaluating the scientific evidence.

On July, 30, 2001, Canada's "Marihuana Medical Access Regulations" came into force.[22] These regulations permit the possession and production of marijuana for medical purposes and were developed by Health Canada after it had reviewed the scientific evidence regarding the therapeutic value of smoked marijuana and conducted its own survey in 2000-2001 to gather and analyze data regarding the medical uses of marijuana. While Health Canada's official position mirrors that of the AMA, i.e., scientific studies supporting the safety and efficacy of marijuana for

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[21] Lords Report § 8.6 at 41. The United Kingdom, unlike the United States, allows physicians to prescribe an unapproved medicine to a particular patient, so long as certain conditions are followed. *See generally*, Lords Report at 22.

[22] Marihuana Medical Access Regulations, SOR 2001-227, § 2 *et seq.* (June 14, 2001) (Can.), *available at* http://www.hc-sc.gc.ca/hecs-sesc/ocma/index.htm. These regulations resulted from a year-long effort to address several issues revolving around the Ontario Court of Appeal's decision that the then existing exemptions to the Controlled Drugs and Substances Act were unconstitutional. *See R. v. Parker*, 2000 W.C.B.J. LEXIS 10970, 75 C.R.R. (2d) 233, 47 W.C.B. (2d) 116 (July 31, 2000) (*available at* http://www.ontariocourts.on.ca/decisions/2000/july/parker.htm); Regulatory Impact Analysis Statement for the Marihuana Medical Access Regulations amending the Narcotic Control Regulations (7/4/2001), *available at* http://www.hc-sc.gc.ca/hecs-secs/ocma/index.htm.

therapeutic claims are, to date, inconclusive, it nevertheless developed regulations to allow certain persons the ability to possess and cultivate marijuana for medical use.

Consistent with the IOM, the House of Lords, and the weight of scientific evidence and personal experiences attesting to marijuana's efficacy, Canada's new law permits doctors to recommend and prescribe medical marijuana to certain persons who are suffering from severe pain, muscle spasms, anorexia, weight loss, and nausea, and who have not found relief from conventional therapies.[23]

B. SYNTHETIC THC IS APPROVED AS A PRESCRIPTION DRUG, BUT IS OFTEN NOT AS EFFECTIVE, DESIRABLE, OR SAFE AS SMOKING MARIJUANA.

Marinol—the brand name of dronabinol and a synthetic isomer of THC—is not a satisfactory treatment alternative for many patients for at least four reasons. First, while Marinol is approved by the Food and Drug Administration to treat nausea and vomiting associated with cancer chemotherapy and anorexia associated with weight loss in patients with AIDS, it paradoxically is often vomited before it can counteract the vomiting. 64 Fed. Reg. 35,928 (1999). Moreover, many patients suffering from the symptoms for which Marinol is approved, are unable to swallow the drug. As a result, patients are often unable to ingest a sufficient quantity of the drug to benefit from its effects. *See* Declaration of Dr. Howard

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[23] Office of Cannabis Medical Access, *Medical Access to Marijuana – How the Regulations Work*, *available at* http://www.hc-sc.gc.ca/hecs-sesc/ocma/bckdr_1-0601.htm.

Maccabee, SER 123 ¶ 9; Declaration of Dr. Marcus Conant, SER 61 ¶ 15. In contrast, neither vomiting nor the inability to swallow diminishes the efficacy of THC delivery by smoking marijuana.

Second, Marinol delays relief to patients. Marinol is ingested while the active ingredients in smoked marijuana are inhaled. As a result, patients in need of immediate relief must often suffer for an extended period of time before Marinol takes effect. By contrast, smoking marijuana is a more efficient delivery mechanism that provides the blood stream with the therapeutic properties of marijuana almost instantaneously, resulting in prompt relief for patients:

> smoking . . . delivers a 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., Institute Of Medicine News Conference Marijuana and Medicine: Assessing the Science Base (Mar. 17, 1999).[24]

Third, smoking marijuana has less debilitating psychoactive side effects than Marinol. 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 three times more psychoactive than THC delivered to the lungs by smoked

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[24] The complete text is *available at* http://www4.nationalacademies.org (search for "Watson and Marijuana").

cannabis. IOM Report at 36.[25] Therefore, not only do patients on Marinol suffer a prolonged wait for relief, but they 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 marijuana can regulate their dose of THC, achieving the desired therapeutic effect without experiencing the same intensity of psychoactive side effects.

> [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.[26]

Fourth, marijuana contains other effective active ingredients not contained in Marinol. Marinol is composed of only a single compound, THC. By contrast, marijuana is a complex botanical substance, containing over 400 constituents and approximately 66 cannabinoids, which fall into 10 groups of closely related

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[25] Citing Razdan, R., *Structure-activity relationships in cannabinoids*, 38 Pharmacology Rev. 75-149 (1986).

[26] Select Committee on Science and Technology, House of Lords, Sess. 1997-98, *Cannabis: The Scientific and Medical Evidence: Evidence* (Nov. 4, 1998) ("Lords Evidence"). 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. John M. McPartland & Patty L. Pruitt, *Medical Marijuana and Its Use by the Immunocompromised*, 3 Alternative Therapies 39, 43 (1997).

cannabinoids. IOM Report at 24. The main cannabinoids include delta9-THC, delta8-THC, cannabidiol ("CBD"), cannabinol, cannabichromene, 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 [of cannabis] 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.[27]

For example, CBD, which is not psychoactive, has been shown to have potential neuroprotective and anti-inflammatory uses.[28]

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[27] Lords Evidence at 32; *see also* John M. McPartland & Patty L. Pruitt, *Side Effects of Pharmaceuticals Not Elicited by Comparable Herbal Medicines: The Case of Tetrahydrocannabinol and Marijuana*, 5 Alternative Therapies 57, 60 (1999).

[28] *See* A.J. Hampson et al., *Cannabidiol and (-)delta-9-tetrahydrocannabinol are neuroprotective sntioxidants*, 95 Proceedings of the National Academy of Sciences 8268 (July 1998) (addressing neuroprotection use); A.M. Malfait, et al., *The nonpsychoactive cannabis constituent cannabidiol is an oral anti-arthritic therapeutic in murine collagen-induced arthritis*, 97 Proceedings of the National Academy of Science 9561 (Aug. 2000) (addressing anti-inflammatory/anti-arthritic uses). These articles are available at http://www.pnas.org/all.shtml (search for the desired author).

C. MARIJUANA HAS RECOGNIZED ANALGESIC, ANTIEMETIC, ANTI-INFLAMMATORY, AND APPETITE-ENHANCING PROPERTIES.

1. Marijuana is an effective painkiller.

Patients with various pain syndromes claim significant relief from marijuana.[29] In fact, British researchers have recently reported that cannabis extract sprayed under the tongue was effective in reducing pain in 18 of 23 patients who were suffering from intractable pain.[30] The validity of their experiences is corroborated by studies in which cannabinoids have been shown to be effective analgesics in animal pain models.[31] This is particularly true for patients suffering from neuropathic pain.

Neuropathic pain is a symptom commonly associated with a variety of illnesses or conditions, including metastic cancer, HIV/AIDS, multiple sclerosis

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[29] *See, e.g.*, Lords Report §§ 5.26-5.30 at 24; IOM Report at 53-56.

[30] Clive Cookson, *High Hopes for Cannabis to Relieve Pain: British Association Science Festival in Glasgow*, Financial Times, September 4, 2001, at National News pg. 4, *available at* http://news.ft.com/ft/gx.cgi/ftc?pagename=View&c=Article&cid=FT3WWJOM6RC&live=true&query=cannabis.

[31] *See, e.g.*, William J. Martin, *Basic Mechanisms of Cannabinoid-Induced Analgesia*, IASP Newsletter (International Association for the Study of Pain) Summer 1999, at 89 ("There is now unequivocal evidence that cannabinoids are antinociceptive [capable of blocking the appreciation or transmission of pain] in animal models of acute pain").

(MS), and diabetes, and it can also be a side effect of the recommended treatments for various conditions.[32] 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.[33] But, there is no approved treatment for such pain that is satisfactory for a majority of patients.[34] As a result, some patients must reduce or discontinue their HIV/AIDS therapy because they can neither tolerate nor eliminate the debilitating side effects of the antiretroviral first-line medications.[35]

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[32] Many of the reverse transcriptase and protease inhibitors commonly prescribed as part of the "AIDS Cocktail" cause side effects including peripheral neuropathy, nausea, and vomiting. *See, e.g.*, Physician's Desk Reference 889 (Didanosine), 895 (Stavudine) (54th ed. 2000).

[33] *See, e.g.*, David M. Simpson et al., *Selected Neurologic Manifestations of HIV Infection: Dementia and Peripheral Neuropathy*, Improving the Management of HIV Disease, Dec. 1999; Nathalie Do Quang-Cantagtrel et al., *Opioid Substitution to Improve the Effectiveness of Chronic Noncancer Pain Control: A Chart Review*, 90 Anesthesia & 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, available at* http://www.neuro.wustl.edu/narc/peri-neuropathy.html ("Treatment of neuropathic pain . . . is notoriously difficult. Even narcotics may not fully relieve [it].").

[34] *See supra* note 33.

[35] *Id.*; SER 91-94; ER 102 ¶ 6.

2. Marijuana is effective in treating nausea, anorexia and wasting.

Nausea, anorexia, and wasting are common symptoms of many cancers and AIDS.[36] These symptoms are also the common adverse side effects of chemotherapy and other aggressive therapies used to treat those diseases and associated pain.[37] While other antiemetics are available, not all patients respond to these therapies.[38]

Marijuana can provide critical relief for persons suffering from acute or chronic nausea and vomiting who do not respond to conventional therapies.[39] As

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

[37] The nausea-inducing properties of opioid analgesics used to treat pain are uncontroverted. *See*, *e.g.*, Am. Med. Ass'n, Encyclopedia Of Medicine 98 (Charles B. Clayman ed., 1989) ("Nausea [and] vomiting . . . may occur with narcotic analgesic drugs."); The Merck Manual of Diagnosis and Therapy 1223 (Robert Berkow ed., 16th ed. 1992) (same).

[38] *See*, *e.g.*, Declaration of Dr. Marcus Conant, SER 61 ¶ 15 (conventional drugs fail to relieve severe nausea and vomiting for some patients); Declaration of Dr. Howard Maccabee, SER 123 ¶ 9 (same); Declaration of Dr. Debasish Tripathy, ER 142 ¶ 6; IOM Report at 157 ("Few therapies have proved successful in treatment of the AIDS wasting syndrome.").

[39] A New York State-sponsored study examined the effects of herbal cannabis on cancer chemotherapy patients who were unresponsive to standard antiemetics and found that 78% responded positively to cannabis. Vincent Vinciguerra et al., *Inhalation Marijuana as an antiematic for cancer chemotherapy,* N.Y.S.J. Med. 525 (Oct. 1988). Several other states have

the Institute of Medicine explains, "[t]he critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but whether some group of patients might obtain added or better relief from marijuana or cannabinoid drugs." IOM Report at 153. The IOM unequivocally concludes that there is indeed a group of patients to whom marijuana offers relief and that even the potentially harmful effects of smoking marijuana may be outweighed by the benefit provided.

> It is possible that the harmful effects of smoking marijuana for a limited period of 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.

Similarly, marijuana affords essential relief to patients suffering from anorexia and wasting syndromes for whom no other medications have worked.[40]

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undertaken similar trials with similar results. *See generally* Richard E. Musty & Rita 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. Cannabis Therapeutics 29 (2001). *See also* Lords Report § 5.12, at 21 (finding cannabis effective in alleviating acute nausea and vomiting); Declaration of Dr. Howard Maccabee, SER 123 ¶ 8.

[40] 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 § 5.15, at 22 (noting cannabis can counteract anorexia and wasting); Declaration of Dr. Marcus Conant, SER 59 ¶ 10; ER 265-66 (*Conant* permanent injunction describing AIDS patient suffering from life-threatening wasting syndrome who needs herbal cannabis to stimulate appetite).

3. Marijuana is effective in treating muscle spasticity.

Current treatments for painful muscle spasms, commonly associated with multiple sclerosis ("MS") and spinal cord injuries, have only limited effectiveness and their use is complicated by various adverse side effects. IOM Report at 164. A growing body of clinical and preclinical literature demonstrates that cannabinoids are effective in controlling the debilitating symptoms of MS.[41]

Conventional treatments have limited effectiveness for bladder dysfunction and pain associated with MS.[42] Marijuana, however, has been shown to be effective in alleviating these problems. Lords Report §§ 5.19-5.23, at 23. In addition, a survey of British and American MS patients reports that after ingesting marijuana a significant majority experienced substantial improvements in controlling muscle spasticity and pain.[43] An extensive neurological study found that herbal

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[41] *See* David Baker et al., *Cannabinoids control spasticity and tremor in a multiple sclerosis model*, 404 Nature 117 (Mar. 2, 2000); Lords Report §§ 5.19-5.23, at 23.

[42] *See* Institute of Medicine, *Multiple Sclerosis: Current Status and Strategies for the Future* 143, 171 (Janet E. Joy & Richard B. Johnston, eds., National Academy Press 2001), *available at* http://www.nap.edu/books/0309072859/html.

[43] Paul Consroe *et al., The Perceived Effects of Smoked Cannabis on Patients with Multiple Sclerosis*, 38 European Neurology 44 (1997) (reporting 96.5% of subjects with symptoms experienced lessened nighttime spasticity and 95.1% experienced reduced muscle pain, and greater than 70% of subjects reported

cannabis provided relief from both muscle spasms and ataxia (loss of coordination), a multiple benefit not achieved by any currently available medications.[44]

4. Marijuana is effective in controlling seizures.

Clinical experience and emerging research further indicate that marijuana can help control epileptic seizures.[45] Cannabidiol (CBD), one of the primary (and nonpsychoactive) cannabinoids present in the cannabis plant, appears to be of particular benefit, allowing patients who ingest it at certain times to avoid seizure activity. Some epileptics who cannot tolerate other antiseizure medications have been able to use marijuana to successfully control their seizures, without experiencing debilitating side effects.[46]

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decreased night leg pain, depression, tremor, anxiety, spasms on walking, leg weakness, trunk numbness, and facial pain).

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

[45] Lords Report § 5.31, at 24..

[46] *See* Jomar M. Cunha, *Chronic Administration of Cannabidiol to Healthy Volunteers and Epileptic Patients*, 21 Pharmacology 175 (1980); *R. v. Parker*, *supra* note 22, at *3 (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 marijuana to control seizures notwithstanding the prohibition of medicinal marijuana use under Canadian drug control statutes at that time).

5. The side effects of marijuana are no more severe and often less severe than the side effects of many currently sanctioned medications.

The IOM examined the various potential harms associated with the medical use of marijuana and determined that "the acute side effects of marijuana use are within the risks tolerated for many medications," although its long-term chronic use may implicate concerns related to smoking. IOM Report at 126. Indeed, marijuana is considered to have a very wide margin of safety.[47] In contrast, many of the commonly prescribed antiemetic medications cause moderate to severe side effects in patients, including confusion and marked sedation.[48] The side effects of marijuana use can be summarized as follows:

- Marijuana shows no indication of having an immunosuppressant effect.[49]
- The ingestion of marijuana raises the heart rate, but there is no evidence that this increase poses a risk of cardiac arrest in patients who do not

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[47] *See R. v. Parker*, *supra* note 22 at *48-49 (noting wide margin of safety of, and no evidence of overdose fatality from cannabis); ALJ Opinion at 56-60.

[48] *See, e.g.*, Physician's Desk Reference 3293, 3050 (54th ed. 2000) (side effects of Phenergan include sedation, confusion, and occasional nausea; side effects of Thorazine include suppression of cough reflex, drowsiness, fainting and dizziness upon initial dosing, and occasional muscle spasms).

[49] *See* IOM Report at 110; D. Abrams, *Short Term Effects of Cannabinoids on HIV-1 Viral Load*, presented at the 13th International AIDS Conference, Durban, South Africa (July 2000) (the use of cannabis does not adversely affect the immune system of HIV patients taking antiretroviral therapies).

have pre-existing heart problems or who are otherwise in a high-risk group.[50]

- Some studies have suggested that marijuana smokers, like tobacco 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.[51] However, "[t]here is conflicting evidence on whether regular marijuana use harms the small airways of the lungs," and it is therefore unlikely that the pulmonary side effects from smoking marijuana will be more severe than the side effects from smoking tobacco, a widely available and government-sanctioned drug.[52] Moreover, particularly for persons suffering terminal illnesses, any such potential side effect is of little significance.

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[50] *See* IOM Report at 121.

[51] Sanford H. Barsky *et al.*, *Histopathologic and Molecular Alterations in Bronchial Epithelium in Habitual Smokers of Marijuana, Cocaine, and/or Tobacco*, 90 J. Nat'l Cancer Inst. 1198 (1998).

[52] IOM Report at 115. 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* Lynn Zimmer and John P. Morgan, Marijuana Myths, Marijuana Facts 113-15 (1997); Stephen Sidney *et al.*, *Marijuana use and cancer incidence*, 8 Cancer Cause & Control 722 (1997).

- The ability to titrate the dose of cannabinoids permits marijuana smokers to limit their intake of the drug to a dose that minimizes the impairment of their mental functioning.[53]
- The prescribed use of many common medications for pain, anxiety, and even hypertension may produce tolerance and some measure of physiological dependence; similarly, some patients who use marijuana on a chronic basis may develop mild physiological dependence and experience withdrawal symptoms. Marijuana dependence and withdrawal, however, is comparatively subtle.[54]

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[53] *See* Lords Evidence at 178.

[54] IOM Report at 90-91 (stating that compared to tobacco and alcohol, dependence on cannabis is relatively rare and that marijuana withdrawal "has been reported only in a group of adolescents in treatment for substance abuse problems and in a research setting where subjects were given marijuana or THC daily [and then precipitously withdrawn from it]." Even then, the withdrawal symptoms "were short lived" and "[i]n four days they had abated.") (*citing* T.J. Crowley, et al., *Cannabis dependence, withdrawal, and reinforcing effects among adolescents with conduct symptoms and substance use disorders*, 50 Drug & Alcohol Dependence 27-37 (1998)); M. Haney, et al., *Abstinence symptoms following smoked marijuana in humans*, 141 Psychopharmacology 395-404 (1999); R. Jones, et al., *Clinical studies of tolerance and dependence*, 282 Annals of New York Academy of Sciences 221-239).

D. THE PERSONAL EXPERIENCES OF BOTH MEDICAL PROVIDERS AND PATIENTS SUPPORT SCIENTIFIC AND GOVERNMENT FINDINGS THAT MARIJUANA CAN BE AN EFFECTIVE THERAPEUTIC.

The medicinal value of marijuana is accepted by many physicians. As noted above, in a 1991 Harvard survey of more than 2400 oncologists, 44% of respondents had recommended the use of marijuana for the control of nausea and vomiting to at least one cancer patient. Almost half considered cannabis to be therapeutically useful and would prescribe it were it lawful to do so.[55]

In addition, many physicians find that marijuana's efficacy rivals or surpasses that of other antiemetic drugs for certain patients, including Compazine and Marinol.[56] When comparing marijuana to Marinol, 44% of oncologists believed that smoked marijuana was more effective.[57]

While many physicians who recommend marijuana do not consider it the first line of defense against the symptoms or side effects of their patients' serious

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[55] SER 30-35; *see also* Declaration of Dr. Marcus Conant, SER 61 ¶ 16; Declaration of Dr. Debasish Tripathy, SER 145 ¶ 4; Declaration of Dr. Neil Flynn, SER 92 ¶ 11; Declaration of Dr. Stephen Follansbee, SER 109 ¶ 23 (marijuana recommendations are warranted for patients who fail to respond to other treatments).

[56] *See, e.g.*, Declaration of Dr. Neil Flynn, SER 93 ¶ 11 (marijuana's "success rate far surpasses that for Compazine").

[57] *See supra,* note 16.

illnesses, they do recognize it as a valuable medication for those patients who cannot tolerate or who do not respond well to conventional medications.[58]

Individuals such as the four individual *Amici* who have joined in this brief can also attest to the efficacy of smoking marijuana as a result of their previous inclusion in the federal government sponsored cannabis program. While the federal government no longer operates the program, it continues to supply marijuana to previously enrolled patients and the participants in the San Mateo County study, and upon approval, will be supplying marijuana for the additional 10 University of California scientific studies.[59] For this reason alone, it is disingenuous and hypocritical for the government to on the one hand recognize the relief that federally supplied marijuana affords these individuals, but on the other hand attempt to prevent doctors from fully discussing the potential benefits and side effects, including recommending marijuana where appropriate.

IV. CONCLUSION

Convincing scientific evidence and clinical experience demonstrate that smoking marijuana provides medical benefits that are not replicated by synthesized drugs. Recent government sponsored studies in the United States and Great Britain confirm this conclusion. Canada has now approved usage of medical marijuana. In

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[58] *See* Declaration of Dr. Marcus Conant, SER 59 ¶ 10; Declaration of Dr. Stephen Follansbee, ER 109 ¶ 25.

[59] *See supra*, note 2.

addition, the collective weight of scientific studies, patients' personal experiences, physicians' clinical successes, and government-sponsored studies provides a convincing basis for the recommendation of medical marijuana by medical doctors

where appropriate. Clearly, the "public interest" is not advanced by threatening, intimidating or prohibiting doctors from exercising their best medical judgment.

For the foregoing reasons, the District Court's permanent injunction should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Ninth Circuit Rule 32(e)(4), I certify that the Amicus Curie brief is proportionately spaced, has a typeface of 14 points or more and contains **6919** words, exclusive of the table of contents, table of authorities, certificate of compliance, appendices, and certificate of service. This certification is based upon the word processing program used in preparing this brief.

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Date	Steven C. Willey