

**UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF COLUMBIA**

DURK PEARSON and SANDY SHAW,

ET AL.,

Plaintiffs,

v.

CASE NO. 97-CV-00462 (WBB)

BARRY R. MCCAFFREY, AS

DIRECTOR OF NATIONAL

DRUG CONTROL POLICY,

ET AL.,

Defendants.

**FIRST AMENDED COMPLAINT FOR
DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF**

Plaintiffs Durk Pearson, Sandy Shaw, Julian M. Whitaker, M.D., Jeffrey A. Singer, M.D., Richard D. Fisher, M.D., Henry N. Blansfield, M.D., William Regelson, M.D., the American Preventive Medical Association, and the Life Extension Foundation hereby file this Complaint against Defendants Barry R. McCaffrey (as Director of the United States Office of National Drug Control Policy); Donna E. Shalala (as Secretary of the United States Department of Health and Human Services); Thomas A. Constantine (as Administrator of the United States Drug Enforcement Administration); and the Hon. Janet Reno (as Attorney General of the United States), seeking a declaration that the federal policy prohibiting physicians from recommending and prescribing medicinal marijuana to seriously ill and terminally ill patients, and prohibiting the use of physician recommended and prescribed marijuana under the laws of Arizona, California, Connecticut, and Virginia violates the U.S. Constitution and is contrary to federal law.

BRIEF STATEMENT OF THE CASE

Under Arizona, California, Connecticut, and Virginia law physician recommendation and prescription of medicinal marijuana for seriously ill and terminally ill patients, and the prescribed use of that marijuana by those patients, is lawful. The voters of Arizona and California recently passed propositions making physician recommendation and prescription, along with prescribed use by patients, lawful.

On December 30, 1996, Defendants McCaffrey, Shalala, and Reno announced in a nationally broadcast press conference ("Press Conference") and on February 11, 1997, the Office of National Drug Control Policy ("ONDCP") published in the Federal Register (62 Fed. Reg. 6164) a new federal policy ("Federal Policy") to civilly and criminally prosecute and impose administrative sanctions against any physician who prescribed marijuana to seriously ill or terminally ill patients and to prosecute civilly and criminally any patient who possessed or used prescribed medicinal marijuana in those states where such prescription and use is legal.

At the Press Conference, Defendant Reno stated that "U.S. attorneys in [Arizona and California] will continue to review cases for prosecution and DEA officials will review cases as they have to determine whether to revoke the [DEA] registration of any physician who recommends or prescribes so-called Schedule I controlled substances." She further stated "What we have urged state and local officials to do is to undertake these cases, to pursue these cases, and to make arrests because the law is still on the books that it is unlawful in these states. If the defense is raised -- hey, a doctor prescribed this substance for me and the prosecutors in Arizona or California conclude that they cannot proceed because of the state initiative, then we will work with them, number one, in terms of seizing the drugs, and in reviewing what further action should be taken." Defendant Shalala stated that "What the physicians in this country want to know from us is -- look, we've got a state law on our books now in California and Arizona and there's a federal law. What's the law? And the law is that marijuana and these other drugs continue to be illegal. That's what they need to know." Defendant Shalala further stated that "national law prevails here. We've made it clear. And to preserve that, we will enforce the core of federal laws."

Under the new Federal Policy, the Federal Government (1) will prosecute any physician who prescribes or recommends medicinal marijuana to patients and will prosecute any patient who uses prescribed marijuana, (2) will revoke the DEA registration numbers of any physician who prescribes or recommends medicinal marijuana to patients, (3) will exclude from Medicaid and Medicare any physician who prescribes or recommends medicinal marijuana to patients, and (4) will enforce all federal sanctions against physicians and patients. The Federal Policy requires federal agents to enforce such sanctions and to induce state and local law enforcement authorities to arrest physicians and patients who, respectively, prescribe and use marijuana, in those States where such prescription and use is legal.

The Federal Policy casts a pall of censorship over Plaintiff physicians' marijuana prescriptions and recommendations to their seriously ill and terminally ill patients, thereby violating the Plaintiffs' First Amendment rights. The Federal Policy is a content-based suppression of speech that also has a chilling effect upon the exercise of First Amendment rights to discuss, prescribe, and recommend medicinal marijuana by physicians with their colleagues, with their patients, and with scientists. It is substantially overbroad, infringing the free speech rights of patients, physicians, and scientists not before the Court.

In violation of constitutional limits on federal jurisdiction under the Commerce Clause and on federal power under the Ninth and Tenth Amendments, the Federal Policy invades reserved State police powers over health and

safety and medical practice, deprives Plaintiffs of the enjoyment of their rights, including those protected by State laws and protected under State Constitutions, regulates the heretofore exclusively State regulated intrastate practice of medicine, and impermissibly directs State law enforcement officers to violate State law and arrest physicians who prescribe and recommend medicinal marijuana (and patients who use recommended or prescribed marijuana) in those States where that prescription, recommendation, and prescribed use is legal.

The Federal Policy excludes from Medicaid and Medicare physicians who recommend or prescribe medicinal marijuana in excess of Congressionally delegated authority.

The Federal Policy terminates the DEA scheduled drug registration of physicians who recommend or prescribe medicinal marijuana without advance notice and an opportunity for comment in violation of the Administrative Procedure Act (APA).

The penalties and sanctions included in the Federal Policy infringe Plaintiff Pearson and Shaw's freedom to consult with Plaintiff physicians and others like them and Plaintiff physicians' patients and others like them concerning means to maximize the clinical benefit-to-risk ratio of medicinal marijuana; threaten to destroy the reputations, seize the property of, and prosecute and incarcerate Plaintiff physicians if they prescribe and recommend medicinal marijuana in accordance with State law; subject Plaintiff physicians' patients to agony, nausea, vomiting, disability, and risk of loss of life that could be minimized or eliminated by medicinal marijuana, to loss of property, to prosecution, to criminal sanctions, and to potential incarceration; and violate all Plaintiffs' civil liberties.

Under laws, regulations and policies of the Defendants, all plaintiffs herein may be subjected to extensive and intrusive Federal Government investigations and may be liable to criminal prosecution, fines, imprisonment, civil penalties, forfeitures, special parole terms, loss of civil rights, loss of employment, and loss of additional benefits and privileges, and other sanctions intended to enforce prohibition of the recommendation and prescription and the recommended and prescribed use of medicinal marijuana.

Officers and agents of the Defendants have expressly threatened to harass, prosecute, and penalize, and otherwise censure and impose sanctions upon, plaintiffs and other persons who prescribe or recommend medicinal marijuana and who use prescribed marijuana in accordance with State laws.

None of the plaintiffs promote the use of marijuana for recreation. The relief sought herein by Plaintiffs is strictly limited to appropriate medical use of marijuana when such use is in accord with State law.

Plaintiffs seek a declaratory judgment that the Federal Policy violates the First, Ninth, and Tenth Amendments, and other constitutional limitations, and the jurisdictional limits of the Commerce Clause of the United States Constitution. Plaintiffs also seek a declaratory judgment that those aspects of the Federal Policy that terminate physician participation in Medicaid and Medicare and scheduled drug registration exceed the delegated authority of HHS and DEA.

Plaintiffs seek injunctive relief, precluding enforcement of the Federal Policy against them.

JURISDICTION

This Court has jurisdiction over this matter pursuant to 5 U.S.C. §§ 702 and 706 (hereinafter "Administrative Procedure Act") and 28 U.S.C. §§ 1331; 2201.

VENUE

This Court has venue over this action pursuant to 28 U.S.C. § 1391(e).

DESCRIPTION OF THE PARTIES**I. Plaintiffs**

DURK PEARSON and SANDY SHAW ("P & S") are scientists and authors who have a primary residence in Nevada and a secondary residence in California. P & S wish to consult with physicians (who prescribe and recommend medicinal marijuana to patients suffering serious illness or terminal illness) and their patients in California, Arizona, Virginia, and Connecticut to explain techniques by which marijuana may be reliably and efficiently delivered to patients without combustion and attendant combustion carcinogens. Pearson has scientific experience with the controlled retorting, distillation, and pyrolysis of organic matter in inert atmospheres from his research and development work in oil shale to oil conversion and recovery. He is a co-inventor of U.S. Patent No. 4065183 for this process. P & S have been scientific collaborators for thirty-two years and are husband and wife. Pearson has degenerative spinal arthritis and wishes to consult with a California physician concerning whether medicinal use of marijuana would be an appropriate treatment for the persistent, variable, and sometimes severe pain that he suffers. Shaw has temporal lobe epilepsy and wishes to consult with a California physician concerning whether medicinal marijuana would be an appropriate adjunct treatment in her case. P & S fear that consultations with physicians and patients concerning the reduced carcinogen administration of medicinal marijuana will subject P & S and the physicians and patients with whom they consult to invasive and extensive Federal Government investigations and possible criminal prosecution. P & S also fear that consultations with a California physician concerning whether they may obtain relief from the medicinal use of marijuana will subject P & S and that physician to invasive and extensive Federal Government investigations and possible criminal prosecution.

JULIAN M. WHITAKER, M.D. ("Dr. Whitaker") is a physician licensed to practice medicine in California and Washington. He is the Clinical Director of The Whitaker Wellness Institute in Newport Beach, California and the editor of *Health & Healing*, the nation's largest single editor health newsletter with approximately 500,000 subscribers. Many of those whom Dr. Whitaker treats are patients who suffer chronic and debilitating illnesses involving intractable nausea from cancer chemotherapy (and would be allowed to use medicinal marijuana under California law). A minority of those patients are terminally ill in the latter stages of disease. Dr. Whitaker wants to avail himself of the right afforded by California law to recommend medicinal marijuana to those of his seriously ill and terminally ill patients for whom other palliative care has not relieved persistent chemotherapy-induced nausea. He fears that making such a recommendation will violate the Federal Policy and render him subject to criminal prosecution, revocation of his DEA scheduled drug registration, and exclusion from Medicaid and Medicare, among other potential punishments and sanctions.

JEFFREY A. SINGER, M.D. ("Dr. Singer") is a physician licensed to practice medicine in Arizona. He has been in private practice in general surgery since 1981 in Phoenix, Arizona. He is board certified by the American Board of Surgery, a Fellow of the American College of Surgeons, a Fellow of the Southwestern Surgical Congress, and a Fellow of the International College of Surgeons. Dr. Singer seeks to recommend and prescribe medicinal marijuana to those of his patients who suffer serious or terminal illness as allowed by Arizona law. He fears that making such recommendations and prescriptions will violate the Federal Policy and render him subject to criminal prosecution, revocation of his DEA scheduled drug registration, and exclusion from Medicaid and Medicare, among other potential punishments and sanctions.

RICHARD D. FISHER, M.D. ("Dr. Fisher") is a physician licensed to practice medicine in Arizona. He has been in a private family practice since 1977. He is board certified in family practice with a certificate of added qualifications in geriatrics. He frequently treats terminally ill patients with malignancies and those undergoing chemotherapy who suffer excruciating pain and nausea for whom other palliative care is not effective. Several such patients are now under his care. He wants to recommend and prescribe medicinal marijuana to those patients as allowed by Arizona law. He fears that making such recommendations and prescriptions will violate the Federal Policy and render him subject to criminal prosecution, revocation of his scheduled drug registration, and exclusion from Medicaid and Medicare, among other potential punishments and sanctions.

HENRY N. BLANSFIELD, M.D. ("Dr. Blansfield") is a physician licensed to practice medicine in Connecticut. Dr. Blansfield is a volunteer physician for the American Free Clinic in Danbury, Connecticut. At the clinic, Dr. Blansfield treats several patients undergoing chemotherapy treatment for cancer and therapy for AIDS. Dr. Blansfield believes that many of the patients at the clinic would benefit from the use of medicinal marijuana in combating the negative side effects associated with cancer, cancer chemotherapy, AIDS, and AIDS therapy, including wasting, nausea, and vomiting. Indeed, Dr. Blansfield seeks to prescribe medicinal marijuana to those patients in which traditional anti-emetic drugs such as Marinol and Zofran have failed to provide needed relief. Dr. Blansfield refrains from prescribing medicinal marijuana out of fear of prosecution by the federal government, fear of losing his DEA drug registration, and fear of losing his Medicaid and Medicare privileges.

WILLIAM REGELSON, M.D. (Dr. Regelson) is a Professor of Internal Medicine and a medical oncologist licensed to practice medicine in Virginia. In the course of his practice, Dr. Regelson has seen many cancer patients that would benefit from medicinal marijuana. Indeed, before the Federal Policy was promulgated, Dr. Regelson prescribed medicinal marijuana to many of those patients in accordance with Virginia law. However, because of fear of federal prosecution, fear of losing his DEA drug registration, and fear of losing his Medicaid and Medicare privileges, Dr. Regelson now refrains from prescribing medicinal marijuana to patients who would benefit from its use.

AMERICAN PREVENTIVE MEDICAL ASSOCIATION is a non-profit health care advocacy organization, founded in October 1992, with 474 current members, including 234 M.D.s and D.O.s (collectively "physicians"), 14 of whom are licensed in Arizona; 65 of whom are licensed in California; 13 of whom are licensed in Connecticut, and 14 of whom are licensed in Virginia. APMA's purpose is to protect and promote freedom of personal choice in health care. APMA's physician members in Arizona, California, Connecticut, and Virginia wish to recommend and prescribe medicinal marijuana to certain of their patients who suffer from serious illnesses, unremitting pain, and intractable nausea (e.g., from cancer, from cancer chemotherapy, from AIDS, and from AIDS therapy) (for which other palliative care has not provided adequate relief), in conformance with laws of the states in which they practice medicine. The Federal Policy prohibits them from doing so.

LIFE EXTENSION FOUNDATION ("LEF") is a non-profit membership organization dedicated to pursuing therapies to extend the healthy human lifespan and supporting scientific research aimed at eliminating human disease and suffering. LEF has approximately 40,000 members, including individuals who are under the care of physicians and who suffer serious illnesses and terminal illnesses, including cancer and AIDS. Approximately 736 of LEF's members identify themselves as M.D.'s or D.O.'s. Those of LEF's members who are resident in Arizona, California, Connecticut, and Virginia and suffer serious illness or terminal illness and who have intractable nausea and/or pain are denied by the Federal Policy the opportunity to receive relief from medicinal marijuana in accordance with State law.

II. Defendants

BARRY R. MCCAFFREY is the Director of the United States Office of National Drug Control Policy and is the author of the February 11, 1997 Policy. Defendant McCaffrey is being sued in his official capacity.

THOMAS A. CONSTANTINE is the Administrator of the United States Drug Enforcement Administration and is being sued in his official capacity.

DONNA E. SHALALA is the Secretary of Health and Human Services and is being sued in her official capacity.

THE HON. JANET RENO is the Attorney General of the United States and is being sued in her official capacity.

FACTS

I. BRIEF LEGAL HISTORY OF PHYSICIAN RECOMMENDATION AND PRESCRIPTION OF MARIJUANA UNDER STATE LAW

Voters of California and Arizona recently passed propositions that would allow physicians to prescribe or recommend marijuana to patients suffering from severe illnesses such as AIDS and cancer and would allow those patients to use marijuana as so prescribed or recommended. The California law would allow patients (to whom marijuana prescriptions or recommendations have been given) to grow marijuana for their own use or obtain it from their caregivers.

Between the late 1970's and late 1980's, thirty-six state legislatures passed laws that either established therapeutic research programs to study medicinal use of marijuana in patients or legalized the medicinal use of marijuana.

On March 27, 1979, Virginia became the first state to legalize the *prescription* of medicinal marijuana for specific disease conditions. *See* VA. CODE § 18.2-252.1. Subsection A of the Act precludes the prosecution of any individual who possesses medicinal marijuana pursuant to a lawfully written prescription for the treatment of cancer and glaucoma. Subsection B of the Act precludes prosecution of physicians who prescribe medicinal marijuana in the treatment of cancer or glaucoma. Subsection C of the Act precludes the prosecution of pharmacists who dispense or distribute medicinal marijuana to any individual who has a lawfully issued prescription from a physician for the treatment of cancer or glaucoma. The Federal Policy conflicts with this law, attempts unconstitutionally to supplant it, and threatens imminent criminal sanctions against physicians, pharmacists, and patients who violate the Federal Policy even if the medicinal marijuana prescribed is cultivated, processed, prescribed, and used wholly within Virginia in accordance with State law.

On July 1, 1981, Connecticut legalized the *prescription* of marijuana. *See* CONN. GEN. STAT. §§ 21a -246 and 21a-253. The Act allows physicians to apply for a license (from the Commissioner of Consumer Protection) to prescribe medicinal marijuana for glaucoma and the side effects of chemotherapy. *See* CONN. GEN. STAT. §§ 21a -246(a). The Act requires the commissioner to license the physician without unnecessary delay. *Id.* The Act requires the physician to renew his or her license annually. *See* CONN. GEN. STAT. §§ 21a -246(b). The Act further requires manufacturers, wholesalers, repackagers, suppliers, compounders, mixers, or cultivators of

medicinal marijuana within the state to first obtain a license to do so from the commissioner. *See* CONN. GEN. STAT. §§ 21a -246(a). That license must be renewed annually. *Id.*

The Connecticut law allows patients to possess and use medicinal marijuana pursuant to a valid prescription from a licensed physician for the treatment of glaucoma or the side effects of chemotherapy. CONN. GEN. STAT. §§ 21a -253. The Federal Policy conflicts with this law, attempts unconstitutionally to supplant it, and threatens imminent criminal sanctions against physicians, pharmacists, and patients who violate the Federal Policy even if the medicinal marijuana prescribed is cultivated, processed, prescribed and used wholly within Connecticut in accordance with State law.

On November 5, 1996, the voters of California approved Proposition 215 (codified at CAL. HEALTH & SAFETY CODE § 11362.5) allowing seriously ill and terminally ill individuals to possess and use medicinal marijuana upon the recommendation of a physician. Proposition 215 allows a California physician to recommend medicinal marijuana to patients if (1) they are seriously ill and (2) the use of marijuana would benefit them. Proposition 215 also allows patients suffering from serious illness or terminal illness to obtain from caregivers, grow for their own use, possess and use marijuana upon the recommendation or prescription of a physician. The Federal Policy conflicts with this law, attempts unconstitutionally to supplant it, and threatens imminent criminal sanctions against physicians, pharmacists, and patients who violate the Federal Policy even if the medicinal marijuana is cultivated, processed, recommended, and used wholly within California in accordance with State law.

On November 5, 1996, the voters of Arizona approved Proposition 200 (codified at ARIZ. REV. STAT. ANN. § 13-3412.01) which allows physicians to *prescribe* otherwise illegal substances (including medicinal marijuana) to certain seriously ill or terminally ill patients. The Federal Policy conflicts with this law, unconstitutionally attempts to preempt it, and threatens imminent criminal sanctions against physicians, pharmacists, and patients who violate the Federal Policy even if the marijuana is cultivated, processed, prescribed, and used wholly within Arizona in accordance with State law.

THE FEDERAL GOVERNMENT'S RESPONSE TO STATE LAWS ALLOWING MEDICINAL USE OF MARIJUANA.

Since the passage of Virginia's marijuana prescription law in 1979 (the first state to legalize medical prescription of marijuana), Congress has not enacted any law to nullify the State laws or prohibit physicians in those or any other states from prescribing medicinal marijuana in accord with state law. On October 28, 1996, on the eve of passage of Propositions 215 and 200, the Defendants--without authorization from Congress-- unilaterally changed federal law. On that date, Defendant McCaffrey stated publicly that any physician recommending or prescribing medicinal marijuana under state law would be prosecuted. Those comments were published to a nationwide audience. After the passage of Propositions 215 and 200, Defendants McCaffrey, Shalala and Reno reaffirmed, also to a nationwide audience, that the Federal Government would prosecute any physician who prescribed or recommended medicinal marijuana under state law and would prosecute any patient who possessed or used prescribed medicinal marijuana.

Between November 5, 1996 and February 11, 1997, federal officials warned physicians not to prescribe or recommend marijuana and promised to prosecute those who did prescribe or recommend its use to seriously ill or terminally ill patients. Defendant Constantine warned that the Federal Government would "take very, very

serious action against" physicians who prescribed or recommended medicinal marijuana to their patients. Defendant Reno threatened to use "surveillance and informers" to identify physicians who prescribed or recommended medicinal marijuana to their patients.

In the February 11, 1997 Federal Register the ONDCP announced the Federal Policy regarding prescription and recommendation of medicinal marijuana. Under the Federal Policy, (1) physicians who recommend and prescribe medicinal marijuana to patients in conformity with state law and patients who use recommended and prescribed medicinal marijuana pursuant to a recommendation or prescription authorized under state law will be prosecuted; (2) physicians who recommend and prescribe medicinal marijuana to patients in conformity with State law will be excluded from Medicare and Medicaid; and (3) physicians who recommend and prescribe medicinal marijuana to patients in conformity with State law will have their scheduled drug DEA registrations revoked. The Federal Policy also encourages state and local law enforcement officials to arrest and prosecute physicians suspected of prescribing or recommending medicinal marijuana and to arrest and prosecute patients who use medicinal marijuana pursuant to a prescription or recommendation valid under state law. The Federal Policy also encourages the IRS to issue a revenue ruling disallowing any medical deduction for medical marijuana lawfully obtained under state law.

Plaintiff physicians truly and in good faith believe, in conformity with the laws of the States in which they practice, and in the exercise of their best medical judgment, that medicinal marijuana will be beneficial to certain of their patients, particularly in the management and treatment of unrelenting pain, intractable nausea and wasting syndrome associated with cancer, cancer chemotherapy, AIDS, and AIDS therapy. They wish to recommend and prescribe medicinal marijuana for those purposes. Plaintiffs Pearson and Shaw and Plaintiff physicians' patients desire such treatment to reduce their pain and suffering.

Congress has not authorized the preemption of State laws that allow physician prescription and recommendation of medicinal marijuana for seriously ill or terminally ill patients.

CAUSE OF ACTION I: VIOLATIONS OF THE U.S. CONSTITUTION

A. THE FEDERAL POLICY IS AN UNCONSTITUTIONAL PRIOR RESTRAINT

AND CONTENT-BASED RESTRICTION ON PROTECTED SPEECH

THAT IS SUBSTANTIALLY OVERBROAD IN VIOLATION

OF THE FIRST AMENDMENT

Plaintiffs reallege and restate paragraphs 1 through 40 and incorporate them herein.

The Federal Policy prohibits Plaintiff physicians from prescribing or recommending medicinal marijuana in conformity with Arizona, California, Connecticut, and Virginia law. The Federal Policy also prohibits Plaintiff physicians' patients from receiving recommended and prescribed marijuana in conformity with Arizona, California, Connecticut and Virginia law. The immediate investigation and criminal prosecution of physicians and patients, revocation of physician DEA scheduled drug registrations, and exclusion from Medicare and Medicaid

announced in the Federal Policy stifles the free exchange of scientific information concerning the therapeutic use of medicinal marijuana in conformity with State law. The Federal Policy is an unconstitutional prior restraint and unconstitutional content-based restriction on protected speech. The Federal Policy is substantially overbroad, producing a chilling effect on protected speech of physicians, scientists, and patients not before the Court.

B. THE FEDERAL POLICY VIOLATES THE NINTH AMENDMENT

Plaintiffs reallege and restate paragraphs 1 through 38 and incorporate them herein.

Arizona, California, Connecticut, and Virginia have all passed laws authorizing physician prescription and/or recommendation of medicinal marijuana for seriously ill or terminally ill patients. Those laws protect rights retained by Plaintiff physicians who are licensed, and patients who are resident, in those states. The State power to protect those rights is limited only to the extent that it violates the United States Constitution or federal law duly enacted by Congress or promulgated by administrative agencies within constitutional limits. Congress has never specifically authorized federal preemption of State law permitting physician prescription and recommendation of medicinal marijuana or patient intrastate use and/or home cultivation of medicinal marijuana in accordance with State law. The Federal Policy thus violates the Ninth Amendment.

C. THE FEDERAL POLICY VIOLATES THE TENTH AMENDMENT

Plaintiffs reallege and restate paragraphs 1 through 40 and incorporate herein.

The Federal Policy impermissibly supplants the laws of Arizona, California, Connecticut, and Virginia without a specific congressional mandate and attempts to regulate the conduct of state law enforcement officers by inducing them to violate State law. The Federal Policy impermissibly invades an historic province of State police power (health and safety regulation and medical practice regulation) and supplants it. The Federal Policy attempts to induce State law enforcement officers not to follow State law but to pursue the contrary Federal Policy by arresting physicians, pharmacists, and patients who recommend, prescribe, distribute, grow at home for medical use, and use medicinal marijuana for purposes authorized under State law. The Federal Policy thus violates the Tenth Amendment.

D. THE FEDERAL POLICY VIOLATES THE COMMERCE CLAUSE

Plaintiffs reallege and restate paragraphs 1 through 40 and incorporate them herein.

Neither the intrastate recommendation and prescription of medicinal marijuana nor the intrastate cultivation and consumption of recommended or prescribed medicinal marijuana is "commerce with foreign nations and among the several states" within the meaning of Article I, Sec. 8, Clause 3 of the United States Constitution. Neither Congress nor the administrative agencies may lawfully regulate the entirely intrastate recommendation, prescription, home cultivation for medical use, and medical use of medicinal marijuana under State law, for to do so exceeds constitutional Commerce Clause limits.

CAUSE OF ACTION II: THE FEDERAL POLICY**EXCEEDS DEFENDANTS' DELEGATED SCOPE OF AUTHORITY**

Plaintiffs JULIAN M. WHITAKER, M.D.; JEFFREY A. SINGER, M.D.; RICHARD D. FISHER, M.D.; HENRY N. BLANSFIELD, M.D.; WILLIAM REGELSON, M.D.; and AMERICAN PREVENTIVE MEDICAL ASSOCIATION reallege and restate paragraphs 1 through 40 and incorporate them herein.

Defendants are without statutory authority to regulate the intrastate practice of medicine via the Controlled Substances Act and Social Security Act.

The Controlled Substances Act provides the specific bases for the DEA to revoke the DEA registration of licensed physicians. None of those enumerated bases include provision for the revocation of the DEA registrations of physicians who prescribe or recommend medicinal marijuana to patients in accordance with state law. Accordingly, the Federal Policy to revoke the DEA registration of physician that recommend or prescribe medicinal marijuana exceeds the scope of authority granted to the DEA by Congress.

The Social Security Act provides the specific bases for the Secretary of Health and Human Services to exclude a physician from participating in Medicare and Medicaid programs. None of those enumerated bases include the ability of the Secretary to exclude a physician from participating in Medicare and Medicaid because the physician recommended or prescribed medicinal marijuana to his/her patient in accordance with state law. Accordingly, the Federal Policy to exclude physicians from participating in Medicare and Medicaid because they prescribed or recommended medicinal marijuana exceeds the scope of authority granted to the Secretary by Congress.

**CAUSE OF ACTION III: VIOLATIONS OF THE ADMINISTRATIVE
PROCEDURE ACT**

Plaintiffs JULIAN M. WHITAKER, M.D.; JEFFREY A. SINGER, M.D.; RICHARD D. FISHER, M.D.; HENRY N. BLANSFIELD, M.D.; WILLIAM REGELSON, M.D.; and AMERICAN PREVENTIVE MEDICAL ASSOCIATION reallege and restate paragraphs 1 through 40 and incorporate them herein.

The Federal Policy contains two final rules: (1) A physician's scheduled drug registration may be revoked by DEA if the physician recommends or prescribes medicinal marijuana to his or her patients and (2) a physician may be excluded from participating in Medicare and Medicaid by the Secretary of HHS if the physician recommends or prescribes medicinal marijuana to his or her patients. Both rules were promulgated without advance notice and opportunity for comment as required by the Administrative Procedure Act, 5 U.S.C. § 701 et seq. ("APA"). Accordingly, the Federal Policy violates the APA.

IRREPARABLE HARM

Plaintiff Physicians, Plaintiff organizations, members of Plaintiff organizations, Plaintiff scientists and patients have suffered irreparable harm due to Defendants' policy to prosecute civilly and criminally physicians who recommend and prescribe medicinal marijuana and patients who use recommended and prescribed medicinal

marijuana (and in California, grow recommended or prescribed medicinal marijuana for their own use) pursuant to state law.

Plaintiff Physicians, Plaintiff organizations, members of Plaintiff organizations, Plaintiff scientists and patients have suffered irreparable harm due to Defendants' policy to exclude physicians who recommend and prescribe medicinal marijuana in accordance with state law from participating in Medicare and Medicaid. Plaintiffs will continue to suffer harm unless the federal government is enjoined from enforcing its policy to exclude physicians from Medicare and Medicaid based on their prescription or recommendation of medicinal marijuana in accordance with state law.

The First Amendment of the United States Constitution guarantees the right of physicians to prescribe and recommend medicinal marijuana to seriously ill and terminally ill patients without fear of government retribution. The Commerce Clause limits federal jurisdiction and does not permit federal regulation to reach wholly intrastate physician prescription and recommendation of medicinal marijuana nor its intrastate cultivation for medical use in accord with state law. The Tenth Amendment of the United States Constitution precludes the Federal Government from directing the manner in which the States regulate the intrastate practice of medicine and provide for the health of their citizens. The Ninth Amendment of the United States Constitution protects the unenumerated rights of a physician to provide needed treatment to a seriously ill or terminally ill patient (regulated under state laws) and the right of a patient to receive that treatment. The Federal Policy violates those rights. An administrative agency may not take any action that is in excess of that authority granted to it by Congress. By authorizing the revocation of DEA registrations and Medicaid and Medicare privileges, the Federal Policy exceeds Congress' grant of authority to the detriment of Plaintiffs. The Administrative Procedure Act prohibits the promulgation of a final rule without notice and opportunity to comment on the proposed rule. The Federal Policy is such a rule to the detriment of Plaintiffs. The Federal Policy threatens imminent and harsh sanctions against physicians, including Plaintiffs, who prescribe and recommend the use of medicinal marijuana to their seriously ill and terminally ill patients. Those sanctions include arrest and prosecution for drug trafficking, revocation of the physician's DEA registration, and exclusion from participating in Medicare and Medicaid. Patients using and cultivating medicinal marijuana in accordance with state law risk criminal prosecution for drug possession, cultivating, and trafficking. The Federal Policy substantially impedes the ability of physicians, including Plaintiffs, to provide the best possible care to their patients and arrests the advancement of medical science and the dissemination of scientific information to seriously ill and terminally ill patients and the physicians who treat them.

RELIEF REQUESTED

The Plaintiffs respectfully request that this Honorable Court declare in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act):

- (a) That the Federal Policy violates the First Amendments rights of Plaintiffs and is substantially overbroad violating the First Amendment rights of others not before the Court;
- (b) That the Federal Policy violates the Ninth Amendment;
- (c) That the Federal Policy violates the Tenth Amendment;

That the Federal Policy violates the Commerce Clause of the U.S. Constitution;

(e) That the Federal Policy exceeds the delegated authority Congress granted to HHS and DEA; and

(f) That the Federal Policy revoking scheduled drug DEA registration and excluding Medicare and Medicaid participation violates the Administrative Procedure Act.

The Plaintiffs additionally request that this Honorable Court:

(a) Enjoin the Federal Government from enforcing the Federal Policy against Plaintiffs;

(b) Enjoin the Federal Government from investigating and prosecuting Plaintiffs when they prescribe, recommend, grow at home for medical use, and when patients, including Plaintiff patients, use medicinal marijuana in accordance with State law;

(c) Enjoin the DEA from revoking the scheduled drug registration of Plaintiff physicians who prescribe and recommend medicinal marijuana in accordance with State law;

(d) Enjoin HHS from excluding from Medicare and Medicaid Plaintiff physicians who prescribe and recommend medicinal marijuana in accordance with State law; and

(e) Grant such other and further relief as may be appropriate.

Respectfully submitted,

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