UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

DURK PEARSON and SANDY SHAW,

ET AL.,

Plaintiffs,

v.

BARRY R. MCCAFFREY

ET AL.,

Defendants.

PLAINTIFFS' APPLICATION FOR PRELIMINARY INJUNCTION

Plaintiffs, by counsel and pursuant to Fed. R. Civ. P. 65(a) and Local Rule 205(c), hereby apply to this Honorable Court for a preliminary injunction enjoining the Department of Justice ("DOJ"), Department of Health and Human Services ("HHS"), the Drug Enforcement Administration ("DEA"), and the Office of National Drug Control Policy ("ONDCP") from initiating civil, criminal, and administrative proceedings against (1) Plaintiff physicians who practice medicine in Arizona, California, Connecticut and Virginia and who seek to recommend and prescribe medicinal marijuana to certain of their seriously ill and terminally ill patients in accord with state law; (2) Plaintiff patients who seek to obtain and use prescribed medicinal marijuana in accord with State law; and (3) Plaintiff scientists who seek to consult with Plaintiff physicians and patients regarding non-combustion means by which to inhale medicinal marijuana. Plaintiffs seek the immediate issuance of an injunction enjoining the aforesaid proceedings until such time as this court issues a decision on the merits of the underlying case. In support, Plaintiffs respectfully refer the Court to Plaintiff's Amended Complaint filed herein; the Affidavits supplied in a simultaneously filed Exhibits Volume, and the following.

I. THE PLAINTIFFS

Plaintiff American Preventive Medical Association ("APMA") is a non-profit health care advocacy organization, founded in October 1992, with 474 current members, including 234 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 physician members in Arizona, California, Connecticut, and Virginia are unable to prescribe and recommend medicinal marijuana cultivated, prescribed, recommended, and administered entirely intrastate, in accordance with state law, to patients residing within those respective states without fear of imminent federal civil, criminal, and administrative action against them. *See* Exhibit 1: Affidavit of Dr. Michael Jansen, President APMA.

Plaintiff Life Extension Foundation ("LEF") is a non-profit membership organization dedicated to pursuing

therapies to extend the healthy life span of humans. LEF also supports 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 terminal illnesses such as cancer and AIDS. Some LEF members who reside in Arizona, California, Connecticut, and Virginia desire to use medicinal marijuana to alleviate the side effects associated with their life threatening diseases (including the nausea, vomiting, wasting syndrome and unremitting pain associated with cancer, cancer chemotherapy, AIDS, and AIDS therapy). Those patients seek to use medicinal marijuana cultivated, prescribed, recommended, and administered intrastate in accord with state law. Those patients do not do so, fearing imminent federal civil and criminal prosecution. *See* Exhibit 2: Affidavit of William Faloon, President of Life Extension Foundation.

Plaintiff Julian M. Whitaker, M.D. ("Dr. Whitaker") is a physician licensed to practice medicine in California and Washington. Dr. Whitaker practices medicine at the Whitaker Wellness Institute, 4321 Birch Street, Suite 100, Newport Beach, California. Dr. Whitaker treats approximately 200 patients suffering from the debilitating side effects of chemotherapy (including nausea and vomiting) and from unremitting cancer pain. Dr. Whitaker seeks to recommend medicinal marijuana to those of his patients resident in California who so suffer when all other FDA-approved palliative and anti-emetic treatments have failed. Dr. Whitaker will recommend marijuana cultivated and grown solely within California in strict conformance with California law to patients residing in California. He refrains from doing so now, fearing that the United States will take adverse civil, criminal, and administrative action against him. *See* Exhibit 3: Affidavit of Julian M. Whitaker, M.D.

Plaintiff Jeffrey A. Singer, M.D. ("Dr. Singer") is a physician licensed to practice medicine in Arizona. Dr. Singer practices medicine at the Southwest Surgical, P.C., 1728 West Glenndale Avenue, Suite 401, Phoenix, Arizona. Dr. Singer treats approximately 200 patients per year who have cancer and are undergoing chemotherapy. Dr. Singer seeks to prescribe and recommend medicinal marijuana to cancer patients undergoing chemotherapy who are not responding to traditional anti-emetic and palliative drug treatments. He refrains from doing so now, fearing that the United States will take adverse civil, criminal, and administrative action against him. *See* Exhibit 4: Affidavit of Jeffrey A. Singer, M.D.

Plaintiff Richard D. Fisher, M.D. ("Dr. Fisher") is a physician licensed to practice medicine in Arizona. Dr. Fisher practices medicine at the Fisher Medical Group, 10503 West Thunderbird, Suite 366, Sun City, Arizona. Dr. Fisher frequently treats terminally ill cancer patients undergoing chemotherapy. Approximately 50 to 60 of Dr. Fisher’s cancer patients per year do not respond to traditional anti-emetic and palliative drug therapies and suffer from cancer pain and chemotherapy induced nausea and vomiting. Dr. Fisher seeks to recommend medicinal marijuana to those 50 to 60 patients. Dr. Fisher seeks to recommend and prescribe medicinal marijuana to those of his patients resident in Arizona who continue to suffer after all FDA-approved palliative and anti-emetic treatments have failed. He refrains from doing so now, fearing that the United States will take adverse civil, criminal, and administrative action against him. *See* Exhibit 5: Affidavit of Richard D. Fisher, M.D.

Plaintiff Henry N. Blansfield, M.D. is a physician licensed to practice medicine in Connecticut. Dr. Blansfield is a volunteer physician for the Americares Free Clinic in Danbury, Connecticut. At the clinic Dr. Blansfield treats several patients undergoing cancer chemotherapy. He also treats patients with AIDS. Dr. Blansfield believes that many of those patients would benefit from the use of medicinal marijuana in combating the negative side effects associated with chemotherapy and AIDS therapy, including wasting, nausea, and vomiting. Indeed, Dr. Blansfield seeks to prescribe medicinal marijuana to those patients for whom traditional anti-emetic drugs such as Marinol and Zofran have failed to provide needed relief. Dr. Blansfield refrains from prescribing or recommending medicinal marijuana, fearing that the United States will take adverse civil, criminal, and administrative action

against him. *See* Exhibit 6: Affidavit of Henry N. Blansfield, M.D.

Plaintiff William Regelson, M.D. is an oncologist licensed to practice medicine in Virginia. In his practice, Dr. Regelson has seen many cancer patients that would benefit from the medicinal use of marijuana. Indeed, in the past in accord with Virginia law, Dr. Regelson has prescribed medicinal marijuana to many of those patients. However, fearing that the United States will take adverse civil, criminal, and administrative action against him, Dr. Regelson now refrains from prescribing or recommending medicinal marijuana to those patients who would benefit from its use. *See* Exhibit 7: Affidavit of William Regelson, M.D.

Plaintiffs Durk Pearson and Sandy Shaw ("P&S") are scientists and authors with a primary residence in Nevada and a secondary residence in California. P&S seek to consult with physicians (who prescribe and recommend medicinal marijuana to seriously or terminally ill patients) in Arizona, California, Connecticut, and Virginia concerning a method for delivering medicinal marijuana that does not involve combustion. The P&S method involves electrically preheating air to a controlled temperature that is hot enough to evaporate and entrain the active ingredients in marijuana but not hot enough to cause combustion. The electrically heated air is passed through a bed of marijuana and is then cooled before the patient inhales it. The P&S process of controlling the temperature surrounding the marijuana produces fewer carcinogens than are generated by partial combustion of marijuana in a cigarette or pipe. More sophisticated methods produce even less carcinogens by retorting the marijuana in an inert gas. P&S fear federal civil and criminal prosecution of themselves and those with whom they consult if they communicate to physicians information concerning the method they have developed. *See* Exhibit 8: Affidavit of Durk Pearson and Exhibit 9: Affidavit of Sandy Shaw.

Plaintiff Durk Pearson has degenerative spinal arthritis and desires to consult with Plaintiff Dr. Whitaker or another California physician concerning the appropriateness of using medicinal marijuana to treat the variable and sometimes extreme pain associated with his condition. Through the years Mr. Pearson has exhausted all other methods of palliative treatment with only partial and variable alleviation of his pain. Plaintiff Pearson fears that if he consults with a California physician concerning medicinal marijuana he, or his physician, or both of them may be subject to federal civil and criminal prosecution. *See* Exhibit 8: Affidavit of Durk Pearson.

Plaintiff Sandy Shaw suffers from temporal lobe epilepsy only partially controlled by FDA-approved epilepsy drugs and wishes to consult with Plaintiff Dr. Whitaker or another California physician concerning the appropriateness of medicinal marijuana as an adjunct therapy for her condition. Plaintiff Shaw fears that if she consults with a California physician concerning medicinal marijuana she, or her physician, or both of them may be subject to federal civil and criminal prosecution. *See* Exhibit 9: Affidavit of Sandy Shaw.

II. THE LAWS OF THE STATES OF ARIZONA, CALIFORNIA, CONNECTICUT, AND VIRGINIA AFFORD SERIOUSLY ILL AND TERMINALLY ILL PATIENTS ACCESS TO MEDICINAL MARIJUANA PURSUANT TO PHYSICIAN RECOMMENDATION OR PRESCRIPTION

Four states have enacted legislation authorizing the prescription, recommendation, and recommended or prescribed use of medicinal marijuana within their borders. Those states are Arizona (physician may recommend and prescribe medicinal marijuana to seriously ill patients); California (physicians may recommend and distribute

medicinal marijuana to seriously ill patients); Connecticut (physicians may prescribe medicinal marijuana to patients undergoing chemotherapy or treatment for glaucoma); and Virginia (physicians may prescribe medicinal marijuana to cancer and glaucoma patients).

On March 27, 1979, the Virginia legislature enacted legislation permitting physicians licensed in Virginia to prescribe medicinal marijuana to cancer and glaucoma patients without being subject to civil and criminal penalties. *See* VA. CODE § 18.2-252.1 (attached as Exhibit 10). The law also permits pharmacies to dispense and patients to use medicinal marijuana based on a valid prescription without being subject to civil and criminal penalties. *See* VA. CODE § 18.2-252.1. Such patients are also protected under state law. *See* Id.

On July 1, 1981, the Connecticut legislature enacted legislation permitting physicians licensed in Connecticut to prescribe medicinal marijuana to glaucoma and chemotherapy patients residing in Connecticut without being subject to civil and criminal penalties. *See* CONN. GEN. STAT. §§ 21a-246 and 21a-253 (attached as Exhibit 11). To avoid civil or criminal sanctions, a Connecticut physician must obtain a license from the Commissioner of Consumer Protection and obtain the marijuana from a source licensed by the Commissioner. *See* CONN. GEN. STAT. §§ 21a-246(a) and (b). Patients suffering from glaucoma or the side effects of chemotherapy may use medicinal marijuana pursuant to a physician's prescription without being subject to criminal prosecution. *See Id.*

On November 5, 1996, voters of California enacted Proposition 215. That proposition allows physicians to recommend the use of medicinal marijuana to seriously ill and terminally ill patients residing in the state without being subject to civil and criminal penalties. *See* CAL. HEALTH & SAFETY CODE § 11362.5 (attached as Exhibit 12). Seriously ill patients may obtain and use medicinal marijuana based upon that recommendation without being subject to criminal prosecution. *See Id.*

On November 5, 1996, the voters of Arizona enacted Proposition 200. That proposition allows physicians licensed in the state to recommend and prescribe the use of medicinal marijuana to seriously ill and terminally ill patients residing in the state without being subject to civil and criminal penalties. *See* AZ. REV. STAT. § 13-3412.01 (attached as Exhibit 13). To avoid civil and criminal prosecution under Proposition 200, the physician who wishes to prescribe medicinal marijuana must have relevant scientific information to support its use. The physician must obtain a written opinion from another physician licensed in Arizona that the use of medicinal marijuana is medically indicated. Patients suffering from a serious illness may use medicinal marijuana pursuant to a physician's prescription without being subject to criminal prosecution. *See Id.*

III. THE FACTUAL PREDICATE FOR THE ADOPTION OF MEDICINAL MARIJUANA LAWS

Arizona, California, Connecticut, and Virginia have each passed laws to permit physicians licensed in their respective states to prescribe medicinal marijuana to patients for certain serious or terminal conditions. Endowed with inherent state police powers which embrace the regulation of medical practice, those states may "prescribe regulations to promote the general health . . . and good of the people" consistent with the Constitution of the United States. *Barbier v. Connolly*, 113 U.S. 27, 31 (1885); *see also Jacobson v. Massachusetts*, 197 U.S. 11, 125 (1905) and *Holden v. Hardy*, 169 U.S. 366, 392. The four states have enacted these laws upon a determination that certain seriously ill and terminally ill patients within their borders and under the care of physicians licensed in those states may benefit from access to medicinal marijuana for therapeutic reasons. The central issue is whether the Federal Government's Policy, 62 Fed. Reg. 6164 (Feb. 11, 1997), impermissibly

invades the province of reserved State police powers. Resolution of that issue does not turn on whether the Federal Government agrees that marijuana is safe or effective for a particular use. Rather, it turns on a determination of which of the conflicting powers, state or federal, prevails.

Nevertheless, the States do rest their judgments on substantial scientific evidence corroborating the value of medicinal marijuana in the treatment of a number of serious and terminal conditions, including cancer, AIDS, glaucoma, arthritis, and epilepsy.

In 1974, the Federal Government published a report entitled Marihuana and Health in which the National Institute on Drug Abuse proclaimed:

> The modern phase of therapeutic use of cannabis began about 140 years ago when O'Shaughnessey reported on its effectiveness as an analgesic and anticonvulsant. At about the same time Moreau de Tours described its use in melancholia and other psychiatric illnesses. Those who saw favorable results observed that cannabis produced sleep, enhanced appetite and did not cause physical addiction.

The Federal Government's 1975 report on *Marijuana and Health* commences with a discussion of the medicinal benefits of marijuana: "Cannabis is one of the most ancient healing drugs" and "[o]ne should not . . . summarily dismiss the possibility of therapeutic usefulness simply because the plant is the subject of current sociopolitical controversy."

In 1985, the Food and Drug Administration approved a synthetic form of one of the active constituents in marijuana, tetrahydrocannabinol (THC), for use in the treatment of nausea and vomiting in cancer chemotherapy patients. When the agency approved THC, it acknowledged that the evaluation of the risks and benefits of the THC pill was based on the risks and benefits of marijuana. In fact, the agency stated that "the risks to the public health from illicit use of the THC pill are likely to be similar to marijuana . . . . The effects of pure THC are essentially similar to those of cannabis containing THC in equivalent amounts."

Prior to 1992, under research protocols approved by the U.S. Food and Drug Administration, six state health agencies conducted clinical trials to determine the efficacy of marijuana as an antiemetic for cancer patients. Those trials were conducted in California, Georgia, New Mexico, New York, Michigan, and Tennessee. They compared marijuana to antiemetics available by prescription, including the FDA-approved synthetic THC pill. Marijuana was found to be an effective and safe antiemetic in each of the studies and more effective than other drugs for many patients.

In September of 1996, Francis L. Young, an Administrative Law Judge with the United States Department of Justice, Drug Enforcement Administration, recommended that DEA reclassify marijuana from DEA Schedule I to Schedule II. Schedule I drugs are those substances that (1) have a "high potential for abuse"; (2) have "no current accepted medical use"; and (3) are considered unsafe for use under medical supervision. 21 U.S.C. § 812(b)(1). In contrast, Schedule II drugs are those substances that (1) have "a high potential for abuse"; (2) have "currently accepted medical use . . .or accepted medical use with severe restriction"; and (3) have the potential to "lead to severe psychological or physical dependence." 21 U.S.C. § 812(b)(2). The ALJ based his determination upon uncontroverted record evidence of the effectiveness of medicinal marijuana in the treatment of emesis in cancer patients; in the treatment of nausea and vomiting resulting from chemotherapy treatments; and in the treatment of spasticity resulting from multiple sclerosis and other causes. He also based his determination upon a finding that "marijuana, in its natural form, is one of the safest therapeutically active substances known to man." *See* Exhibit

14. The Administrator of the Drug Enforcement Administration refused to follow the reclassification recommendation of the ALJ. *See* Exhibit 15.

A 1991 scientific survey of oncologists found that almost one half (48 percent) of those responding would prescribe medicinal marijuana to some of their patients if it were legal to do so. Over 44 percent of survey respondents reported having actually recommended the illegal use of marijuana for the control of nausea and vomiting in cancer patients.

Several studies have compared the FDA approved THC pill with marijuana. In 1979, Dr. Alfred Chang and his colleagues published a peer-reviewed, scientific study on the antiemetic effects of marijuana, finding marijuana had a more consistent effect than oral THC pills. Chang's results were consistent with those of Sallan and others who published similar study results in The New England Journal of Medicine. As many as one-fifth of AIDS patients surveyed disliked the psychoactive side effect of synthetic THC. A 1996 survey conducted by a Hawaiian researcher found that 98.4 percent of AIDS patients surveyed were aware of the medical value of marijuana and 36.9 percent had used it as an antiemetic. Of those who had used it, 80 percent preferred it over prescription drugs including synthetic THC. Several state studies confirm that medicinal marijuana is capable of greater user control and has less psychoactive side effects than synthetic THC.

In 1992, the Federal Government ordered a halt to research on the medical use of marijuana. Studies then underway had reached late-Phase III (the stage that confirms effectiveness and assesses adverse effects in large and diverse populations). Phase IV is used to describe post-marketing reporting on drug safety and effectiveness.

IV. THE FEDERAL POLICY

The Clinton Administration has threatened to arrest and prosecute physicians who recommend or prescribe medicinal marijuana to their patients under state law. The Administration has also threatened to arrest and prosecute patients who use physician recommended or prescribed medicinal marijuana. On October 28, 1996, shortly before the passage of Proposition 200 and 215 in Arizona and California, Defendant Barry R. McCaffrey, the Director of the Office of National Drug Control Policy ("ONDCP"), publicly stated that the Federal Government would prosecute any physician who recommended or prescribed medicinal marijuana in accordance with state law along with their patients. Defendant McCaffrey's statement suggested a dramatic shift in federal policy concerning the legalization of medicinal marijuana by the states.

In response to the passage of Proposition 200 and 215, Defendant McCaffrey, on December 2, 1996, testified on behalf of the Clinton Administration before the Senate Committee on the Judiciary. During that testimony he reaffirmed the Clinton Administration's policy on medicinal marijuana stating that "Deputy Assistant Attorney General Mary Lee Warren affirmed this principle to Los Angeles County Sheriff Brad Gates . . . . [I]t should be clear, however, that, whatever the applicable state law, those who distribute or use marijuana act in violation of federal law and are therefore subject to federal prosecution." *See* Exhibit 19A: Statement by General Barry R. McCaffrey before the Senate Committee on the Judiciary.

On December 29, 1996, Defendant McCaffrey incorrectly claimed (in a column syndicated by Scripps-Howard News Service) that "no clinical evidence demonstrates that smoked marijuana is good medicine." *See* Exhibit 19B: Barry R. McCaffrey, *Should Government Sanction Medicinal Use of Marijuana*, DAYTON DAILY

NEWS, December 20, 1996, at 19A. He has consistently described medical marijuana as "Cheech and Chong medicine."

On December 30, 1996, Defendant McCaffrey announced a government sponsored public relations effort to proclaim the unscientific view that medical marijuana has no therapeutic benefits. While Defendant McCaffrey has repeatedly denied the existence of scientific evidence supporting the therapeutic benefits of medicinal marijuana, the facts are to the contrary. There are numerous well-designed scientific studies, including randomized, double blind, and placebo-controlled trials, which establish the therapeutic value of medicinal marijuana.

During the December 30 press conference, Defendant McCaffrey reiterated the federal government's new policy, that it would prosecute any physician who prescribed or recommended medicinal marijuana and their patients who used it. *See* Exhibit 20: Transcript of Press Conference "The Administration's Response to the Passage of California Proposition 215 and Arizona Proposition 200." In that press conference Defendant Reno informed physicians that DOJ would prosecute physicians who violate federal law by recommending or prescribing medicinal marijuana along with their patients who use it. At the same press conference, Defendant Shalala warned that physicians found to prescribed or recommended medicinal marijuana would be excluded from participating in Medicare and Medicaid. *See* Exhibit 20.

In the February 11, 1997 Federal Register the ONDCP announced the new Federal Policy (hereinafter "Policy") regarding prescription and recommendation of marijuana. *See* Exhibit 21. Under the Policy, (1) physicians who recommend and prescribe medicinal marijuana to patients in conformity with state law (and patients who use marijuana pursuant to state law) will be civilly and criminally prosecuted; (2) physicians who recommend or prescribe marijuana to patients in conformity with State law will be excluded from Medicare and Medicaid; and (3) physicians who recommend or prescribe marijuana to patients in conformity with State law will have their DEA drug registrations revoked. The Policy also urges state authorities to arrest physicians who recommend and prescribe medicinal marijuana under state law and patients who use medicinal marijuana pursuant to those recommendations or prescriptions under state law.

On February 27, 1997, the Department of Health and Human Services in conjunction with the Criminal Division of the Department of Justice forwarded a letter providing a further explanation of the new Policy to the national, state, and local medical organizations located in the United States. *See* Exhibit 22.

V. IMPACT ON PLAINTIFFS

The Policy threatens imminent and severe sanctions against Plaintiff physicians if they recommend and prescribe the use of medicinal marijuana to their patients even when such recommendation and prescription is in accord with state law. Those sanctions include arrest and prosecution for drug trafficking, revocation of physicians' DEA registrations, and exclusion from Medicare and Medicaid. Patients using medicinal marijuana in accord with state law risk federal civil and criminal prosecution for drug possession and trafficking.

The Policy prevents physicians from providing the best possible care to their patients. It chills the advancement of medical science (much of which occurs as a result of clinical experience). It blocks the dissemination of scientific information to seriously ill and terminally ill patients and to the physicians who treat them. It denies seriously ill and terminally ill patients the full benefit of physician advice. It prevents physicians from fully informing patients of

all treatment options and from aiding patients who suffer from uncontrollable pain, nausea, and vomiting due to cancer or AIDS, severe pain from arthritis and inadequately controlled epilepsy.

STATEMENT OF POINTS AND AUTHORITIES

VI. SUMMARY OF ARGUMENT

The Policy violates physician and patient First Amendment rights. Under the First Amendment the speech in issue (prescription, recommendation, and scientific consultation) is fully protected. The Federal Government's Policy is an unconstitutional prior restraint. Prior restraints are presumptively unconstitutional and pass constitutional muster in only the narrowest of circumstances (for limited national security reasons or to prevent publication of obscenity when procedural safeguards and prompt judicial review are provided). The Policy is also an unconstitutional content-based suppression of protected speech, targeting physician-patient communication involving recommendation and prescription of medicinal marijuana. The Federal Government may not impose content-based restrictions on speech without a compelling state interest and a least restrictive means to achieve a constitutional end.

As explained herein, the government lacks a compelling interest. Its means, total suppression of prescription and recommendation, are not narrowly tailored to achieve the constitutional end of banning interstate trafficking in illicit drugs, and there are numerous less restrictive alternatives. The Policy effectively prohibits physicians from communicating to patients the risks and benefits of medicinal marijuana and prohibits scientists from communicating to physicians and their patients safer ways of using the drug. Indeed, physicians, patients, and scientists, including the Plaintiffs, have refrained from communicating in fear of prosecution under the Policy.

Because the Policy suppresses the speech of all physicians in those states where medicinal marijuana is legal, and because it chills all patient communication with physicians, scientists, and patients concerning the benefits of medicinal marijuana and concerning safer ways of using it, the speech ban reaches communication of doctors, patients, and scientists not before the Court. The policy thus suffers from a fatal and substantial unconstitutional overbreadth.

The effect of the Government's censorship is dire. Some of the most vulnerable and needy among us, cancer and AIDS patients who suffer from uncontrollable pain, nausea, vomiting or wasting, are left with neither information concerning, nor legal protection for their use of, a therapy that would be recommended or prescribed by their physicians were it not for the Policy. The Policy creates a conflict between a physician's moral and ethical duties along with his State statutory prerogatives, on the one hand, and a federal ban, on the other.

The Policy violates the Tenth Amendment. Under the Policy all states (including those where medicinal marijuana is legal) are effectively coerced and cajoled into aiding federal authorities in the apprehension and prosecution of those who violate the Policy. Moreover, the Policy effectively negates the laws of Connecticut, Virginia, Arizona and California, commandeering those states to enforce the Policy and avoid enforcement of their own laws.

The Policy violates the Ninth Amendment. The right of a physician to recommend and prescribe needed treatment to a seriously or terminally ill patient (regulated under state law) and the right of a patient to receive that treatment (regulated under state law) are unenumerated in the Constitution, albeit closely akin to rights to life and privacy that are protected variously under the First, Fourth, Fifth, Ninth, and Fourteenth Amendments. The foregoing federally unenumerated rights (which have been enumerated under State law) are violated by the

Policy.

The Policy violates the Commerce Clause. Neither the intrastate recommendation and prescription of marijuana nor the intrastate cultivation, growth, and use in accord with state law of medicinal marijuana substantially affects the channels or instrumentality of interstate commerce as contemplated by Article 1, Section 8 of the United States Constitution. Having no such effect, neither Congress nor the administrative agencies may regulate medicinal marijuana authorized for prescription and prescribed use in accord with the laws of Arizona, California, Connecticut, and Virginia.

The Policy violates the Administrative Procedure Act ("APA"). Contrary to the United States Constitution, the Policy imposes two rules of general applicability (revocation of Medicare benefits and revocation of DEA registrations). It does so without notice and an opportunity for comment required by the APA before the adoption of final rules.

The Policy exceeds ONDCP's statutory authority. The Policy announces that physicians who prescribe and recommend medicinal marijuana under state law will have their DEA prescription drug licenses revoked and will be prohibited from participating in Medicare and Medicaid. Neither the Controlled Substances Act ("CSA") nor the Social Security Act provides authority to the Federal Government to revoke licenses or participation in Medicare and Medicaid based on the intrastate recommendation or prescription of medicinal marijuana in accord with state law.

VII. ARGUMENT

A. STANDARD FOR PRELIMINARY INJUNCTIONS

A moving party is entitled to a preliminary injunction if that party demonstrates (1) a likelihood of success on the merits; (2) the likelihood that the moving party will suffer irreparable harm absent relief; (3) that other interested parties will not suffer substantial harm if the Court grants the relief requested; and (4) that the public interest favors granting the relief sought. *The Uniformed Division of Officers Association Local 17 International union of Police Association, AFL-CIO v. Nicholas Brady*, 1988 U.S. Dist. LEXIS 15750 (1988) (quoting *Washington Metropolitan Area Transit Commission v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977)).

B. PLAINTIFFS ARE LIKELY TO SUCEED ON THE MERITS

1. The Policy Is an Unconstitutional Prior Restraint

The Policy constitutes a classic prior restraint on fully protected scientific speech. Speech between a physician and patient is protected. In fact, the dialogue between the physician and patient has received heightened protection due to the nature of that relationship and the potential consequences to the health of patients if the communication is not open. *See e.g. Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 884 (1992) (discussing the relationship of trust needed between physicians and patients); *see also Whalen v. Roe*, 429 U.S. 210, 221-222 (1990) (recognizing as a fundamental the right to decide independently, with the advice of a physician, to acquire and to use needed medication); *City of Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416,445 (1983) (discussing the physician's right to exercise his or her best medical judgment and the patient's right to rely on the medical advice of the physician). A patient and a physician's discussion of various therapeutic approaches to the treatment of illness are also fully protected under the First Amendment.

A prior restraint on speech is an "administrative [or] judicial order[] *forbidding* certain communications when issued in advance of the time that such communications are to occur." *Alexander v. U.S.*, 507 U.S. 544, 550 (1993), *citing* N. Nimmer, Nimmer on Freedom of Speech s. 4.03, p. 4-14 (1984) (emphasis in original). The Supreme Court has repeatedly held that "[a]ny system of prior restraints of expression bear[s] a heavy presumption against its constitutional validity." *Bantam Books, Inc. v. Sullivan,* 372 U.S. 58, 70 (1963); *accord Forsyth County v. Nationalist Movement,* 505 U.S. 123, 130 (1993); *Freedman v. Maryland,* 380 U.S. 51, 57 (1965); *Niemotko v. Maryland,* 340 U.S. 268, 271 (1951). The Government "carries a heavy burden of showing justification for the enforcement of such a restraint." *Organization for a Better Austin v. Keefe,* 402 U.S. 415, 419 (1971). The Supreme Court has recognized only an "extremely narrow class of cases" which can satisfy the high burden, such as when the nation is at war and information concerning the location of military transport ships could be leaked to the enemy. *Near v. Minnesota,* 283 U.S. 697, 716 (1931); *see also New York Times Co. v. United States,* 403 U.S. 713, 726 (1971) (Brennan J., concurring). Imposition of blanket speech bans, such as the Policy ban on recommendation and prescription of medicinal marijuana, do not fall within the narrow class of cases capable of overcoming the constitutional presumption against prior restraints. Consequently, the Policy cannot stand because "the danger of censorship and of abridgment of our precious First Amendment freedom is too great" to be countenanced. *See Forsyth,* 505 U.S. at 131; *Southeastern Promotions, Ltd. v. Conrad,* 420 U.S. 546, 560 (1975).

2. The Policy Is an Unconstitutional Content-Based Restriction on Speech

The Policy effectively prohibits Plaintiff physicians from communicating to their seriously ill and terminally ill patients, in accordance with state law, any benefits of medicinal marijuana and effectively prohibits scientists from communicating with physicians and patients regarding safer ways of using medicinal marijuana. Under the First Amendment the Federal Government may not prohibit protected speech because it disapproves of its content.

Government limitations on speech are presumed invalid when the specific motivating ideology or the opinion or perspective of the speaker is the rationale for the restriction. *Rosenburger v. University of Virginia,* 115 S.Ct. 2510, 2516 (1995). In *Texas v. Johnson,* 491 U.S. 397, 414 (1989), the Court stated that "if there is a bedrock principle underlying the First Amendment, it is that the government may not prohibit the expression of an idea simply because society finds the idea itself offensive or disagreeable." In *Consolidated Edison Co. v. Public Service Comm'n.,* 477 U.S. 530 (1980), the Court held content restrictions subject to strict scrutiny when public officials disapprove of the speaker's views. *See also Police Department v. Mosely,* 408 U.S. 92, 95 (1972) ("the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content"). To protect the rights of the speaker and listener, government regulations of speech, especially regulations that censor speech of a particular speaker based on content, are subject to strict scrutiny. *Perry Education Association v. Perry Local Educators' Ass'n,* 460 U.S. 37, 45 (1983) and *Police Dep't v. Mosely,* 408 U.S. 92, 95 (1972). Indeed, recent Supreme Court decisions have held that content-based censorship is presumptively invalid unless applied to expressions that are constitutionally proscribed. *R.A.V. v. City of St. Paul,* 112 S.Ct. 2538, 2542-43 (1992).

One federal court has already granted injunctive relief (enjoining under the First Amendment the Federal Government's enforcement of the Policy's ban on physician recommendation) in response to the pleas of California physicians.

The Policy imposes punishment on physicians solely based on the content communicated between physician and patients. Because all recommendation and prescription of medicinal marijuana is prohibited, patients are denied a

full understanding of the medical alternatives for the treatment of their illnesses, of the roles those treatments can play in nausea and pain management, and of the basis for fully informed consent. Moreover, the Policy prohibits an entire category of speech (recommendation of medicinal marijuana). Categorical bans are content-based and thus require strict scrutiny. *See, e.g., Perry Education Association v. Perry Local Educators' Association,* 460 U.S. 37 (1983).

The Court imposes the following test for evaluating content-based restrictions on speech. Such restrictions will pass constitutional muster only (1) if they are backed by a compelling state interest and (2) if they are narrowly tailored, choosing the least restrictive means to further the articulated interest. The regulation must pass the entire test to survive constitutional review. *See Sable Communications, Inc. v. FCC,* 492 U.S. 115, 126 (1989) ("The Government may . . . regulate the content of constitutionally protected speech in order to promote a compelling interest if it chooses the least restrictive means to further the articulated interest"); *see also Simon & Schuster v. New York,* 502 U.S. 105, 118 (1991).

The Policy does not satisfy the test. While the Federal Government does have an interest in prohibiting the illicit interstate drug trade, it does not have a compelling interest in intrastate medical practice including regulating communication among physicians, scientists, and patients concerning the therapeutic applications of drugs for administration to seriously ill or terminally ill patients intrastate. The second practice of medicine depends upon the freedom of physicians to recommend and prescribe drugs. The recommendation or prescription of medicinal marijuana to seriously ill and terminally ill patients is information important to disease management and treatment of the seriously ill and terminally ill. The Policy blocks the exchange of that information among physicians, scientists, and patients, to the great detriment of patients in dire need of relief from pain, nausea, vomiting, and AIDS and cancer wasting.

Next, the Policy is not the least restrictive means to achieve a constitutional end. To the contrary, the Policy seeks to limit all communication regarding the recommendation and prescription of medicinal marijuana to patients without requiring any nexus to the illicit interstate drug trade. Physicians have a right and duty to exercise their best professional judgement and fully disclose to patients all therapies appropriate for treating disease, including the risks and benefits of each therapy. Fully informed patient consent to treatment is impossible without such full disclosure. The Policy effectively censors every conceivable recommendation or prescription involving medicinal marijuana in violation of the First Amendment, evincing no tailoring, let alone the narrow tailoring required. *Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 445 (1983). Numerous less restrictive alternatives are available to the Federal Government. If the Federal Government seeks to block the illicit drug trade, it could effectively achieve that end with a policy (1) that proscribed interstate shipment of all marijuana and (2) that required proof of written prescription or recommendation in full accordance with state law to avoid federal prosecution.

3. The Policy is Substantially Overbroad

Under the First Amendment overbreadth doctrine an individual whose own speech or conduct may be prohibited is permitted to challenge a statute on its face "because it also threatens others not before the court, those who desire to engage in legally protected speech but may refrain from doing so rather than risk prosecution or undertake to have the statute invalidated." *Brockett v. Spokan Arcades, Inc.*, 105 S.Ct. 2794, 2802 (1985); *Board of Airport Commissioners of the City of Los Angeles v. Jews for Jesus,* 107 S.Ct. 2568, 2572 (1987). A statute may be invalidated on its face when the overbreadth is substantial.

The Policy is substantially overbroad and has a chilling effect on doctor-patient communication. To provide

adequate care for patients, physicians must enjoy ample communicative freedom: to diagnose disease, to apprise patients of all known treatments useful in disease management or cure and of known risks and benefits of each such treatment, and to recommend and prescribe therapeutic options. The speech in issue is scientific, deliberative, and life affecting in nature. It is fragile. The Policy censors it with the full suppressive weight of federal law and the threat of imminent prosecution and adverse administrative action.

Those patients not before the Court who would benefit from prescription or recommendation of medicinal marijuana, including cancer patients suffering from chemotherapy induced nausea, cancer pain, AIDS therapy-induced nausea, AIDS pain, and AIDS and cancer wasting syndrome are denied access to vital information on how medicinal marijuana can substantially reduce or eliminate such nausea and pain and can improve appetite and thus help curb wasting. Indeed, the Policy precipitates preventable pain and death in patients by denying them access to vital information on therapies that can prolong life by making more aggressive treatment tolerable and by relieving discomfort.

To lawfully prescribe medication that contains narcotics or other controlled substances physicians are required to be registered with (and need to obtain a license from) the DEA. The Federal Policy provides for the revocation of that registration and licensing if physicians recommend or prescribe marijuana. Revocation of a physician's DEA registration effectively ends his or her medical practice. Moreover, many physicians treat patients who are enrolled in the Medicare and Medicaid programs. Barred from those programs merely because they recommend and or prescribe medicinal marijuana, physicians will suffer a substantial loss of income, loss of freedom to practice their profession, and loss of reputation in the community. Their patients will be denied the on-going benefits of the doctor-patient relationship. Finally, the Policy provides that DOJ and HHS will forward letters to state medical boards informing those entities that DEA will take adverse action against physicians who recommend and prescribe medicinal marijuana. The Policy effectively forces state medical licensing boards to take the position that recommending and prescribing marijuana is not permissible even though such activity is lawful in Arizona, California, Connecticut, and Virginia.

Due to the sanctions imposed by the Policy, physicians are afraid to recommend or prescribe medicinal marijuana to patients in need of the therapeutic benefits the drug provides. Physicians are in the position of having to withhold information from patients who have a right (and a need) to receive it. Physicians, including those not before the Court, fear that if they communicate about or prescribe medicinal marijuana in accordance with state law they will be federally prosecuted, will lose their prescription writing ability, and will be prohibited from participating in Medicare and Medicaid. *See* Exhibits 3, 4, 5, 6, and 7: Affidavits of Drs. Whitaker, Singer, Fisher, Blansfield, and Regelson. As a result of the Policy the physician-patient relationship is jeopardized and lacks that free flow of therapeutic information necessary to effective disease management and treatment. The Policy thus violates the First Amendment Overbreadth Doctrine. Accordingly, the Policy has a substantial chilling effect on the dissemination and receipt of health information beneficial to the life and well being of seriously ill and terminally ill patients.

4. The Policy Violates the Tenth Amendment

The Tenth Amendment provides that "powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. CONST. amend. X. In *New York v. United States*, 112 S.Ct. 2408, 2416 (1992), the Court stated that if a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States; but if a power is an attribute of state sovereignty reserved by the Tenth Amendment it is necessarily a power the Constitution has not conferred on Congress. *Id.* at 2417.

The Constitution creates a Federal Government of limited powers. *Gregory v. Aschcroft*, 501 U.S. 452, 457 (1991) ("[N]o one disputes the proposition that [t]he Constitution created a federal government of limited powers"). The Federal Government may not invade the province of state sovereignty reserved by the Tenth Amendment. *New York v. United States*, 505 U.S. 144, 155 (1992). If a power is an attribute of state sovereignty reserved by the Tenth Amendment, it is necessarily a power the Constitution has not conferred on Congress. *Id.* Regulation of the intrastate practice of medicine is an attribute of state sovereignty that lies at the heart of the state's police power. The Constitution has not conferred that power upon Congress. No general federal police power exists. *See United States v. Lopez*, 115 S. Ct. 1624, 1642 (1995) (J. Thomas, concurring). Congress may not "commandeer the legislative process of the States by directly compelling them to enact and enforce a federal regulatory program." *Id., citing Hodel v. Virginia Surface Mining and Reclamation Ass'n*, 452 U.S. 264, 288 (1981). The Court has "never . . . sanctioned . . . a federal command to the States to promulgate and enforce laws and regulations." *Id. citing Coyle v. Smith*, 221 U.S. 559, 565 (1911).

The Policy effectively nullifies the laws of four states, Arizona, California, Connecticut, and Virginia. The Policy effectively supplants those laws with a uniform federal ban on an important aspect of medical practice. Moreover, it directs state law enforcement officers to aid in the arrest and prosecution of physicians and patients who adhere to State law but violate the Policy. It thus operates to commandeer the States' legislative processes, rendering State law ineffectual and directing the State's law enforcement officers to follow a contrary federal policy. By so invading the police power of these four states and commandeering their regulation of medical practice, the Policy violates the Tenth Amendment.

5. The Policy Violates the Ninth Amendment

The Ninth Amendment provides that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." U.S. CONST. amend. IX. Taken together, the Ninth and Tenth Amendments define the fundamental "theory of American government, National and State – the theory of reserved rights and of delegated powers. The former article specifies *rights*, the latter specifies *powers*." Knowlton H. Kelsey, "The Ninth Amendment of the Federal Constitution," 11 Ind. L.J. 309 (1936). The Ninth Amendment provides that while certain enumerated rights have been expressly protected by the Constitution, their enumeration in the Constitution should not be taken to deny or disparage any unenumerated rights which were not specifically delineated.

The Ninth Amendment has not been the subject of much judicial exposition, finding its principal development in *Griswold v. Connecticut*, 381 U.S. 479 (1965). There Justice Douglas found the unenumerated right to privacy one protected by the Ninth Amendment, among others. The dearth of precedent on the amendment does not rob it of constitutional validity. To the contrary, as Chief Justice Marshall stated in *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 174 (1803), "[i]t cannot be presumed that any clause of the Constitution is intended to be without effect."

There is perhaps no more fundamental substantive right than that to life protected by the Fifth and Fourteenth Amendments against deprivation without due process. The Court has repeatedly recognized the right to privacy, an unenumerated right (*see, e.g., Planned Parenthood v. Casey*, 505 U.S. 833 (1992)), which—in the context of health care for seriously ill and terminally ill patients—acquires special meaning. *Id.* At 915; *Rochin v. California*, 342 U.S. 165 (1952); *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942).

Indeed, the Court has recognized that the liberty right protects numerous unenumerated individual, life-affecting elections of the most personal nature. "Our cases have long recognized that the Constitution embodies a promise that a certain private sphere of individual liberty will be kept largely beyond the reach of government." *Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 772 (1986), *citing Carey v. Population Services International*, 431 U.S. 678 (1977); *Moore v. East Cleveland*, 431 U.S. 494 (1977); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925); *Meyer v. Nebraska*, 262 U.S. 390 (1923); and *Whalen v. Roe*, 429 U.S. 589, 598-600 (1977). For example, this Court has recognized as fundamental and, so, beyond the Government's reach, the right to bear or beget a child, *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); to establish a home and raise children, *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923); to marry, *Loving v. Virginia*, 388 U.S. 1 (1967); to procreate, *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942); to use contraceptives, *Griswold v. Connecticut*, 381 U.S. 479 (1965); to direct the upbringing and education of a child, *Pierce v. Society of Sisters*, 268 U.S. 510, 534-535 (1925); to decide independently, with the advice of a physician, to acquire and to use needed medication, *Whalen v. Roe*, 429 U.S. 210, 221-222 (1990); and to refuse unwanted medical treatment, *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 281 (1990). In each of these cases, the Court has protected "personal autonomy" from government violation. In each of these cases, the rights protected are unenumerated.

The right of a physician to recommend and prescribe effective treatment to a seriously ill or terminally ill patient (as regulated under state law) and the right of a patient to receive that treatment (as regulated under state law) are unenumerated in the Constitution, albeit closely akin to rights to life and privacy protected variously under the First, Fourth , Fifth, Ninth, and Fourteenth Amendments. This physician-patient exchange is fundamental, as is the patient's desire to ingest recommended or prescribed medicines capable of alleviating pain or helping the patient manage a serious illness or a terminal illness. The Court has already recognized as fundamental the right to advice of a physician for the purpose of acquiring and using needed medication in *Whalen v. Roe*, 429 U.S. 210, 221-222 (1990). The companion unenumerated right of a physician to recommend and prescribe needed treatment to a seriously ill or terminally ill patient (as regulated under state law) and the right of a patient to receive that treatment (as regulated under state law) are also fundamental. Accordingly, those rights, retained by the people, are protected under the Ninth Amendment from federal denial or disparagement. The Policy cannot survive review under the Ninth Amendment.

6. The Policy Violates the Commerce Clause

Article 1, Section 8 of the Constitution of the United States empowers Congress "to regulate commerce with foreign nations, among the several states, and with Indian Tribes." U.S. CONST. art. 1, § 8. In *United States v. Lopez*, 115 S.Ct. 1624, 1629 (1995), the Supreme Court examined Congress' power under the Commerce Clause and identified three broad categories of activities that may be regulated. The Court held that Congress had the authority to regulate the use of channels of interstate commerce, that Congress is empowered to regulate and protect the instrumentalities of interstate commerce (even though the threat may come from intrastate activities), and that Congress has the authority to regulate those activities that have a substantial relation to interstate commerce, i.e., "those activities that substantially affect interstate commerce." *Id.* at 1629-30. In defining the limits of federal power, the Supreme Court in *Lopez* struck down the Gun Free School Zones Act providing that the possession of a firearm in a local school zone does not substantially affect interstate commerce. 115 S.Ct. at 1632. The *Lopez* Court warned that "Federal power" may not be extended so as to reach effects upon interstate commerce so indirect and remote that to embrace them, in view of our complex society, would effectively obliterate the distinction between what is national and what is local and create a completely centralized

government. *Lopez,* 115 S.Ct. at 1628-29; *see also U.S. v. Pappadopoulos*, 64 F.3d 522, 526 (9th Cir. 1995).

The Policy does not fit within the structural categories provided in *Lopez*. The Policy does not seek to regulate the channels of interstate commerce. Rather, the Policy is a direct response to the passage of California's proposition 200 and Arizona's Proposition 215 and seeks to prohibit physician prescription and recommendation of even wholly intrastate sources of medicinal marijuana. Indeed, Virginia has had state legislation permitting physicians licensed in the state to prescribe and recommend medicinal marijuana for cancer and glaucoma patients since 1979. Connecticut has had state legislation permitting physicians licensed in the state to prescribe and recommend medicinal marijuana to treat chemotherapy and glaucoma patients since 1981. Prior to the passage of Propositions 200 and 215, neither Congress nor any Federal agency ever adopted or enforced specific laws to prevent physicians from recommending and prescribing medicinal marijuana in accord with Connecticut or Virginia law. Plaintiffs are unaware of any published case in which the Federal Government has prosecuted a Connecticut or Virginia physician for prescribing medicinal marijuana in accordance with state law. Were the Policy announced by ONDCP a sincere effort to regulate and protect the channels of interstate commerce from Schedule I substances, it would appropriately be limited to prohibiting interstate trafficking, sale or distribution of medicinal marijuana. Instead, it acts wholly intrastate replacing state laws regulating the practice of prescribing and recommending medicinal marijuana, an element embedded in the intrastate practice of medicine and a regulatory arena long reserved to the states.

Second, in *Lopez* the Supreme Court stated that Congress had the power to regulate and protect the instrumentality or persons of interstate commerce. In this case, the Government through its Policy is seeking to usurp state authority to regulate wholly intrastate activities having no substantial relation to, or effect upon, interstate commerce. The wholly intrastate cultivation, recommendation, prescription, and prescribed use of medicinal marijuana under state law is not an instrumentality or person of interstate commerce. The state laws in issue are classic exercises of the police power, designed not to interfere with federal efforts to ban illicit interstate drug trafficking. Instead, the laws fall outside the illicit realm and apply in the very limited context of physician treatment of seriously ill and terminally ill patients within state borders in either clinics or home settings. The intrastate recommendation and prescription of intrastate cultivated medicinal marijuana for the treatment of state resident patients is an essential, constitutionally protected element of the practice of medicine, a province historically under the exclusive control of the states. State authorities, not the Federal Government, have long exclusively regulated all medical practice in so far as it retains its intrastate character.

Finally, the Supreme Court in *Lopez* states that Congress was empowered to regulate those activities that have a substantial effect on interstate commerce. The recommending and prescribing of medicinal marijuana intrastate does not have such an effect. Medicinal marijuana will only be used in the treatment of (and care for) seriously ill and terminally ill patients within the state, relying on state sources of marijuana. *Lopez* holds that the connections to or effect on interstate commerce must be substantial. *Lopez,* 115 S.Ct. 1624; *Pappadopulus*, 64 F.3d at 527. There is no interstate economic impact directly traceable to the wholly intrastate cultivation, prescription, and prescribed use of medicinal marijuana by the seriously ill and the terminally ill. The economic activity attendant to medicinal marijuana under state law is not unlike that found intrastate in *Lopez* and in *Pappadopoulus*.

In *Lopez*, the Federal Government argued that the costs of violent crime substantially affected interstate commerce and justified extension of federal jurisdiction to prohibit possession of a firearm within 1,000 feet of a school. *Lopez,* 115 S. Ct.. at 1632. In *Pappadopoulus*, the Federal Government argued that residential receipt

of natural gas from out-of-state sources substantially affected interstate commerce and justified extension of federal jurisdiction to prosecute the defendant for the federal crime of arson of property used in interstate commerce. *Pappadopoulus*, 64 F.3d at 525.

The *Lopez* Court rejected the Government's "theories . . . in support of § 922(q)," finding it difficult, under such theories, "to perceive any limitation on federal power, even in areas such as criminal law enforcement or education where states historically have been sovereign." 115 U.S. at 1632. The *Pappadopoulus* court also rejected the Government's argument, finding the receipt of natural gas at the *Pappadopoulus* residence from out-of-state sources "insufficient as a matter of law to confer Federal jurisdiction . . . ."

In the two cases, as here, the ties to interstate commerce are "so indirect and remote that to embrace them . . . would effectually obliterate the distinction between what is national and what is local and create a completely centralized government." *Pappadopoulus*, 64 F.3d at 525, *citing Lopez*, 115 S. Ct at 1628-29. The Court will not permit a tenuous link to interstate commerce to justify Federal jurisdiction over intrastate activity. The Court will not permit the Federal Government "to pile inference upon inference in a manner that would bid fair to convert congressional authority under the Commerce Clause to a general police power of the sort retained by the States." *Lopez*, 115 S Ct. at 1634.

The regulation of the prescription and prescribed use of medicinal marijuana for the treatment of seriously ill and terminally ill patients is a regulation of medical practice, a power retained by the States. Only the most tenuous logic can link that matter to Federal regulation of illicit interstate recreational drug trafficking. It, like the criminal activity in *Pappadopoulus* and the possession of a firearm within 1,000 feet of a school in *Lopez*, has too remote a nexus to interstate commerce to be deemed a substantial affect upon that commerce. State sovereignty thus cannot be constitutionally replaced with Federal in the instant case. In sum, the Policy violates the constitutional limits of the Commerce Clause by regulating a wholly intrastate activity that does not substantially affect interstate commerce.

7. ONDCP, DOJ, DEA AND HHS Have Exceeded the Scope of Their Delegated Authority by Authorizing Revocation of DEA Registration and Exclusion of Physicians from Participating in Medicare and Medicaid Programs

The Federal Government has authority to regulate the interstate manufacture, dispensing and distribution of controlled substances via the Controlled Substances Act. The Controlled Substances Act grants the DEA authority to regulate the interstate manufacture and distribution of drugs, not the authority to regulate the practice of medicine. 21 U.S.C. §§ 821-828. Regulation of medical practice is reserved to the states. Legislative History, S. Rep. No. 225, 98th Cong., 2d Sess., *reprinted in* 1984 U.S.C.A.A.N. 3182, 3449 n. 40; *see also Evers v. United States*, 643 F.2d 1043 (5th Cir. 1981) (FDA concurred with the court's dicta that the federal government does not have jurisdiction over the physician's practice of medicine). The Defendants in this case assert that physician recommendation and prescription of medicinal marijuana is inconsistent with the public interest. On that basis, the Defendants contend that they have statutory authority to revoke physicians' DEA registration and Medicare and Medicaid privileges. In interpreting statutory language, the Court must look at the plain meaning of the provision in issue. *See Pilon v. United States*, 73 F.3d 1111, 1119 (D.C. Cir. 1996). If the meaning of the statute is not plain on its face, the Court may then discern its meaning by looking at such sources as the legislative history. *See Burlington N.R. Co. v. Oklahoma Tax Com.*, 481 U.S. 454, 461 (1987).

The term "public interest" lacks any concrete meaning. Legislative history reveals that the statutory authority to revoke a physician's license on "public interest" grounds was added in 1984 and was intended to grant authority to control illicit interstate distribution of prescription drugs. 130 Cong. Rec. H9681 (daily ed. Sept. 18, 1984 (remarks of Rep. Gilman). The 1984 amendment was enacted to address prescription drugs that were being diverted for illicit use by licensed physicians. One of the amendment's goals was to punish physicians who wrote prescriptions in a manner that harmed the public (i.e., writing prescriptions unnecessarily). *Id*. Legislative history reveals that Congress did not intend for the 1984 "public interest" amendment to the Controlled Substances Act to be used as a basis for supplanting state laws regulating the intrastate prescription or recommendation of medicinal marijuana for administration to seriously or terminally ill patients. Congress did not intend for the Controlled Substances Act to be the basis of authority for federal agencies to regulate the practice of medicine. To the contrary, the legislative history of the Controlled Substances Act provides that when the Federal Government is concerned with the practice of medicine, it is to continue to give deference to the opinions of the state licensing authorities. Legislative History, S. Rep. No. 225, 98th Cong., 2d Sess., reprinted in 1984 U.S.C.A.A.N. 3182, 3449 n. 40.

Similarly, Defendants do not have the statutory authority to prohibit physicians from participating in Medicare or Medicaid. The Social Security Act lists specific acts and circumstances under which physicians may be excluded from participating in the Medicare and Medicaid programs. None of those acts includes the intrastate recommending or prescribing of medicinal marijuana in accordance with state law. There is nothing in the Social Security Act that provides HHS with the authority to exclude physicians from participating in the Medicare or Medicaid programs for recommending or prescribing medicinal marijuana in accordance with state law. To the contrary, the Medicare and Medicaid exclusion provisions of the Social Security Act make it quite clear that physicians may not be excluded from such programs without a criminal conviction either by the federal, state or local authorities. See 42 U.S.C. § 1320a-7.

8. The Policy Violates the APA

The 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 a patient in accordance with state law and (2) a physician may be excluded from participating in Medicare and Medicaid by the Department of Health and Human Services if a physician recommends or prescribes marijuana to a patient in accordance with state law. Both of those rules were published in the February 11, 1997 Federal Register without advance notice and opportunity for comment as required by the Administrative Procedure Act ("APA").

The Administrative Procedure Act, 5 U.S.C. § 553, requires that the agency promulgating a rule of general applicability provide the public with notice and an opportunity for comment. To meet the requirements of § 553, an agency must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully. *National Electrical Manufacturers Association v. Environmental Protection Agency*, 99 F.3d 1170 (D.C. Cir. 1996); *Florida Power Light & Co. v. United States*, 846 F.2d 765,771 (D.C. Cir. 1988). That requirement serves two purposes: (1) to ensure public participation and fairness to affected parties after governmental rulemaking authority has been delegated by Congress to unrepresentative agencies comprised of unelected officials and (2) to assure that the agency will have before it facts and information relevant to a particular administrative problem. *MCI Telecommunications Corp. v. FCC*, 313 U.S. App. D.C. 51, 57 F.3d 1136, 1141 (D.C. Cir.1995); *National Ass'n of Home Health Agencies v. Schweiker*, 223 U.S. App. D.C. 209, 690 F.2d 932, 949 (D.C. Cir. 1982).

In publishing its final rules on February 11, 1997, the Federal Government failed to provide interested citizens

with the requisite opportunity for notice and comment. Had the government followed proper administrative procedures it would have been armed with scientific evidence and public comment on the benefits and usefulness of medicinal marijuana and on the death hastening impact its Policy would have on certain cancer chemotherapy, AIDS therapy, and cancer and AIDS wasting patients. Instead, ONDCP made its decision predicated on nothing more that a *non sequitur*: that physician recommendation and prescription of medicinal marijuana intrastate in accordance with state law is part of illicit interstate drug trafficking and that the use of medicinal marijuana by seriously ill and terminally ill patients will "send the wrong message" to recreational drug users. Its basis for decision is both factually incorrect (medicinal marijuana recommended or prescribed intrastate to seriously ill and terminally ill patients does not substantially affect interstate commerce) and counter intuitive (intrastate recommendation and prescription of medicinal marijuana to treat the seriously ill and the terminally ill has no relationship to interstate trafficking in marijuana by recreational users).

C. PLAINTIFFS WILL SUFFER IRREPARABLE HARM WITHOUT RELIEF

Plaintiffs in this suit are physicians and patients. Each will suffer irreparable harm if relief is not granted. Since publication of the Policy, each Plaintiff physician has refrained from informing a single patient of the health benefits of medicinal marijuana. None has prescribed or recommended medicinal marijuana, fearing federal prosecution. Patients in need must now suffer serious and debilitating side effects associated with cancer chemotherapy, AIDS therapy, and cancer and AIDS wasting syndrome that could be alleviated by medicinal marijuana. Plaintiff physicians cannot effectively treat their patients if they are unable to communicate to them the usefulness of medicinal marijuana in disease management, *e.g.*, in treatment of chemotherapy-induced nausea and vomiting; wasting syndrome; and glaucoma. Plaintiff scientists are unable to consult with Plaintiff Physicians and patients regarding carcinogen-minimizing methods of administering and using medicinal marijuana.

At the core of the physician-patient relationship is trust and open and honest interchange. The Policy invades that relationship and denies physicians their right (and obstructs fulfillment of their ethical duty) to disclose fully all treatment options to their patients. The Policy circumscribes the physician-patient relationship with censorship over all discussion of the therapeutic value of medicinal marijuana, depriving patients of vital health information. The censorship engendered by the Policy jeopardizes patient care. In *Elrod v. Burns*, 427 U.S. 347, 373 (1976), the Court stated that the loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable harm.

The patients in this suit will suffer irreparable harm if relief is not granted. The patients rely on their physicians for advice and guidance when attempting to manage serious and terminal disease conditions. Since the promulgation of the Policy, patients of Plaintiff physicians, some of whom suffer from life-threatening diseases, have not sought the advice of those physicians about the use of medicinal marijuana out of fear of federal prosecution. They are not only denied their First Amendment right to receive that vital health information but they are also forced to suffer unnecessary pain and physical injury because of it. Indeed, patients not parties to this suit may experience a hastening of death because they are unaware and cannot lawfully receive medicinal marijuana legal under state law. Indeed, those who suffer chemotherapy and AIDS therapy-induced nausea and vomiting and cannot tolerate drug treatments may die prematurely during the pendency of this case when medicinal marijuana could enable them to tolerate those treatments or to tolerate more aggressive treatments and enjoy greater longevity. Those who suffer from AIDS may find their AIDS therapy intolerable and may suffer life-threatening weight loss due to nausea, vomiting, and loss of appetite (and pain associated with food consumption and AIDS wasting syndrome). Those patients may die prematurely during the pendency of this case when medicinal marijuana could enable them to tolerate AIDS therapy and experience greater appetite and tolerance for food. Thus both

physicians and patients have been irreparably harmed.

D. OTHER INTERESTED PARTIES WILL NOT SUFFER SUBSTANTIAL HARM IF RELIEF IS GRANTED

The Government will not suffer substantial harm if the requested relief is granted. Arizona, California, Connecticut, and Virginia have laws that permit physicians to recommend or prescribe medicinal marijuana for seriously and terminally ill patients and closely regulate those practices. Moreover, the Federal Government retains the full power to arrest, prosecute, and punish anyone who resells physician recommended or prescribed marijuana or who transports it across state lines. Plaintiffs in this case are seeking a preliminary injunction so that they might be free to give and/or receive the most appropriate medical care in compliance with their respective state laws. They are not seeking protection for non-medical use of illicit drugs or for drug trafficking -- the banning of which is the Federal Government's statutory mandate.

The Federal Government has an interest in protecting interstate commerce from the illicit drug trade. That interest will not be harmed if physicians and patients who reside within the states of Arizona, California, Connecticut, and Virginia are allowed physician recommended or prescribed medicinal marijuana intrastate in strict adherence to state regulation. Arizona, California, Connecticut, and Virginia permit prescription or recommendation of medicinal marijuana only in certain statutorily specified medical circumstances. Physicians who are licensed to practice medicine in Arizona and California may only recommend and prescribe medicinal marijuana for the seriously ill and the terminally ill. In California physicians may only recommend medicinal marijuana for the following disease conditions: cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief. CA. HEALTH & SAFETY CODE § 11362.5(a) (West 1997). In Arizona, physicians are permitted to prescribe medicinal marijuana only to seriously ill patients if the prescription is supported by another doctor and by medical literature on the condition being treated. AZ. REV. STAT. § 13-3412.01. In Connecticut, physicians may only recommend and prescribe medicinal marijuana for treatment in patients undergoing chemotherapy and in glaucoma patients. CONN. GEN. STAT. §§ 21a-246 and 21a-253. In Virginia, physicians may only recommend and prescribe medicinal marijuana for the treatment of cancer and glaucoma patients. VA. CODE § 18.2-252.1. With those constraints on the use of medicinal marijuana there can be no sound argument that any legitimate interest of the Federal Government will be harmed by grant of the requested injunctive relief.

E. THE PUBLIC INTEREST FAVORS GRANTING THE RELIEF SOUGHT

The public has a vested interest in receiving the best and most current medical information and care available from physicians. When a patient is faced with the prospect of dying or being forced to live with debilitating pain, the withholding of information on a medicine that can alleviate that pain and prolong life contravenes the public interest. If the Policy is left in place many Americans suffering from serious illness and terminal illnesses will suffer needlessly. They will be denied an effective and inexpensive treatment. The public interest is thus best served by grant of the requested injunctive relief.

VII. CONCLUSION

For the reasons stated above, Plaintiffs respectfully request that this Honorable Court grant Plaintiffs Application for Preliminary Injunction and enjoin the Federal Government from initiating administrative, civil and criminal proceedings against Plaintiffs for communicating information regarding the medicinal use of marijuana and for recommending, prescribing, and using medicinal marijuana in accordance with the laws of Arizona, California,

Connecticut, and Virginia. The Plaintiffs respectfully request that the preliminary injunction issue forthwith and remain in full force and effect until such time as this Court decides the entire case on the merits.

Respectfully submitted,
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