Conant v. McCaffrey

A federal class-action lawsuit
on behalf of physicians who recommend
and seriously ill patients who need
medical marijuana

Class Action Complaint for Declaratory and Injunctive Relief

LOWELL FINLEY (State Bar #104414)
GRAHAM A. BOYD (State Bar #167727)
JONATHAN WEISSGLASS (State Bar #185008)
ALTSHULER, BERZON, NUSSBAUM,
BERZON & RUBIN
177 Post Street, Suite 300
San Francisco, California 94108
Telephone: (415) 421-7151

DANIEL N. ABRAHAMSON (State Bar #158668)
The Lindesmith Center
110 McAllister Street, Suite 350
San Francisco, California 94102
Telephone: (415) 554-1900

ANN BRICK (State Bar #65296)
AMERICAN CIVIL LIBERTIES UNION
FOUNDATION OF NORTHERN CALIFORNIA, INC.
1663 Mission Street, Suite 460
San Francisco, California 94103
Telephone: (415) 621-2493

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

DR. MARCUS CONANT, DR. DONALD NORTHFELT, DR. ARNOLD LEFF, DR. DEBU TRIPATHY, DR. NEIL FLYNN, DR. STEPHEN FOLLANSBEE, DR. ROBERT SCOTT, III, DR. STEPHEN O'BRIEN, DR. MILTON ESTES, JO DALY, KEITH VINES, JUDITH CUSHNER, VALERIE CORRAL, on behalf of themselves and all others similarly situated; BAY AREA PHYSICIANS FOR HUMAN RIGHTS; and BEING ALIVE: PEOPLE WITH AIDS/HIV ACTION COALITION, INC.,

Plaintiffs,

v.

BARRY R. McCAFFREY, as Director, United States Office of National Drug Control Policy; THOMAS A.

CONSTANTINE, as Administrator, United States Drug Enforcement Administration; JANET RENO, as Attorney General of the United States; and DONNA SHALALA, as Secretary of Health and Human Services,

Defendants.

Contents

Plaintiffs Dr. Marcus Conant; Dr. Donald Northfelt, Dr. Arnold Leff, Dr. Debu Tripathy, Dr. Neil Flynn, Dr. Stephen Follansbee, Dr. Robert Scott, III, Dr. Stephen O'Brien, Dr. Milton Estes, Jo Daly, Keith Vines, Judith Cushner, and Valerie Corral bring this class action on their own behalf and on behalf of a class of similarly situated physicians and patients; and plaintiffs Bay Area Physicians for Human Rights, and Being Alive: People with HIV/AIDS Action Coalition, Inc. bring this action on their own behalf and on behalf of their members. Plaintiffs, on information and belief, hereby allege:

I. INTRODUCTION

1. This class action seeks a declaration that physicians and patients have the right, protected by the First Amendment to the U.S. Constitution, to communicate in the context of a bona fide physician-patient relationship, without government interference or threats of punishment, about the potential benefits and risks of the medical use of marijuana. Physician and physician organization plaintiffs in this action further seek appropriate injunctive relief protecting them from criminal prosecution, revocation of federal prescription drug licenses, or any other punishment or retaliation resulting from their discussions with or recommendation to patients in the context of a bona fide physician-patient relationship regarding the potential benefits or risks of the medical use of marijuana.

2. For at least two decades, hundreds of physicians in California have recommended use of marijuana, often as a medicine of last resort, to seriously ill patients suffering from debilitating conditions including cancer, AIDS and glaucoma. Although patients have long faced state criminal liability if they obtained marijuana, even for medical purposes, it had never been suggested that a physician's discussion of marijuana as a medical option was illegal or otherwise sanctionable. All of this changed on November 5, 1996, when California voters approved Proposition 215 -- the Compassionate Use Act of 1996. For the first time, it is legal under state law for a seriously ill patient to possess and cultivate marijuana for medical purposes if a physician has recommended, either orally or in writing, that the use of medical marijuana is medically appropriate. Also for the first time, federal officials, including defendants named herein, have declared illegal (or at least administratively sanctionable) the longstanding practice of physicians discussing the risks and benefits of medical use of marijuana with their patients.

3. Defendants' threats against physicians are having their intended effect. Throughout California, numerous physicians have censored the range of medical advice they offer to their patients, refusing to provide guidance concerning the risks or benefits from medical marijuana even when

it is the only medicine that a physician believes will be effective. By effectively gagging physicians, defendants have intruded into the physician-patient relationship, an area traditionally protected from government interference. Defendants have also undermined patient confidence in physicians, jeopardizing the ability of patients to complete arduous medical treatments like chemotherapy. The harms caused by physicians withholding medically appropriate information and recommendations concerning marijuana will continue so long as defendants persist in threatening serious sanctions against the physicians for such activity.

II. PARTIES

PLAINTIFFS

4. Plaintiff Marcus Conant is a physician who has practiced medicine for 33 years in San Francisco. Dr. Conant is the Medical Director of the Conant Medical Group, the largest private AIDS practice in the United States. He is a Professor at the University of California Medical Center in San Francisco and is the author or co-author of over 70 publications on treatment of AIDS. He is responsible for dozens of presentations, book chapters, news articles, and lectures on the same subject. Dr. Conant received his medical degree from Duke University in 1961. After his residency, Dr. Conant specialized in dermatology, a practice area that led him to identify the first cluster of patients with Kaposi's sarcoma, a now well-recognized symptom of AIDS. In 1981, he founded a Kaposi's sarcoma clinic, one of the nation's first specialized AIDS practices. Currently, he and his colleagues provide primary care for over 5,000 HIV infected patients, including approximately 2,000 patients with active AIDS. In his AIDS practice, Dr. Conant prescribes aggressive treatments combining several different drugs -- a so-called cocktail -- that are recently emerging as the first effective treatment for AIDS. However, these drugs often cause severe nausea and vomiting, a situation made all the worse when the patient is suffering from AIDS wasting syndrome, which causes a steady, uncontrolled weight loss. For many patients, traditional anti-nausea drugs and appetite stimulants are effective. He prescribes Marinol -- a synthetic version of one of the primary chemicals in marijuana -- for many of his patients. However, for a some medical marijuana proves to be the best, if not the only viable, treatment option. Dr. Conant currently treats at least 100 patients for whom he believes marijuana is a medically appropriate form of treatment for nausea and loss of appetite in AIDS patients. Dr. Conant is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Conant feels compelled and coerced into censoring his conversations with patients, curtailing severely the information he feels able to provide to patients regarding the risks and benefits of medical marijuana. He directs his staff likewise to curtail their discussions with patients. Dr. Conant does tell his patients that the active ingredient in Marinol is THC, a chemical also found in marijuana, but he states even this minimal information with extreme reluctance and fear due to defendants' threats. If defendants persist in their threats against physicians, Dr. Conant may instruct his staff to cease discussing marijuana with patients altogether.

5. Plaintiff Donald Northfelt is a physician who has practiced medicine for ten years. After working for eight years in a specialized AIDS practice in San Francisco, he moved to Palm Springs, California, where he has practiced for the past two years. He is an Assistant Clinical Professor of Medicine at the University of California, San Diego and previously held the same title at the University of California, San Francisco. Dr. Northfelt received his medical degree from the University of Minnesota in 1985, after which he completed an internship and residency at UCLA in 1988. He received specialist training in hematology and oncology at the University of California, San Francisco from 1988 through 1991. He is a frequent lecturer on specialized

AIDS care and is the author or co-author of over 35 peer-reviewed publications, 16 book chapters, and 18 other publications on the treatment of AIDS. Dr. Northfelt's current practice focuses on care for AIDS patients and, in particular, AIDS patients suffering from cancer. Currently, he provides treatment for approximately 200 cancer patients and 300 AIDS patients. For his cancer patients, Dr. Northfelt frequently prescribes chemotherapy, a treatment that generally provokes distressing nausea and vomiting. While many patients respond to conventional anti-nausea drugs like Compazine or Reglan for nausea, Dr. Northfelt finds that these drugs are not effective for some patients. If unable to control the nausea, Dr. Northfelt fears that patients will discontinue chemotherapy, risking a quick progression of the cancer. As a treatment of last resort, Dr. Northfelt finds that medical marijuana is an appropriate, even necessary, form of treatment to control nausea and make chemotherapy bearable. In his AIDS practice, Dr. Northfelt prescribes aggressive treatments combining several different drugs -- a so-called cocktail -- that are recently emerging as the first effective treatment for AIDS. However, these drugs often cause severe nausea and vomiting, a situation made all the worse when the patient is suffering from AIDS wasting syndrome, which causes a steady, uncontrolled weight loss. For many patients, traditional anti-nausea drugs and appetite stimulants like Megace and Marinol are effective, but for a few medical marijuana proves to be the only viable treatment option. Dr. Northfelt currently treats at least twelve patients for whom he believes marijuana is a medically appropriate form of treatment for nausea and vomiting caused by chemotherapy or for nausea and loss of appetite in AIDS patients. Dr. Northfelt is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Northfelt feels compelled and coerced to censor his conversations with patients, withholding information, recommendations or advice regarding use of medical marijuana, even when he deems this information to be crucial to the patient's care and well-being. Dr. Northfelt will continue to censor his patient communications so long as defendants threaten the loss of his prescription drug license, his Medicare and Medicaid participation, and his freedom from criminal prosecution.

6. Plaintiff Arnold Leff is a physician who has practiced medicine for 11 years in Santa Cruz, California. Dr. Leff received a B.S. from the University of Cincinnati in 1963 and graduated from the University of Cincinnati Medical School in 1967. He did his internship and fellowship in internal medicine at the University of Cincinnati Medical Center Hospitals during 1967-69. Dr. Leff has held a number of positions in the fields of drug control policy and public health, including Deputy Associate Director for the White House Drug Abuse Office under President Richard Nixon from 1971-72 and Director of Health Services for Contra Costa County, California from 1979-83. He also served as a clinical professor at the University of Cincinnati College of Medicine from 1971-79 and at the University of California from 1979-84. Dr. Leff is a family practitioner who principally practices in the areas of geriatrics and AIDS. He has been an AIDS specialist since 1985, and currently treats approximately 110 patients for AIDS in a practice that includes approximately 4,000 patients overall. For many of these patients, Dr. Leff prescribes Marinol, a synthetic version of a primary active ingredient of marijuana (THC), to combat nausea and to stimulate appetite. In some cases, however, he finds that Marinol is inappropriate because patients cannot tolerate or effectively absorb it. Dr. Leff currently treats at least 20 patients for whom he believes marijuana is medically appropriate in responding to treatment-induced nausea or for appetite stimulation. In some cases, he believes medical marijuana is the only effective medicine. Dr. Leff is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Leff feels compelled and coerced to withhold information, recommendations or advice to patients regarding use of medical marijuana, and therefore has withheld such information, recommendations and advice. During

the weeks following defendants' threats against physicians, three patients have asked Dr. Leff whether medical marijuana would be an appropriate treatment, but Dr. Leff refused to discuss or recommend medical marijuana for these patients because of fear of sanction by defendants.

7. Plaintiff Debu Tripathy is a physician specializing in breast cancer at the University of California at San Francisco Mount Zion Breast Care Center. Dr. Tripathy received his B.S. from the Massachusetts Institute of Technology. He graduated from Duke Medical School in 1985 and completed his internship and residency in internal medicine at Duke in 1988. In 1991, Dr. Tripathy completed a fellowship in hematology and oncology at the University of California at San Francisco. From 1991-93, he was a Clinical Instructor in Medicine and since 1993 he has been an Assistant Clinical Professor of Medicine at the University of California at San Francisco. Dr. Tripathy is an oncologist and a member of the American Society of Clinical Oncology. He has performed a number of research studies and published many articles on breast cancer. Dr. Tripathy exclusively treats breast cancer patients and has approximately 1,000 active patients. He currently prescribes chemotherapy, a treatment often causing significant nausea, to approximately 100 patients. For many of these patients, conventional anti-nausea medications are effective, but for at least 20 patients whom he currently treats, Dr. Tripathy believes medical marijuana is a medically appropriate and preferable form of treatment. In many of these cases it is the only viable form of treatment for the nausea caused by chemotherapy. Dr. Tripathy is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Tripathy feels compelled and coerced to withhold information, recommendations and advice to patients regarding use of medical marijuana, and therefore has withheld such information, recommendations and advice.

8. Plaintiff Neil Flynn is a Professor of Clinical Medicine in the Division of Infectious Diseases of the Department of Internal Medicine at the University of California at Davis School of Medicine, and attending physician in the University Medical Center's Aids and Related Disorders Clinic. Dr. Flynn received his B.A. from the University of California at Los Angeles in 1970. He graduated from the Ohio State University Medical School in 1973 and did his internship and residency in internal medicine at Loma Linda University Hospital from 1973-76. He then completed a fellowship in infectious diseases at the University of California at Davis from 1976-78. He is certified in Internal Medicine and in Infectious Diseases by the American Board of Internal Medicine. Dr. Flynn is the author of numerous publications about infectious diseases and has received hundreds of thousands of dollars in grants and awards for his research on HIV and AIDS since establishing the Clinic in 1983. He participates in the care of approximately 1,500 AIDS patients, and is the primary physician for 200 AIDS patients. For many AIDS patients, Dr. Flynn prescribes Compazine, Marinol, or Reglan for nausea. Sometimes, however, these drugs fail to control nausea. Further, Compazine and Reglan make approximately 25 to 33 percent of patients experience stiffness in their movements. In order to stimulate appetite in patients suffering from AIDS wasting, Dr. Flynn prescribes Megace or Marinol. In some cases, however, these drugs are ineffective. Dr. Flynn believes that medical marijuana is medically appropriate as a drug of last resort for a small number of patients for whom prescription drugs are ineffective. Dr. Flynn is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Flynn feels compelled and coerced to withhold information, recommendations or advice to patients regarding use of medical marijuana and, therefore, has withheld such information, recommendations and advice. Only with great fear and reluctance does Dr. Flynn engage in even limited communications regarding medical marijuana.

9. Plaintiff Stephen Follansbee is a physician who has practiced medicine for 20 years in San

Francisco, California. He is the Chief of Staff for Davies Medical Center, an Associate Clinical Professor of Medicine at the University of California School of Medicine and the Assistant Director of the Bay Area Community Consortium, the leading group of medical professionals treating AIDS in and around San Francisco. Dr. Follansbee received an M.A. from Harvard University in 1972 and graduated from the University of Colorado School of Medicine in 1977. He completed his residency and fellowship at the University of California in 1982. Dr. Follansbee specializes in the treatment of infectious diseases, with a particular focus on treating complications of AIDS, and is the author or co-author of 40 publications on the subject. He currently consults on or serves as the primary physician for over 500 patients, many of whom suffer severe nausea, vomiting or weight loss. Dr. Follansbee finds that Marinol -- a synthetic version of a main chemical component of marijuana -- is an effective treatment for some of these patients, and so has prescribed Marinol for 14 patients during the past 6 months. He finds, however, that some patients are unable to tolerate or effectively absorb Marinol. For those patients, he believes medical marijuana can be an appropriate form of treatment. For any patient with an infectious disease, Dr. Follansbee believes it medically necessary to have a full and open discussion about any marijuana use, so that he can ensure that, if the patient does use marijuana for any purpose, the patient does so in a manner that minimizes the risk of infection or other medical complications. Dr. Follansbee is aware of defendants' threats to prosecute criminally, revoke the prescription licenses of, or otherwise sanction physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Follansbee has curtailed information, recommendations and advice to patients regarding use of medical marijuana and feels he may need to stop discussing marijuana at all. Only with significant fear and reluctance does Dr. Follansbee engage in even limited communications regarding medical marijuana.

10. Plaintiff Robert Scott, III, is a physician who has practiced medicine for 19 years in Oakland, California. Dr. Scott received a B.S. from Parsons College in 1963 and an M.S. and M.Ed. from the University of Illinois at Urbana in 1965 and 1968 respectively. He graduated from the University of California at San Francisco Medical School in 1974. Dr. Scott completed an internship in medicine at Emory University in 1975 and a residency in internal medicine at Stanford University in 1977. Dr. Scott practices internal medicine and has over 2,000 patients. Approximately 350 of these patients are infected with HIV. For many of these patients, Dr. Scott prescribes drugs for nausea, anorexia, or pain. In some cases, however, prescription drugs are inappropriate because patients cannot tolerate them or the drugs are ineffective. Dr. Scott currently treats at least 75 patients for whom he believes medical marijuana is a medically appropriate form of treatment for nausea, anorexia, or pain. For some patients, he believes medical marijuana is the only effective medicine. Dr. Scott is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Scott has curtailed information, recommendations and advice to patients regarding use of medical marijuana. Only with great fear and reluctance does Dr. Scott engage in even limited communications regarding medical marijuana.

11. Plaintiff Stephen O'Brien is a physician practicing medicine at the East Bay AIDS Center in Berkeley, California. Dr. O'Brien received his B.A. and B.S. from the University of Washington in 1986. He graduated from the University of Washington Medical School in 1990 and completed a residency in internal medicine at the University of California at San Francisco in 1993. Dr. O'Brien was employed at the University of California at San Francisco as a clinical instructor in medicine from 1993-94 and an assistant clinical professor of medicine from 1994-95. From 1993-95 he was co-director for HIV managed care at the University of California at San Francisco. Dr. O'Brien is a general practitioner who, with one or two exceptions, treats

only AIDS patients. Dr. O'Brien specializes in advanced AIDS treatment. He has approximately 200 patients, about 70 percent of whom have a T- Cell count below 100. For many of these patients with advanced AIDS, Dr. O'Brien prescribes Compazine, Marinol, or Reglan for nausea; Megace or Marinol to stimulate appetite; and prescription pain medication for severe pain. In some cases, however, these drugs are ineffective. Dr. O'Brien estimates that medical marijuana is a medically appropriate, and often preferable, form of treatment for 25 percent of his patients for nausea, as an appetite stimulant to combat wasting syndrome, and for adjunctive pain control. For some of these patients, he believes medical marijuana is the only effective medicine. Dr. O'Brien is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. O'Brien feels compelled and coerced to withhold information, recommendations or advice to patients regarding use of medical marijuana, and therefore has withheld such information, recommendations and advice. Only with significant fear and reluctance does Dr. O'Brien engage in even limited communications regarding medical marijuana.

12. Plaintiff Milton Estes has been a physician in Mill Valley, California for 22 years, is Medical Director and Senior Physician for the Forensic AIDS Project of the City and County of San Francisco, and is an Associate Clinical Professor at the University of California at San Francisco. Dr. Estes received his A.B from the University of Chicago in 1964 and graduated from the University of Chicago Pritzger School of Medicine in 1968. He did his post graduate training at St. Lukes Hospital in San Francisco. Dr. Estes is in private family practice and is the largest private provider of HIV care in Marin County. He has served and continues to serve on numerous boards and committees, and is an active lecturer on AIDS issues. Dr. Estes has approximately 1,500 patients, of whom about 150 are infected with HIV. A number of his HIV patients experience severe nausea related to the medications they are taking as well as loss of appetite and resulting problems maintaining adequate nutrition. In order to combat nausea and weight loss, Dr. Estes has prescribed Marinol and other prescription drugs. For some patients, however, such drugs are too slow in acting and do not afford effective relief. Where conventional approaches fail or a patient poorly tolerates oral medication, Dr. Estes believes medical marijuana can often be an appropriate form of treatment. Dr. Estes is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, Dr. Estes feels compelled and coerced to withhold information, recommendations or advice to patients regarding use of medical marijuana, and therefore has chosen to avoid completely any communication regarding marijuana with his patients, even when he believes it medically appropriate to discuss the subject.

13. Plaintiff Bay Area Physicians for Human Rights ("BAPHR") is a California non-profit corporation with over 150 physician members who reside and work in the San Francisco Bay Area. Founded in July 1977, BAPHR is the oldest existing association of lesbian and gay physicians in the nation. The organization has as its primary purpose the promotion of health and wellness in the gay and lesbian community, with a particular focus on the prevention, treatment and cure of HIV and AIDS. The members of BAPHR are collectively responsible for treating the majority of AIDS patients in the Bay Area. BAPHR and its members have a longstanding and direct interest in the ability of its member physicians to provide complete and accurate medical information to their patients, without fear of reprisal from governmental authorities. Some physician members of BAPHR treat patients for whom they believe medical marijuana is a medically appropriate form of treatment, especially for AIDS related complications including AIDS wasting syndrome. Physician members of BAPHR are aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Due to fear caused by these threats, physician members of BAPHR

feel compelled and coerced to withhold information, recommendations or approval for patients regarding use of medical marijuana, and therefore have withheld such information, recommendations and approval.

14. Plaintiff Jo Daly is a 50 year old woman currently battling her second occurrence of cancer. Plaintiff Daly is a resident of San Francisco, California, where she was police commissioner from 1980-86. In 1988, plaintiff Daly was diagnosed with cancer of the colon, which spread to her ovaries and lymph nodes. In 1995, she was diagnosed with lung cancer for which she has received three rounds of aggressive chemotherapy, was hospitalized for three months, and was prescribed 27 different medications. During chemotherapy, plaintiff Daly experienced severe nausea and vomiting. In order to combat these side effects, she tried a number of prescription drugs, including Marinol -- a synthetic version of a main chemical component of marijuana. However, her constant and persistent vomiting left her unable to keep medication in her stomach long enough to ingest it. As her situation continued to deteriorate and she came near to losing hope completely, she was given marijuana by a friend. She found that by inhaling about three puffs of marijuana when she felt nausea coming on, she could defeat her nausea, regain her appetite, and sleep through the night. Plaintiff Daly is certain that she would not have survived her third round of chemotherapy without the use of medical marijuana. It enabled her to reduce drastically her use of more powerful and often debilitating prescription drugs. Plaintiff Daly places great importance in her ability to discuss medical marijuana with her physicians, since she wants to ensure that the marijuana will not interfere with other treatments or otherwise cause risks outweighing its benefits. Prior to defendants' threats against physicians, plaintiff Daly discussed her medical marijuana use with each of her physicians, including eight oncologists, and none expressed disapproval. Indeed, plaintiff Daly's primary oncologist expressly approved her use of medical marijuana. Plaintiff Daly is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Because of defendants' threats, plaintiff Daly fears that her physicians will censor the range of medical advice provided to her and interfere with her ability to receive full and accurate medical advice. She believes, as well, that defendants' threats put her physicians in jeopardy if she discusses medical marijuana, and so has limited her communications to her physicians. The curtailment of communication -- both from her physicians to her and from her to her physicians -- has stripped her of the security and confidence she needs to undergo and survive the extremely difficult treatment required for her cancer.

15. Plaintiff Keith Vines is a 46 year old AIDS patient. He has served as an Assistant District Attorney in San Francisco since 1985, including two years working as a felony prosecutor in a federally funded Drug Strike Force where he secured a conviction in what was then the county's second largest drug seizure. Prior to working in the District Attorney's office, he worked for three years in private practice and for six years as a prosecutor in the United States Air Force as a Judge Advocate with the rank of captain. Plaintiff Vines tested positive for HIV in the mid 1980's and by 1990 his health began to deteriorate. In 1993 he was diagnosed with AIDS wasting syndrome, a condition characterized by severe, progressive weight loss and breakdown of muscle tissue. Plaintiff Vines lost 45 pounds before being placed on an experimental growth hormone to help regain much needed muscle mass. For the past three years, he has suffered from a chronic and acute loss of appetite, a condition that, if not addressed, can result in malnourishment and thwart the efficacy of the hormone treatment and the antiviral medications he is prescribed. To stimulate his appetite, his physician prescribed Marinol, a synthetic version of one of marijuana's main active components. However, Plaintiff Vines found Marinol to be only marginally effective and highly erratic in its effects. He strongly objected to the drowsiness and "buzz" caused by Marinol. Two of plaintiff Vines' physicians suggested he use medical marijuana, and he found that a few puffs were sufficient to stimulate his appetite, while avoiding feeling the "buzz"

caused by Marinol. Plaintiff Vines continues to use medical marijuana no more than a couple of times per week before dinner to enable him to eat. Plaintiff Vines is aware of defendants' threats against physicians, and he fears that these threats will cause his physician to censor the medical advice provided to him. He feels that the success of his continued treatment depends in large part on a trusting and confident relationship with his physician, but that defendants' intrusion into that relationship will cause him to lose confidence in his physician and so jeopardize his medical treatment.

16. Plaintiff Judith Cushner is a 51 year old breast cancer survivor who has been in remission for three years. She is at risk of either the recurrence of the initial cancer or the growth of a second cancer (a risk that increased as a result of her earlier therapies). She is therefore gravely concerned about her ability to receive full and adequate medical advice about her condition now and in the future. Plaintiff Cushner is a resident of San Francisco, California, where she has been the director of a preschool for 15 years. She is an active member of her synagogue and a mother of two children. Plaintiff Cushner was diagnosed with an aggressive cell growth and underwent a lumpectomy and lymph node removal. She then received eight months of chemotherapy and eight weeks of radiation therapy followed by several years of hormone therapy. The chemotherapy caused plaintiff Cushner to suffer severe nausea. To offset the side effects of chemotherapy, including nausea, doctors prescribed Compasine. That drug, however, made plaintiff Cushner feel worse. Her oncologist also prescribed Marinol, but it did not relieve plaintiff Cushner's nausea and made her groggy. She also had difficulty swallowing the Marinol capsules because of mouth sores also caused by chemotherapy. Unable to obtain relief from her severely debilitating nausea, plaintiff Cushner considered abandoning chemotherapy. However, a nurse gave her marijuana, and plaintiff Cushner's nausea diminished almost immediately with no side effects. Plaintiff Cushner inhaled a few puffs of marijuana several times per week for the remainder of her chemotherapy, and then stopped using marijuana. Plaintiff Cushner informed her oncologist, radiation oncologist, and surgeon that she was using medical marijuana, and they all supported her marijuana use. The trust she established with her oncologist was critical in plaintiff Cushner's ability to complete chemotherapy. She encountered a woman in a cancer patients' support group who stopped her chemotherapy because of nausea and other side effects that could not be contained with prescription drugs and died as a result. Plaintiff Cushner is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. She believes that defendants' threats against physicians who recommend medical marijuana will seriously interfere with her ability to build and maintain the kind of bond with her physicians that previously saved her life. Plaintiff Cushner has no doubt that defendants' threats will lead to more deaths of other cancer patients, and she fears for her own well-being if she is unable to communicate freely and openly with her physician in the event her cancer recurs. Plaintiff Cushner believes that, if she faces a recurrence of cancer, information, recommendations, and advice about the risks and benefits of medical marijuana will be necessary for her effective treatment.

17. Plaintiff Valerie Corral is a 44 year old woman who has experienced severe and protracted seizures. Plaintiff Corral is a resident of Santa Cruz, California. In 1973 plaintiff Corral suffered severe head injuries in a car accident. The head trauma caused grand mal seizures, sometimes as many as five times per day. To prevent these seizures, plaintiff Corral was given anti-epileptic drugs, including Mysoline (primadone), Dilantin (phenytoin), and Phenobarbital. For pain she was prescribed Percodan and Valium, upon which she became physically dependent. For two years under this treatment regimen, plaintiff Corral lived in a drug-induced stupor. She took more and more drugs in a futile attempt to control the spasms, but the seizures became more frequent. After losing hope about treatment with anti-epileptic drugs, and aware that marijuana had been shown to control seizures in rats, plaintiff Corral began using medical marijuana. She soon found

that she could control her seizures completely with medical marijuana alone. Whenever she feels the premonition of a seizure, she inhales a puff of marijuana. Whereas she previously took up to 15 pills a day yet could barely function, plaintiff Corral now uses only a modest amount of medical marijuana and experiences none of the debilitating side effects of prescription drugs. For many years, plaintiff Corral's physicians have approved her use of medical marijuana. She is aware of defendants' threats against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana. Plaintiff Corral fears that these threats will deter physicians from providing information, recommendations or advice she needs.

18. Plaintiff Being Alive: People with HIV/AIDS Action Coalition, Inc., is a California non-profit group with over 2,000 members who reside in and around Los Angeles County, California. Plaintiff Being Alive is comprised of individuals who have tested positive for HIV or who are living with HIV/AIDS. Among other services, the organization sponsors regular medical updates, publishes three newsletters, and organizes peer-led support groups. Members of plaintiff Being Alive include patients being treated for AIDS, many of whom desire information from their treating physicians regarding the potential risks and benefits of using medical marijuana in the treatment of their specific illnesses and the alleviation of their symptoms. Patient members of Being Alive equally wish to be able to speak freely to their physicians about marijuana use, so that the physicians will be fully informed about patients' medical conditions. These patients depend on free and open communications with their physicians in order to receive effective treatment, yet due to defendants' threats against physicians who discuss medical marijuana, these patients have suffered a curtailment of the flow of information between them and their physicians.

DEFENDANTS

19. Defendant Barry R. McCaffrey is sued in his official capacity as Director of the U.S. Office of National Drug Control Policy.

20. Defendant Thomas A. Constantine is sued in his official capacity as the Administrator of the U.S. Drug Enforcement Administration.

21. Defendant Janet Reno is sued in her official capacity as Attorney General of the United States.

22. Defendant Donna Shalala is sued in her official capacity as Secretary of Health and Human Services.

CLASS ALLEGATIONS

23. Plaintiffs bring this action on behalf of themselves and all other persons similarly situated pursuant to F.R.C.P. Rule 23(a) and (b)(2). The class, as proposed by plaintiffs, consists of:

> (a) All physicians present and future who are licensed by and practicing medicine in California and who, using their best medical judgment in the context of a bona fide physician-patient relationship, have discussed, recommended or approved the medical use of marijuana for their patients, or but for defendants' threats of punishment, would discuss, recommend or approve or consider discussing, recommending or approving the medical use of marijuana for their patients; and
>
> (b) All patients in California who seek to communicate with their physicians or receive the recommendation or approval of their physician, in the context of a bona

fide physician-patient relationship, regarding the medical use of marijuana.

24. The requirements of Rule 23(a) and (b)(2) are met in that the class is so numerous that joinder of all members is impracticable; there are questions of law and fact common to the class (including whether defendants' threats violate the First Amendment as applied to plaintiffs); the claims of the representative parties are typical of the claims of the class; the representative parties will fairly and adequately represent the interests of the class because they are represented by counsel with extensive experience in class action litigation and constitutional litigation, including claims under the First Amendment; and the parties opposing the class have acted on grounds generally applicable to the class, thereby making appropriate final injunctive and corresponding declaratory relief with respect to the class as a whole.

III. JURISDICTION AND VENUE

25. This court has jurisdiction over all causes of action herein pursuant to 28 U.S.C. §§1331 and 1361.

26. Venue is proper in this court under 28 U.S.C. §1391(e).

IV. FACTUAL BACKGROUND

A. Medical Use of Marijuana

27. The recommendation of medical marijuana for certain patients is within the mainstream of medical practice in communities throughout the United States. Thousands of physicians have recommended the use of medical marijuana to their patients based on those physicians' belief and experience that marijuana is clinically effective in treating specific medical conditions. For example, when more than 2,000 oncologists were randomly surveyed in 1990, forty-four percent reported recommending the use of marijuana to control nausea or lack of appetite to at least one cancer patient undergoing chemotherapy. Doblin, et al., "Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes," Journal of Clinical Oncology, vol. 9, no. 7 (July 1991). In response to defendants' recent threats to act against physicians who recommend the medical use of marijuana, on December 30, 1996, the editorial board of the New York Times acknowledged what most physicians have known for quite some time: "it is difficult to dismiss the testimony from many seriously ill patients and their doctors that marijuana can ease pain, reduce the nausea associated with cancer chemotherapy, stimulate the appetites of AIDS patients who are wasting away, and lower the pressure within the eyes of glaucoma victims."

28. The federal government officially recognizes the medical efficacy of a primary chemical component of marijuana. One of the chief active components of marijuana is the chemical compound tetrahydrocannabinol, also known as THC. In 1985, the Food and Drug Administration approved synthetic THC for use in the treatment of emesis (vomiting), thereby authorizing physicians to legally prescribe this substance. In approving THC, FDA acknowledged that evaluation of the risks and benefits of the THC pill was premised on the medical risks and benefits of marijuana: "The risks to the public health from illicit use of THC are likely to be similar to marihuana. . . . The effects of pure THC are essentially similar to those of cannabis containing THC in equivalent amounts." 47 Fed. Reg. 10082-83. In 1991, FDA expanded the approved uses of THC to include treatment of weight loss in patients with AIDS. Again, the government's approval was based on widespread reports of medical benefits derived from marijuana. In 1989, the most recent year for which data is available, physicians prescribed nearly 100,000 doses of THC under the brand name Marinol. For many patients, however, THC

in capsule form is not an adequate substitute for marijuana. Some patients suffering from nausea are unable to take a THC pill orally. The single, large dose delivered by a THC pill is overwhelming, causing dysphoria (a sense of mental confusion and uneasiness) in some patients. Many chemotherapy patients develop mouth sores such that swallowing a pill can be extremely painful. For some cancer and AIDS patients, nausea is so severe that swallowing any pill, even for the express treatment of the nausea itself, is difficult, if not impossible. Finally, THC pills cost tens of thousands of dollars annually, making their cost prohibitive to some patients.

29. Scientific studies, as well as the practice and observations of numerous physicians over many years, confirm the medical efficacy of marijuana in treating a range of symptoms associated with specific illnesses:

(a) *Cancer*: About one-half of all cancer patients treated with anticancer drugs suffer from profound nausea and vomiting. Nausea and vomiting threaten the effectiveness of chemotherapy and endanger the patient's well- being. Retching, which may last for hours or even several days after treatment, can literally tear the esophagus and fracture ribs. Vomiting results in fluid loss. Apprehensive of chemotherapy's side effects, many cancer patients eat almost nothing because they cannot stand the sight or smell of food. With each successive treatment, these patients lose weight and strength. Their complaints may cause doctors to lower the dose, thereby jeopardizing the effectiveness of the therapy. For many patients the side effects of chemotherapy seem worse than the cancer itself and may lead them to discontinue treatment altogether, not only to eliminate the physical discomfort but also to regain some control over their lives -- even when discontinued treatment will lead to death. Among cancer patients who experience severe nausea and vomiting, 30 percent to 40 percent report that the commonly used antiemetics do not work. This same patient group have found smoked marijuana to be effective in the prevention of nausea and vomiting - often more effective than FDA-approved pharmaceutical medications. Stephen Jay Gould, Alexander Professor of Geology at Harvard University and renowned essayist on biological evolution is among the first survivors of a previously incurable cancer, abdominal mesothelioma. When Professor Gould started intravenous chemotherapy:

> Absolutely nothing in the available arsenal of antiemetics worked at all. I was miserable and came to dread the frequent treatments with an almost perverse intensity. . . . I had heard that marihuana often worked well against nausea. I was reluctant to try it because I have never smoked any substance habitually (and didn't even know how to inhale). Moreover, I had tried marihuana twice [in the sixties]. . . and had hated it. . . . Marihuana worked like a charm. . . . [T]he sheer bliss of not experiencing nausea - and not having to fear it for all the days intervening between treatments - was the greatest boost I received in all my year of treatment.

(b) *AIDS/HIV*: Over 300,000 Americans have died of AIDS; an estimated one million are infected with the human immunodeficiency virus, at least 500,000 of whom are already severely ill. Despite hopeful signs that newly developed drugs are increasingly effective at combating the virus, these drug therapies often have debilitating effects that can undermine the efficacy of the medication; prevent the patient's compliance with the strict regimen of medication required by the new drug protocols; and erode a patient's desire or willingness to continue treatment in light of

increased pain and discomfort, regardless of the possible long-term benefits. Common symptoms of HIV- related conditions and frequent side effects of standard AIDS therapies include severe nausea, vomiting, loss of appetite, chronic diarrhea, joint pain, dizziness, and fatigue. AIDS wasting syndrome, a deadly byproduct of the disease, describes the progressive loss of weight and muscle mass caused by this constellation of symptoms and side effects. Thousands of AIDS patients nationwide smoke marijuana to alleviate these symptoms and side effects, often with considerable success. Marijuana, because it stimulates appetite, helps counteract wasting, and thereby allows AIDS patients to gain weight and remain properly nourished, prolonging their lives. Marijuana also has been found effective in alleviating diarrhea and fatigue, which can be both cause and effect of numerous AIDS-related conditions.

(c) *Glaucoma*: Glaucoma is the second leading cause of blindness in the United States. Glaucoma occurs when fluid pressure within the eyeball increases, eventually damaging the optic nerve. Various medications are used to treat glaucoma including beta-blockers, epinephrine-like eye drops, miotics, and carbonic anhydrase inhibitors. However, a large percentage of glaucoma patients cannot tolerate the side effects of these drugs. Beta- blockers may cause depression, aggravate asthma, slow the heart rate, and increase the risk of heart failure. Epinephrine-like compounds can aggravate hypertension and heart disease. Miotics can cause blurred vision, impaired night vision and cataracts. Carbonic anhydrase inhibitors may cause nausea, diarrhea, headaches, depression and fatigue, kidney stones, and on rare occasions, a fatal blood disorder. Open angle glaucoma, from which about one million Americans suffer, is treatable with marijuana with no indications of deleterious effects. The administration of marijuana results in a dose-related, clinically significant drop in intraocular pressure that lasts several hours. Thus, marijuana can retard the progressive loss of sight, even when conventional medication fails and surgery is too dangerous.

(d) *Epilepsy*: Epilepsy is a disorder of cerebral function in which cerebral neurons spontaneously discharge in an abnormal, excessive, and uncontrolled way. The resulting seizures typically occur as convulsions or lapses of consciousness, often coupled with or followed by varying degrees of sensory, motor, and psychomotor dysfunction. Epilepsy is treated primarily with anticonvulsant drugs, such as phenytoin (Dilantin), primidone (Mysoline) and phenobarbital, which help about 75 percent of the time but are less effective in controlling focal seizures and temporal lobe epilepsy. These anticonvulsant drugs also have potentially serious side effects, including bone softening, anemia, swelling of the gums, nausea, vomiting, dizziness, gastro-intestinal distress, and emotional disturbances. Overdoses or idiosyncratic reactions to these drugs may cause nystagmus (uncontrolled movements of the eyeball), loss of motor coordination, coma, and even death. The anticonvulsant properties of marijuana have been known since ancient times but have been the subject of few modern medical studies. Nonetheless, the medical community and epilepsy sufferers are increasingly recognizing the usefulness of marijuana in treatment of epilepsy.

(e) *Multiple Sclerosis*: Multiple sclerosis is a disorder in which patches of myelin, the protective covering of nerve fibers, in the brain and spinal cord are destroyed and the normal functioning of the nerve fibers is interrupted. Symptoms usually appear in early adulthood, then come and go unpredictably for years. An attack may last

from weeks to months, and remission is often incomplete, with gradual deterioration and eventual severe disability. Common symptoms include tingling, numbness, impaired vision, difficulty speaking, painful muscle spasms, fatigue, emotional disturbance, weakness or paralysis, tremors, and ataxia (inability to coordinate voluntary muscle movements). No effective treatment for MS is known. Moreover, many patients cannot tolerate the immediate side effects of the standard drugs used to alleviate the symptoms of this disease. Corticosteroids, especially adrenocorticotropic hormone (ACTH) and prednisone, provide some relief for the acute symptoms of MS, but they also produce weight gain and sometimes cause mental disturbances. The drugs most commonly used to treat muscle spasms are diazepam (Valium), baclofen and dantrolene. Diazepam, which must be given in large doses, causes drowsiness and can be addictive. Baclofen and dantrolene are of marginal medical utility. Baclofen, a sedative, sometimes causes dizziness, weakness or confusion, and dantrolene is used as a last resort because of potentially lethal liver damage, among other side effects. Increasing numbers of MS patients, doctors and researchers find that marijuana helps relieve tremors and loss of muscle coordination. Its efficacy has also been acknowledged within the legal system as MS patients have successfully used the defense of medical necessity to defeat marijuana possession charges in state courts.

(f) *Paraplegia and Quadriplegia*: Paraplegia is weakness or paralysis of muscles in the lower body caused by disease or injury in the middle or lower part of the spinal cord. If the injury is near the neck, the arms as well as the legs are affected and quadriplegia develops. Paraplegia and quadriplegia are often accompanied by pain and muscle spasms. Standard treatments are opioids for the pain, and baclofen and diazepam for the muscle spasms. Opioids are addictive and tolerance develops. The side effects of baclofen and diazepam are discussed above. Many paraplegics and quadriplegics find that marijuana not only relieves their pain more safely than opioids but also effectively suppresses muscle jerks and tremors. A 1982 survey of forty-three persons with spinal cord injuries indicated that more than half used marijuana for muscle spasms.

30. At least 55 published studies confirm the experience of practitioners and their patients regarding the efficacy of medical marijuana. Among the more notable of these studies are the following:

(a) Vinciguerra *et al.*, "Inhalation Marijuana as an Antiemetic for Cancer Chemotherapy," *The New York State Journal of Medicine*, 525-27 (Oct. 1988). This study involved 56 patients who had no improvement with standard antiemetics. When treated with marijuana, 78 percent demonstrated a positive response. No serious side effects were observed.

(b) Chang, *et al.*, "Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High Dose Methotrexate," *Annals of Internal Medicine*, vol. 91, no. 6, 819-24 (Dec. 1979). This randomized, double- blind, placebo controlled trial of THC and smoked marijuana found a 72 percent reduction in nausea and vomiting, with smoked THC (marijuana) proven more reliable than oral THC.

(c) Official state government research programs in New Mexico, Michigan, Tennessee, New York, Georgia and California concluded that smoked marijuana was effective in controlling nausea and vomiting in chemotherapy patients. Typical

of these programs, the California research found consistently higher than 70 percent of patients found medical marijuana effective, leading the researchers to conclude: "Marijuana has been shown to be effective for many cancer chemotherapy patients, safe dosage levels have been established and a dosage regimen which minimizes undesirable side effects has been devised and tested."

(d) Hepler, R. and Frank, I., "Marijuana smoking and intraocular pressure," *JAMA*, 217, 1932 (1971). This study found that marijuana smoking reduced intraocular pressure.

B. Passage of The Compassionate Use Act

31. On November 5, 1996, the voters of California passed Proposition 215, the Compassionate Use Act of 1996, also known as the Medical Marijuana Initiative, adding section 11362.5 to California's Health and Safety Code. The law took effect at 12:01 a.m., on Wednesday, November 6, 1996.

32. By enacting the Compassionate Use Act, the California electorate codified its desire to "ensure that seriously ill Californians have the right to obtain and use marijuana for . . . illness[es] for which marijuana provides relief." Among the persons for whom voters expressly sought to afford this relief are those suffering from cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, and migraine.

33. As a precondition to deeming that a particular person's use of marijuana is legitimately intended for medical purposes, the Compassionate Use Act requires that the patient secure the recommendation or approval of a physician. Before granting such a recommendation or approval, the Act envisions that a physician will examine a patient, in the context of a bona fide physician-patient relationship, to determine whether the individual is "seriously ill" and whether "the person's health would benefit from the use of marijuana" such that the physician is able to recommend or approve marijuana to the patient as a treatment option. Without this clinical recommendation or approval, patients and their "primary caregivers" are unable to invoke the Compassionate Use Act's protections from criminal prosecution or sanction under state law.

34. The Compassionate Use Act specifically protects physicians: "[N]o physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes." The Act does not conflict with federal law, which classifies marijuana as a Schedule I substance, thereby prohibiting its prescription by physicians. The Act permits physicians only to recommend or approve marijuana for seriously ill patients. As the analysis of the initiative by the Legislative Analyst states: "No prescriptions . . . [are] required by the measure."

C. Federal Response

35. Prior to passage of the Compassionate Use Act, federal officials, including defendants, had never prosecuted, revoked the prescription drug license of, or punished in any way a physician for recommending the use of medical marijuana to a seriously ill patient in the context of a bona fide physician-patient relationship. Until the weeks before the November 1996 elections, no federal official had even threatened any such action. As the election drew near and polls showed Proposition 215 likely to be approved by the voters, defendant McCaffrey began a pattern of threats against physicians. On October 28, 1996, defendant McCaffrey stated on national television that the federal government would prosecute physicians who recommend marijuana for

medical use. Defendant McCaffrey's comments were reported in major newspapers throughout California, including the San Diego Union-Tribune, Los Angeles Times and San Francisco Chronicle.

36. Immediately following passage of the Compassionate Use Act, defendant McCaffrey reaffirmed the federal government's intention to prosecute physicians. On November 5, 1996, defendant McCaffrey stated that the federal government would prosecute doctors who recommend marijuana. On November 7, 1996, the spokesperson for the Drug Enforcement Administration "declined to rule out" prosecutions of physicians.

37. In the weeks following the election, defendants and other federal officials formulated a policy to recommend to President Clinton. Speaking to the press, defendants and other federal officials working in concert with them stated that they plan to prosecute and strip prescription licenses from doctors who give recommendations regarding medical marijuana to even seriously ill people. Defendant Constantine warned members of the press that "we are going to take very, very serious action against" doctors who recommend medical marijuana. Federal law enforcement officials under the jurisdiction of defendant Reno threatened to use "surveillance and informers" to identify physicians recommending marijuana to their patients.

38. On December 30, 1996, defendant McCaffrey issued a statement entitled "The Administration's Response to the Passage of California's Proposition 215 and Arizona's Proposition 200" (hereinafter "Administration Policy"). The Administration Policy represents the consensus of several federal departments and agencies, including the Office of National Drug Control Policy, the Drug Enforcement Administration, and the Department of Health and Human Services. The Administration Policy includes a series of specific threats to physicians:

> (a) *Threats to revoke physicians' license to prescribe drugs:* In order to prescribe medication, physicians need to be registered and to obtain a license from the Drug Enforcement Administration. The Administration policy states that "a practitioner's action of recommending or prescribing Schedule I controlled substances is not consistent with the 'public interest' (as that phrase is used in the federal Controlled Substances Act) and will lead to administrative action by the Drug Enforcement Administration to revoke the practitioner's registration." The revocation of a physician's DEA registration would effectively prevent that physician from practicing medicine.
>
> (b) *Threats of criminal prosecution.* The Administration Policy states that "DoJ will continue existing enforcement programs" regarding criminal possession or conspiracy to possess marijuana. The enforcement criteria include: absence of a bona fide doctor-patient relationship; a high volume of recommendations of marijuana; significant profits from such recommendations; providing marijuana to minors; and/or special circumstances, such as when death or serous bodily injury results from drugged driving.
>
> (c) *Threats to bar Medicare and Medicaid participation.* Physicians, including plaintiff physicians, rely on participation in the federal Medicare and Medicaid programs for a significant portion of their incomes. The Administration Policy declares "the authority of the Inspector General for HHS to exclude specified individuals [who prescribe or recommend Schedule I substances] from participation in the Medicare and Medicaid programs."

(d) *Threats to encourage state licensing boards to revoke physicians' licenses.* The California Division of Licensing governs the issuance and revocation of physician's and surgeon's licenses. Revocation of licenses may follow from adverse federal action against a physician. The Administration Policy advises that DoJ and HHS "will send a letter to licensing boards which states unequivocally that the DEA will seek to revoke the DEA registrations of physicians who recommend or prescribe Schedule I substances." This statement implicitly threatens physicians with loss of state licenses.

39. Widespread press coverage has exposed plaintiff physicians and their class to defendants' threats to prosecute or otherwise punish physicians for discussing medical marijuana with their patients. The repetition and circulation of defendants' threats have caused increased physician intimidation and the chilling of plaintiffs' First Amendment speech rights. According to a January 1, 1997 account in The Washington Post entitled "Federal Warning on Medical Marijuana Leaves Physicians Feeling Intimidated," federal threats against physicians are "already having a chilling effect. Doctors are worried about the potential consequences of losing federal licenses to write prescriptions and being excluded from the Medicare and Medicaid programs or federal contracts or grants. . . ." As a result of defendants' threats, the physician-patient relationship is disrupted and damaged because physicians are afraid to provide their patients with information or recommendations that the physicians believe are in the best interest of their patients' medical well-being. Without complete medical information, patients are unable to provide informed consent -- a fundamental prerequisite to ethical and legally permissible medical practice.

V. CLAIM FOR RELIEF

40. Plaintiffs reallege and incorporate by reference 1 through 39 as if set forth fully herein.

41.The First Amendment to the U.S. Constitution provides that "Congress shall make no law . . . abridging the freedom of speech . . . ."

42. Defendants' threats to enforce federal statutes and regulations in a manner that would punish or penalize physicians seeking to communicate with their patients, using their best medical judgment in the context of a bona fide physician-patient relationship, regarding the potential risks and benefits of medical use of marijuana violate the First Amendment as applied to plaintiffs.

VI. IRREPARABLE HARM

43. Plaintiffs, members of plaintiff organizations, and members of the plaintiff class, have suffered and will continue to suffer irreparable harm due to defendants' challenged policies and practices as described throughout this complaint.

44. Plaintiff physicians have a constitutional right to communicate to their patients a full range of medical information, and, in keeping with well-established norms of professional responsibility and medical ethics, they have a duty to discuss fully the range of treatment options for their patients. Defendants' threats have effectively gagged physicians, forcing them to withhold recommendations and information which they deem to be valuable or even critical. The law has long valued and required free and open discussions between physicians and patients: the doctrine of informed consent presupposes (indeed mandates) fully informed patients, and the doctrine of physician- patient privilege recognizes the sanctity of communications between a physician and a patient. Plaintiff physicians' inability to care for patients adequately; their inability to practice their chosen profession effectively and in good conscience because defendants' threats cause

them to withhold medically appropriate information; the resulting breakdown of the trust that lies at the core of the therapeutic relationship; and the chilling of their constitutionally protected right to free speech all amount to irreparable injury.

45. Plaintiff patients face serious and, in some cases, life-threatening illnesses requiring specialized and competent medical care. Many of these patients are enduring extremely painful and disabling treatments -- medications that produce nausea, vomiting, weight loss, chronic pain, sensory impairment, exhaustion, and other symptoms that sometimes seem unbearable. To complete their treatment effectively, plaintiff patients must have the utmost confidence in their physicians, yet as a result of defendants' repeated threats to physicians, plaintiff patients know that their physicians must censor and curtail their medical advice. When faced with extremely harsh and prolonged treatments like chemotherapy or certain aggressive AIDS treatments, some patients, unable to have confidence in their physicians, may disregard instructions and discontinue treatment, resulting in increased suffering, illness or death. Plaintiff patients' inability to receive full, uncensored medical advice, and defendants' interference with patients' treatment, and the resulting increased risk of suffering, illness, or death, amount to irreparable harm.

VII. PRAYER FOR RELIEF

WHEREFORE,

Plaintiffs accordingly pray for the following relief:

A. A preliminary and permanent injunction enjoining defendants, their agents, employees, assigns, and all persons acting in concert or participating with them from enforcing or threatening to enforce, in criminal, civil, or administrative proceedings, any federal statute, regulation or other provision of law in a manner that would punish or penalize physicians for communicating with their patients, using their best medical judgment in the context of a bona fide physician-patient relationship, regarding potential risks and benefits of medical use of marijuana, including but not limited to oral or written statements, recommendations or approvals by a physician that it is his or her medical opinion, based on his or her current diagnosis of the patient's illness, that the potential benefits of medical marijuana in the treatment of the patient outweigh the potential risks;

B. A declaration pursuant to 28 U.S.C. §§ 2201 and 2202 that defendants' threats to enforce federal statutes, regulations or any other provision of law in a manner that would punish or penalize physicians for communicating with their patients, using their best medical judgment in the context of a bona fide physician-patient relationship, regarding potential risks and benefits of medical use of marijuana violate the First Amendment as applied to plaintiffs;

C. Reasonable attorneys' fees and costs; and

D. Such other and further relief as this court may deem necessary and proper.

Dated: January 14, 1997.

Respectfully submitted,

LOWELL FINLEY
GRAHAM A. BOYD

JONATHAN WEISSGLASS
Altshuler, Berzon, Nussbaum,
Berzon & Rubin

ANN BRICK
American Civil Liberties Union

By: Graham A. Boyd

Attorneys for Plaintiffs

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