Medical Marijuana and the AIDS Crisis

Clinton A. Werner

SUMMARY. The sudden emergence of the AIDS epidemic and the initial lack of effective treatments politicized the patient population into demanding quicker development of and access to promising medications. When numerous AIDS patients demanded marijuana to treat the anorexia and wasting syndrome resulting from both illness and medications, the federal government's Public Health Service closed the only legal source of supply. The federal authorities' abdication of compassion and repression of research spawned a grassroots political movement that repudiated federal regulations. *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-342-9678. E-mail address: <getinfo@haworthpressinc.com> Website: <http://www.HaworthPress.com>*

KEYWORDS. Acquired Immune Deficiency Syndrome (AIDS), HIV, cannabis, marijuana, medical marijuana, delta-9-tetrahydrocannabinol, AIDS-wasting syndrome, azidothymidine (AZT), dronabinol

The AIDS epidemic was a crucial influence on the growth of support for the medical marijuana movement. When federal officials responded to an increasing number of requests for marijuana from a growing population of AIDS patients by closing the Compassionate Use Investigational New Drug (IND) Program that supplied the drug, a grassroots political movement was launched to protect patients from arrest. The numbers of HIV-positive patients, the po-

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Clinton A. Werner, BA, MLS, is the author of a forthcoming book on the history of the medical marijuana movement.

[Haworth co-indexing entry note]: "Medical Marijuana and the AIDS Crisis." Werner, Clinton A. Co-published simultaneously in *Journal of Cannabis Therapeutics* (The Haworth Integrative Healing Press, an imprint of The Haworth Press, Inc.) Vol. 1, No. 3/4, 2001, pp. 17-33; and: *Cannabis Therapeutics in HIV/AIDS* (ed: Ethan Russo) The Haworth Integrative Healing Press, an imprint of The Haworth Press, Inc., 2001, pp. 17-33. Single or multiple copies of this article are available for a fee from The Haworth Document Delivery Service [1-800-342-9678, 9:00 a.m. - 5:00 p.m. (EST). E-mail address: getinfo@haworthpressinc.com].

litical prowess of AIDS activists and the frustrations of AIDS researchers had a profound effect on the revelation to the American public that, with regard to cannabis, the federal government favored prohibition over science and compassion.

The first hints of the coming epidemic appeared at the end of the 1970's and in early 1980 when doctors in New York City, San Francisco, and Los Angeles began to see rare and unusual illnesses appearing among young gay men. The June 5, 1981 edition of the Centers for Disease Control publication, *Morbidity and Mortality Weekly Report* printed the following notice (Center for Disease Control 1981, pp. 305-308): "In the period October 1980-May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at three different hospitals in Los Angeles, CA" the report also noted that, "*Pneumocystis* pneumonia in the United States is almost exclusively limited to severely immunosuppressed patients." A second troubling *MMWR* alert soon followed that linked the development of a rare skin cancer, Kaposi's sarcoma, in gay men to the outbreaks of *Pneumocystis*. The following day news of the burgeoning epidemic was relayed to the general public by the *New York Times'* headline (Altman 1981), "Rare Cancer Seen in 41 Homosexuals."

The syndrome was quickly traced to a breakdown in the immune system, but the causative agent remained unknown. Panicky speculation attributed the dysfunction to everything from water fluoridation to marijuana contaminated with paraquat, a quaternary ammonium pesticide (Shilts 1987). Initially, the illness was referred to as Gay Related Immune Deficiency (GRID), but the appearance of GRID-related opportunistic infections among hemophiliacs, transfusion recipients and intravenous drug users confirmed that the infectious agent lacked specificity to sexual orientation, and it was renamed Acquired Immune Deficiency Syndrome (AIDS).

When AIDS emerged, researchers had no precedent or guide in dealing with this catastrophic collapse of their patients' immune systems. Without an identified causative agent, no treatments could be devised. Doctors were forced to pioneer treatment protocols, resorting to trial and error exploration of off label prescriptions for never-before-seen maladies such as opportunistic infections with *Toxoplasmosis gondii* and *Cryptosporidium parvum*. Dr. Donald Abrams, Assistant Director of the AIDS program at San Francisco General Hospital, recalled the early days of the epidemic (Bayer 2000, p. 70), "We didn't have anything to offer them. [They] died, and the deaths they died, I recall, were very terrible deaths; they were deformed and disfigured and wasted away, Kaposi's sarcoma lesions all over their bodies."

On April 23, 1984, the isolation of the human immunodeficiency virus (HIV) that causes AIDS was announced. Knowledge that the infectious agent is a retrovirus allowed investigators to target their search for effective treat-

ments. Due to the lengthy and involved Food and Drug Administration (FDA) drug approval procedure, however, any promising drugs that were developed were years away from availability. In the meantime, thousands would die without treatments for HIV. There were also myriad problems getting research under way.

There were two possible paths to drug availability: through government-sponsored clinical trials, or by research funded by pharmaceutical corporations in hopes of finding marketable products. Neither the government nor the private sector was eager to develop treatments for AIDS patients. The pharmaceutical companies did not envision that the numbers of AIDS patients would yield enough profits to justify expending millions of dollars on drug research and development (Arno 1992). The advent of AIDS also coincided with the inception of the Ronald Reagan Presidential Administration, which was committed to making deep cuts in domestic spending. Many of these policies adversely affected the ability of the nation's public heath service to respond to the type of public health catastrophe that AIDS was and remains (Shilts 1987).

The fact that the primary population affected by AIDS was gay men had a profound effect on the Reagan Administration's response to the crisis. President Reagan had decried homosexuality and trumpeted the right wing moralism of the Christian Coalition, whose members had flocked to the polls to vote for the former actor. For the first four years of the epidemic, Reagan refused to even utter the word "AIDS." The Reagan-appointed director of the CDC, Dr. James O. Mason complained of having to discuss various forms sexual activity with total strangers (Shilts 1987). Whether the negligence was due to distaste or malice, NIH spending on AIDS was drastically inadequate. In 1982, NIH expenditure for research into Toxic Shock Syndrome equaled $36,100 per death, and that for Legionaire's disease was $34,841 per death. In fiscal 1982, the NIH expenditure per AIDS death was a mere $8,991 (Shilts 1987).

In 1983, the San Francisco Board of Supervisors allocated $2.1 million for AIDS programs. Coupled with the $1 million from the previous year, San Francisco's spending on AIDS "exceeded the funds released to the entire country by the NIH for extramural AIDS research" (Shilts 1987, p. 186). Half of the money was allotted to establish the world's first AIDS clinic at San Francisco's General Hospital, which opened in July 1983.

With no drugs specific to treat HIV, and few available to treat the opportunistic infections that accompanied the resultant immune failure, AIDS patients were desperate. A significant number of the early AIDS-infected population included men who had pioneered the gay rights movement. This was a politically sophisticated group that already had a large activist infrastructure in place when the epidemic appeared. Almost overnight, gay rights activists became AIDS activists, fighting not for equality but for existence. Pressure was brought to bear on the government through protests, marches and demonstra-

tions. A powerful activist group emerged, AIDS Coalition to Unleash Power! (ACT UP) which spread across the country and later, across the globe.

Many members of the gay AIDS population were also well educated and traveled, and used these privileges to their advantage. AIDS patients began researching promising treatments, unapproved by the FDA, but available overseas or across borders, where drug approval and distribution is less stringently regulated. Patients traveled to Mexico and other countries to buy the illicit medications and smuggle them back to the USA, frequently employing techniques developed by marijuana traffickers. In 1987 the first "buyer's clubs" were established in San Francisco and New York City, where they functioned as underground pharmacies for smuggled treatments and alternative therapies such as vitamins and herbs (Arno 1992).

In order to find some effective drug against HIV, the National Cancer Institute (NCI) began soliciting the profit-minded pharmaceutical corporations for compounds for federally funded testing. In 1985 a compound, azidothymidine (AZT), showed some evidence of anti-HIV activity in the laboratory. Responding to pressure from activists and the public-at-large the FDA accelerated the rigorous 3-phase testing requirements and allowed AZT to be widely distributed upon initial evidence of clinical benefit (Arno 1992). For some patients, AZT was effective with manageable side effects. Others were plagued by intolerable headaches, loss of appetite, stomach upset, stomach pain and nausea or vomiting.

One of the primary killers of AIDS patients was a wasting syndrome that resulted from a number of illness-linked influences including oral thrush, anorexia and chronic diarrhea. Wasting is defined as the loss of more than 10% of baseline bodyweight (Bayer 2000). The fact that, for many, AZT further suppressed the appetite and frequently resulted in gastric distress was a dire situation for patients who were already wasting due to the primary disease (Richman et al.1987).

Although AZT was rushed to approval, it proved to be no magic bullet. At best it extended survival by months, slowing viral replication, but not eradicating it (Bayer 2000). It was a cruel irony that the side effects of the only approved antiviral drug for HIV mimicked and aggravated some of the most devastating symptoms of the illness. In order to be effective, the drug had to be taken on a regular schedule, at very frequent intervals through the day and night. This meant that the side effects never had an opportunity to subside. With constantly depressed appetites it was a challenge for PWA's (People with AIDS) on AZT to ingest enough calories to rebuild body mass. Patients affirmed that marijuana usage not only eased and abated the gastrointestinal distress from both illness and remedy, but induced a voracious hunger and a seemingly insatiable compulsion to eat, known as "the munchies." For many

AIDS patients, smoking or eating cannabis became a primary component of their unorthodox treatment arsenal.

In 1983, the first call from an AIDS patient extolling marijuana's benefits reached Robert Randall, founder of the Alliance for Cannabis Therapeutics (ACT). Randall, a glaucoma patient whose suit against federal agencies forced the establishment of the Compassionate Investigational New Drug program for marijuana, had devoted his life to promoting medical marijuana and working to make it a prescription drug. ACT was founded as a nonprofit organization to further this endeavor.

Randall's most successful campaign had been an effort to persuade state legislatures to pass legislation to protect medical marijuana users (primarily cancer and glaucoma patients) from arrest and prosecution. By 1983, 34 states had enacted legislation that made marijuana available though "research programs." Because of marijuana's classification as a Schedule I drug, with the presumption of no recognized medical benefits and a high abuse potential, it could only be distributed for research through the National Institute on Drug Abuse (NIDA). Thus, Randall and the other legal users were provided with marijuana through the IND research exemption, despite the fact that no data was collected. Similarly, the states could only obtain cannabis by enacting specific research programs.

Production of the cannabis for federally approved research was conducted at a 5-acre farm at the University of Mississippi under a contract with NIDA (Randall 1998). The growing demand for marijuana from states with established research programs vastly outpaced the cannabis farm's ability to supply the drug. California alone requested 1 million marijuana cigarettes from NIDA (Randall 1998). In order to meet the needs of the state programs a new production plan would have to be established with state-of-the-art production techniques. Rather than move in this direction, FDA officials turned to synthetic THC as a surrogate for whole cannabis.

A stable method for the delivery of synthesized delta-9-tetrahydrocannabinoid, or THC in sesame oil, was developed for research purposes in the 1970's (Rosenkrantz et al. 1972). Later research established that oral THC had antiemetic properties and was significantly better than a placebo in reducing vomiting caused by chemotherapeutic agents (Sallan, Zinberg and Frei 1975). Despite the clinical evidence of antiemetic activity for oral THC, the researchers suggested that smoking might be a preferable route of administration due to its more reliable absorption compared to gastrointestinal ingestion. Moreover, smoking provides greater opportunity for individual patient control by permitting the patient to regulate and maintain the "high" (Sallan, Zinberg and Frei 1975). Efforts to prepare an aerosol delivery system for THC failed due to (Olsen et al. 1976, p. 86), "excessive tack of the spray and hence poor transport to the lungs."

Despite the irregular absorption and unpredictable mental effects of oral THC, it was the only solution available to stem the push for medical marijuana from the states. On June 26, 1980, an FDA advisory panel rushed to approve, by just one vote, the distribution of synthetic THC pills to oncology patients through a NCI research program (Washington Post 1981, p. A1). Panel member Dr. Charles G. Moertel, director of clinical cancer research at the Mayo Clinic, criticized the action and decried (Washington Post 1981, p. A1), "the current political hysteria for the general release of THC. I wonder if perhaps the weight of this political pressure does not exceed the scientific evidence justifying release." Robert Randall protested the diversion from cannabis to THC, charging that (Washington Post 1981, p. A1), "federal agencies are using their control of the nation's legal marijuana supply to corrupt the intent of the state laws." Only six of 34 states with research laws managed to obtain actual marijuana cigarettes (Randall 1998; Musty and Rossi 2001). The rest of the states were provided with "marijuana capsules," which were actually oral THC pills.

The resulting studies with THC evidenced some anti-emetic activity and the studies with inhaled cannabis found it to be safe and effective against chemotherapy-induced nausea (Randall 1998). With evidence that THC was effective against nausea in hand, the FDA faced the challenge of bringing it to market as a prescription drug. NIDA's chief of research and technology, Robert Willette noted that (Tucker 1979, p. 33), "Since THC isn't patentable, it's going to take a lot of coercion by the government to get a pharmaceutical company to market THC."

The FDA found a distributor for the THC pills in Unimed, a small New Jersey-based company that had no prescription drugs on the market, just over-the-counter remedies, and was eager to expand. After clearing the FDA-approval procedures, THC was given the generic name, dronabinol and marketed as Marinol . THC in the form of dronabinol was moved from a Schedule I to a Schedule II designation, alongside cocaine and morphine, which permitted distribution by prescription in June of 1985. Despite the fact that a synthesized and concentrated version of cannabis' most active compound was rescheduled, the source plant was not. With marijuana withheld, and synthetic THC available by prescription, the state medical marijuana research programs slipped into dormancy.

Along with leading the state movements for medical marijuana, Robert Randall, through ACT, was working for Congressional legislation to move marijuana into the Schedule II designation. Although a bill attracted a broad coalition of supporters, it never moved out of committee.

ACT was also a co-petitioner with NORML (National Organization for the Reform of Marijuana Laws) for public hearings into rescheduling marijuana. After years of litigation against the Drug Enforcement Administration (DEA) in pursuit of these hearings, they were held in front of the DEA's Administra-

tive Law Judge, Francis Young in 1987 and 1988. Judge Young ruled that marijuana has "an acceptable medical use in treatment in the United States" and proclaimed that the Schedule I classification was "unreasonable, arbitrary, and capricious" (Young 1998, p. 68). On December 30, 1989, DEA Administrator Jack Lawn announced his rejection of Judge Young's directive to reschedule.

Between the time of Judge Young's decision and Administrator Lawn's rejection of it, Robert Randall received a call from an AIDS patient in Texas who had reversed his wasting condition with marijuana, but was now facing jail after being arrested for possession. The patient, Steve L. wanted to gain admission into the Compassionate IND Program. Steve's physician agreed to sponsor him and after months of wrangling with evasive agencies, he was approved. The shipment of NIDA joints reached Steve on January 25, 1990, just 18 days before he died (Randall 1991; Randall 1998). Randall wrote an obituary for Steve that ran in *High Times*, a magazine for marijuana users. At the end of the tribute was included the phone number for ACT's offices.

In Panama City, Florida, a young couple was in desperate trouble. Kenny and Barbra Jenks were slipping into the late stages of AIDS. They were impoverished, with few health care resources and had just been arrested by the local narcotics task force and charged with serious felony violations: manufacturing marijuana with intent to distribute. Whittled away to near-skeletal thinness by HIV, the Jenks had been urged to smoke marijuana at an AIDS-support group meeting. After the meeting, they had been slipped a joint, but being "straight arrows" were reluctant to try it. When they eventually did try the marijuana, they discovered the munchies and both began to regain some weight and vitality. The couple became regular users of small amounts of cannabis, but without reliable connections within the "drug culture" or black market they often went without their medicine. Rather than rely on chance, Kenny planted some seeds and had cultivated two short and scraggly plants when they were arrested.

Kenny Jenks, a hemophiliac, had contracted HIV through the clotting factor he took to prevent death from internal bleeding. Barbra, Kenny's high school sweetheart, had contracted the virus from him. When their trailer was raided and agents found the tubing and syringes used for infusing clotting factor, Kenny was accused of being a heroin addict who was growing cannabis to support his habit.

Out on bail, Kenny came across the issue of *High Times* with Steve L.'s obituary and called ACT. Upon hearing the Jenks' story, Randall endeavored to find them legal representation and improved medical care from an AIDS expert who was willing to sponsor their IND application (Randall 1991).

Randall quickly realized the Jenkses' public relations value for promoting the use of marijuana for AIDS patients. They were literally "Ken and Barbi wholesome": salt-of-the-earth, heterosexual, monogamous. They lacked the

homosexual and IV-drug use baggage that right-wing opponents could seize on to distort the issue by discomforting Middle America.

In March of 1991, after Kenny and Barbra had endured the standard institutional delays and had their IND supplies in hand, they joined Randall for a press conference to announce the launch of a new ACT endeavor, Marijuana/Aids Research Service (MARS). The service of the organization was to provide AIDS patients and their doctors with a uniform template with which to apply to the FDA for a Compassionate Use IND. Randall explained (Randall 1998, pp. 359-360), "Prior to MARS, physicians who requested IND forms from the FDA could wait for weeks, even months for the forms. When the papers did arrive there was no explanation about how to complete the 31 questions . . . Physicians who once struggled for hours to answer arcane FDA questions, could sit with an AIDS patient, open a MARS packet, go through a checklist and put an application in the mail in under an hour." The MARS forms were promoted by the Jenks and distributed to AIDS organizations throughout the country.

The AIDS-patient population responded enthusiastically to MARS. Many gay men who comprised the bulk of the AIDS-infected population had a profound distrust of the culture of authority and had never believed the "reefer madness" propaganda. These were largely children of the "Woodstock Nation." They had smoked pot, dropped acid, demonstrated against the war in Vietnam, gleefully violated anti-sodomy laws, and marched for gay liberation. There was little or no stigma associated with cannabis use for these patients, and they were eager for any remedy that worked. Soon, dozens of Compassionate Use IND applications began arriving at the FDA.

In June of 1991, just 3 months after the launch of the MARS effort, the patients receiving Compassionate Use IND marijuana found that their monthly shipments of the drug had been interrupted. The reason for the withholding of the marijuana became clear on June 21 when Dr. James O. Mason, Chief of the US Public Health Service (PHS) and former director of the Centers for Disease Control (CDC), announced the closure of the Compassionate Use IND Program saying (Isikoff 1991, p. A14), "If it's perceived that the Public Health Service is going around giving marijuana to folks, there would be a perception that this stuff can't be so bad. It gives a bad signal . . . there's not a shred of evidence that smoking marijuana assists a person with AIDS." Mason, much as his good friend and booster, Utah Senator Orrin Hatch, was infused with a pious attitude of abstention and priggishness. As director of the CDC, confronting the expanding AIDS crisis, Mason (Shilts 1987, p. 399), "couldn't bring himself to utter the word 'gay' when he met a gay delegation during his first day on the job." In justifying his decision to close the program, Mason expressed concern that AIDS patients taking medical marijuana (Isikoff 1991, p. WH 19), "might be less likely to practice safe behavior."

In response to Mason's abrupt announcement, Robert Randall organized a media blitz that highlighted the patients who were IND cannabis recipients in order to illustrate the political and callous nature of the decision. The well-oiled AIDS activism machinery engaged over the medical marijuana issue and phone trees were activated. The PHS, FDA, DEA and the White House Office of National Drug Control Policy (ONDCP) were clogged with calls from desperate patients, confused loved ones and angry activists. The AIDS-activist group, ACT UP, led a medical marijuana protest in the form of a "die-in" which closed the headquarters of Health and Human Services (HHS). Randall recalled (Randall 1998, p. 380), "what the agencies did not anticipate was the onslaught of public anger . . . This aggressive telephonic battering had a profoundly corrosive effect on institutional morale."

Mason's sudden and unilateral decision for IND closure had cast the ONDCP in a particularly bad light and put the agency in an untenable situation. Less than two months prior to Mason's announcement, ONDCP Assistant Director Herb Kleeber had appeared on the NBC television network's *TODAY* show to caution the ill away from buying cannabis on the black market. Kleeber reassured patients that (Today 1991, p. 25), "no one's been turned down in the last two years. There are over 35 such IND's on the market currently and the waiting period usually is less than one month . . . They can get an exception from the FDA. That's the way to go rather than go out and break the law."

Mason's announcement made Kleeber and the ONDCP seem foolish at best and dishonest at worst. The White House drug policy staff seemed moved and disturbed by the desperation of the calls they received, and initiated a challenge to the Compassionate Use IND's termination. The resulting interagency battle forced the PHS to suspend the closure until the conflict could be resolved.

Mason had planned to completely end the program, forcing Randall, the Jenks and other IND recipients to switch to dronabinol, despite the absence of any clinical data showing it to be safe and effective for their diseases. The ONDCP staff, in contrast, felt that this approach was a duplicitous betrayal of trust. They wanted NIDA to continue providing marijuana to all of those approved to use it, including those who had never received their supplies. In a scolding letter to Mason, Ingrid A. C. Kolb, acting deputy director for demand reduction at the ONDCP, wrote (Ostrow 1992, p. A13), "For HHS to treat this matter as just another bureaucratic decision is unconscionable and, to me, shows an intolerable lack of compassion." With the conflict at a stalemate, the final decision was passed up to HHS Secretary Louis Sullivan. In March of 1992, Sullivan settled the issue with a compromise. The program would close, but the current recipients would receive marijuana for the rest of their lives or until cured. The approved but unsupplied patients, primarily people with

AIDS, were prescribed dronabinol in lieu of cannabis. For HHS, the fix was in and the issue was settled. But no one could explain how someone with nausea and vomiting was supposed to hold down a pill the size of a bath oil bead.

While Randall and the Jenks were promoting MARS, a grassroots medical marijuana movement was germinating in San Francisco. On the same day that Steve L. became the first AIDS patient to receive legal marijuana (Randall 1991), career cannabis dealer and gay activist Dennis Peron's home was raided by San Francisco narcotics officers. Peron operated a marijuana market in the predominantly gay Castro neighborhood and the bulk of his clients were HIV-positive. During the raid, Peron and his housemates, one of whom was in the late stages of AIDS, were physically and psychologically abused by being hogtied, threatened with weapons and taunted with homophobic and AIDS-phobic slurs. The only cannabis tied to Peron was a moderate amount of top-grade marijuana that he and his ill housemate, Jonathan smoked. Peron went free when he and Jonathan explained to the court that the marijuana was an effective medicine against wasting. Two weeks after the trial, Jonathan succumbed to his disease and Peron (1996) recalled, "I kept thinking about how I was going to get even and I kept thinking that every AIDS patient needs pot and that is where I got the idea for a club." Peron knew that if he could openly sell cannabis, with medical use as a justification and a shield, then he would be tormenting and humiliating the narcotics squad while helping the ill.

Peron's first step was to gather enough voters' signatures to qualify a "Hemp Medications" proposition for San Francisco's November ballot. The proposition (Prop P 1996, p. 1) advised "the state of California and the California Medical Association to restore hemp medicinal preparations to the list of available medicines in California."

Peron's timing was perfect. Coincidentally, Prop P qualified for the ballot just days before James Mason announced the Compassionate IND closure and benefited enormously from the resulting publicity and furor over the lack of cannabis for AIDS patients. San Francisco was playing David to the federal government's Goliath, and the local press loved it.

In November, Prop P passed with an impressive 78% of San Francisco's voters saying yes to medical marijuana. Peron celebrated the victory by opening a "cannabis buyer's club" based on the model of the Healing Alternatives Buyer's Club which had sold unapproved medicines to AIDS patients for years without harassment. And since jurors are taken from the voter registration rolls, Peron felt sure that 78% of any jury would vote to acquit him should trouble arise. Peron's clientele grew as word of his operation spread, with some patients and caregivers traveling in from out of state to buy a variety of cannabis products in a safe and clean environment.

When HHS Secretary Sullivan finalized the Compassionate Use IND's closure in early 1992, San Francisco County Supervisor Terence Hallinan initi-

ated an effort inspired by Prop P, to protect local medical marijuana users from being arrested (Hallinan 1998).

At San Francisco General Hospital's Ward 86, the AIDS ward, an increasing number of patients were reporting benefits from using cannabis. The ward's "Volunteer of the Year" for two years running, "Brownie Mary" Rathbun, had earned her nickname by baking marijuana-laced brownies for her "kids with AIDS." In June, 70-year-old Brownie Mary was arrested in the process of baking a large batch of illegal confections. After admitting that she baked the brownies and drove them to San Francisco to give them to AIDS and cancer patients, Brownie Mary was arrested and charged with transporting marijuana, a felony. The arrest of a little old lady for baking marijuana brownies for AIDS patients was the ultimate human interest story and was beamed around the globe by CNN. Rathbun was defiant, vowing (San Francisco Examiner 1992, p. A6), "My kids need this and I'm ready to go to jail for my principles . . . I'm not going to cut any deals with them. If I go to jail, I go to jail."

Dr. Donald Abrams, Assistant Director of the AIDS Program at San Francisco General Hospital, was in Amsterdam attending the International AIDS Conference when he retired to his hotel room, turned on the television and saw the story of Volunteer of the Year, Brownie Mary's arrest.

Also watching as the Brownie Mary saga unfolded was Rick Doblin, founder of the Multidisciplinary Association for Psychedelic Studies (MAPS) which worked to facilitate clinical research into the therapeutic potential of Schedule I drugs. Seeing that Brownie Mary was a volunteer at the world's premier AIDS facility, Doblin sent a letter to the program suggesting that a clinical trial of cannabis as a treatment for AIDS wasting should be conducted at "Brownie Mary's institution" (Abrams 1995). The letter was forwarded to Dr. Donald Abrams who pioneered and directed community-based clinical trials for HIV through San Francisco General Hospital's Community Consortium.

Community-based clinical trials became a third avenue of drug approval, along with federally initiated trials and research by pharmaceutical companies. Doctors treating AIDS patients became researchers, providing the opportunity for the collection and assessment of clinical data. The first drug approved through community-based research was inhaled pentamadine for *Pneumocytis carinii*. Pentamadine had originally been given intravenously, but it was toxic to the kidneys and other organs. Inhaled, the drug was delivered directly to the lungs where it was needed, sparing the rest of the body from some degree of side effects. Therefore, the idea of an inhaled medicine was not anathema to Abrams.

Abrams had also witnessed patients and friends with AIDS using cannabis and seeming to benefit from it. He had seen no serious harm, as with alcohol or cigarettes, or any number of prescription drugs at his disposal. With so many

patients using medical marijuana it seemed as though some data should be gathered in case there was some unknown harm. There were rampant assertions and assumptions that marijuana could further damage the immune system.

Abrams contacted Doblin, and collaboration began to design a protocol for a study of cannabis to treat the AIDS-wasting syndrome. Abrams and Doblin consulted with FDA researchers in designing the trial and ushered it through approval from hospital committees, state and university investigational review boards and the FDA. Efforts to move forward with the research, which would have compared control patients with patients taking dronabinol and patients smoking marijuana, hit a roadblock at NIDA. In order to conduct the trial, Abrams needed marijuana, which only NIDA could supply.

While Abrams and Doblin worked on obtaining cannabis for the study, the San Francisco Board of Supervisors passed a measure to designate medical marijuana use as the lowest police priority. They also declared "Brownie Mary Day" in San Francisco. Rathbun's charges were subsequently dropped in Sonoma County, and she became a local folk hero.

The passage of Prop P and the supporting resolution inspired other communities to take similar actions. As support for medical marijuana grew, so did its use. Dennis Peron moved his buyer's club from a studio apartment to a large former dance studio at one of the city's primary public transportation hubs and he invited the media in to see. Buyer's clubs began appearing in other locations, including New York, Seattle, and Key West.

More initiatives passed and the overwhelming public support for medical marijuana motivated California State legislators to pass a measure that would reclassify cannabis as a Schedule II drug available by prescription. Governor Pete Wilson vetoed the bill, appropriately noting that state law could not make a drug available by prescription.

At San Francisco General Hospital, Abrams was waiting for approval from NIDA of his request for a supply of cannabis for the AIDS-wasting study. For 9 months, Abrams queried NIDA officials about the status of his request and was stymied with assurances and apologies. In April of 1995, Alan Leshner, Ph.D., Director of NIDA informed Abrams that (Leshner 1995), "we cannot comply with your request." Leshner complained that (CNN 1996), "The study was flawed and I couldn't justify using our scarce resources . . . "

Abrams was infuriated and responded with a scathing letter. Abrams (1995) wrote:

> To receive the first communication from your office nine months after we sent the initial submission is offensive and insulting . . . The apparent absence of any possibility to discuss your concerns and to modify the protocol so that we may work together for the benefit of our patients is also unacceptable in my opinion . . . your concerns about the scientific

> merit of the study have not been shared by a number of competent reviewers and investigators.

Abrams closed the letter with a blistering attack:

> Finally the "sincerity" with which you share my "hope that new treatments will be found swiftly" feels so hypocritical that it makes me cringe . . . You had an opportunity to do a service to the community of people living with AIDS. You and your Institute failed. In the words of the AIDS activist community: SHAME!

At this point in the history of the medical marijuana movement a confluence of political deception, scientific frustration and grassroots activism generated a dynamic synergy for reform. Activists used Leshner's rejection and Abrams' response as public relations weapons.

Shortly after NIDA's rejection of the AIDS study the California legislature passed a bill to exempt medical users from prosecution under state law. Governor Wilson also vetoed this bill, and passed the buck saying (San Francisco Chronicle 1995, p. A22), "the Clinton Administration said in August marijuana should not be used for any purpose," referring to Attorney General Janet Reno's refusal to call a moratorium on the arrest of medical users.

Dennis Peron's Cannabis Buyer's Club had grown to accommodate over 10,000 members and relocated to a vast 5-story building in the heart of downtown San Francisco (Peron 1996). It was from this location that a network of activists, patients and suppliers launched a ballot initiative to enact a law to protect medical marijuana users from state anti-marijuana laws. Simultaneously, Donald Abrams and his research team were retooling their clinical trial to obviate any claims from NIDA that it "lacks scientific merit."

California's ballot initiative process allows citizens to enact or repeal laws that legislators have failed to address satisfactorily. In the fall of 1995, California activists began gathering signatures to qualify a medical marijuana proposition for the 1996 election. The effort succeeded following an infusion of cash from a group of wealthy sympathizers and the campaign for Prop 215 began.

Alan Leshner was in a difficult position as director of NIDA. The legislation that established the Institute charged the agency to (NIDA 1972, p. 55), "develop and conduct comprehensive health education, training, research, and planning programs for the prevention and treatment of drug abuse and for the rehabilitation of drug abusers." By definition, NIDA was precluded from facilitating research into the benefits of illicit drugs. If Leshner had violated the mission statement of his Institute, he could face a spate of political assault aimed at embarrassing the Clinton Administration.

Rather than continue to take the heat of public displeasure, Leshner washed his hands of the responsibility and agreed to provide marijuana for any study that passed NIH peer review, a part of the funding process for govern-

ment-sponsored research. Abrams and the THC study team believed that this would work to neutralize political considerations.

In August, just three months before Californians would vote on Prop 215, Abrams received a rejection notice from the NIH. When the peer review panel's comments arrived Abrams began to see how deeply the political reefer madness bias had penetrated. Abrams (1998, p. 166) wrote:

> Two of the three reviewers mentioned in their comments that they were unclear as to why the Consortium investigators would chose to conduct a trial with such a "toxic" substance. The final reviewer was concerned that if patients with AIDS wasting developed increased appetite following marijuana ingestion . . . that they may subsequently develop hyperlipidemia (high cholesterol and triglycerides) and atherosclerosis. The peer review panel seemed to have missed the point: the reason the substance was being studied was because it was being so widely used in the local community. The reviewers apparent lack of insight into the natural history of the HIV-wasting syndrome also was of concern to the once again defeated protocol team.

The rejection of the second proposed study of marijuana use by AIDS patients came at a time when federal mouthpieces, most notably Drug Czar Barry McCaffrey, were trying to make a strong case against Prop 215, and a similar but broader measure in Arizona, by claiming that (Russel 1996, p. A8), "There is not a shred of scientific evidence that shows that smoked marijuana is useful or needed. This is a cruel hoax that sounds more like something out of a Cheech and Chong show." The retired general's argument lacked authority, especially when countered with a world class researcher's complaint that (Kanigal 1996, p. C1), "The government is saying there are no scientific studies proving the medicinal benefits of marijuana, but they're also not letting studies be conducted."

On Election Day, 56 percent of California's voters said "yes" to medical marijuana. It was a decisive victory that was a powerful indictment of the government's unwillingness to deal honestly with the issue. Arizona's more sweeping measure, allowing for the medical use of all Schedule I drugs, passed with 65 percent of the vote. Rather than heeding the will of the voters and redirecting their efforts toward dealing with medical marijuana scientifically, federal authorities moved to squash the uprising. McCaffrey and other opponents insulted voters by saying that they were "asleep at the switch" or were duped by pro-drug millionaires. When this technique failed to illicit a *mea culpa* from the voting public, Attorney General Janet Reno, supported by HHS Secretary Shalala, McCaffrey, and Leshner, threatened that "U.S. Attorneys in both states will continue to review cases for prosecution and DEA officials will re-

view cases for prosecution and DEA officials will review cases, as they have, to determine whether to revoke the registration of any physician who recommends or prescribes so-called Schedule I substances" and that doctors might face "further enforcement action" (CNN 1996). The grim and punitive nature of the press conference clearly illuminated the federal government's brutal indifference to the plight of medical marijuana users. The outcry against the announcement was swift, massive and seething. The public, physicians and their professional organizations were outraged. Editorials across the nation decried the action as an interference with the doctor-patient relationship. A group of San Francisco doctors and patients responded by filing a class action suit against Reno, McCaffrey and DEA Administrator Thomas Constantine for violating the First Amendment to the Constitution.

The eruption of anger was so profound that within a week McCaffrey had retreated from his "not a shred of evidence" soundbite and announced a $1 million review of scientific evidence on marijuana as medicine to be conducted by the National Academy of Science's Institute of Medicine. The NIH also rushed to conduct a 2-day workshop on medical marijuana that continued to invalidate the drug czar's "Cheech and Chong" rhetoric. Rick Doblin, who attended the workshop and was still promoting Abrams' efforts to conduct research assured him that (Doblin 1997), "NIDA, NIH, and the Clinton Administration will have a very difficult time convincing the press that the publicly announced new openness to research is more than a PR front and delay tactic if your next NIH grant gets rejected."

A month earlier, in January, Abrams had met with Leshner at NIDA and discussed the barriers to researching marijuana's benefits. Leshner emphasized to Abrams that the Institute was "the National Institute *on* Drug Abuse, not *for* Drug Abuse" (Abrams 1997). Consequently, Abrams and the marijuana team devised a study to assess the potential harm that marijuana or dronabinol might cause by interfering with the new AIDS drugs, protease inhibitors. The study also included examination of weight gain and other measures that could indicate if there was a therapeutic benefit of cannabis for the subjects.

This third submission by Abrams' team was given special attention in the reviewing process and was promptly approved. On May 12, 1998, the first patients were enrolled in the study and began a 21-day stay at San Francisco General Hospital, during which they were randomized to dronabinol, a dronabinol placebo, or 3.95% THC cannabis in the form of NIDA's cigarettes. Initial results of the study were presented at the XIII International AIDS Conference in South Africa. Early findings indicate that: "Cannabinoids, smoked or oral, do not adversely effect HIV RNA levels after 21 days exposure. Smoked marijuana and dronabinol lead to significant increases in caloric intake and weight" (Abrams 2000). The THC Study Team also suggested that, "Future trials

should investigate the effectiveness of marijuana in: appetite stimulation/ weight gain, nausea, pain" (Abrams 2000). The long-sought research has made a significant contribution to validating the "anecdotal" claims of the tens of thousands of AIDS patients who have used cannabis medicinally. The publication of more detailed findings from the study is pending.

The government's "new openness to research" did not dissuade the public of the notion that federal agencies had placed politics before science. Eventually, medical marijuana initiatives similar to Prop 215 were passed by voters in Arizona, Oregon, Washington, Maine, Nevada, Alaska, and the District of Columbia. In Hawaii, the state legislatures defied federal policy by passing a medical marijuana bill.

When the $1 million IOM report was released in March of 1999, it cautiously affirmed the medical use of marijuana, suggesting that better methods of delivery than smoking be devised.

And although research is proceeding slowly, it is finally underway. NIDA relaxed its restrictions requiring NIH peer review for all medical marijuana research, but added a PHS review panel process before providing medical marijuana to researchers. Several studies are pending in California through a state-funded research program including investigations into marijuana for multiple sclerosis and peripheral neuropathy.

Currently, as evidenced by the success of state ballot propositions, the American general public has generally accepted the idea that cannabis is a safe and effective medicine. The experiences of desperate AIDS patients using medical marijuana helped to change the nation's perceptions of the drug from menace to medicine.

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