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March 16, 1999

**MEMORANDUM**

**TO: DEMAND REDUCTION INTERAGENCY WORKING**

**FROM: Dr. Donald Vereen, ONDCP Deputy Director**

**RE: Institute of Medicine Report**

The purpose of this memorandum is to inform you of the major conclusions of the report *Marijuana and Medicine: Assessing the Science Base* which will be released by the Institute of Medicine (IOM) on Wednesday. IOM prepared this report in response to a January 1997 ONDCP request for a review of the scientific evidence that assesses the potential health benefits and risks of marijuana and its constituent cannabinoids. ONDCP commissioned this IOM study in the belief that an objective and independent evaluation of research regarding the use of marijuana for medicinal purposes was appropriate given the ongoing debate about cannabis and its health effects.

The IOM report represents the most thorough analysis to date of the relevant scientific literature. It summarizes recent advances in molecular and behavioral neuroscience, in particular, and newly elaborated systems of transmitters, receptors, and antagonists – all illuminating the physiological effects of cannabinoids. IOM has addressed all issues that ONDCP requested be examined, including: the science base and gaps in scientific knowledge regarding use of marijuana for medicinal purposes; scientific information about marijuana's mechanism of action; peer-reviewed literature on the uses of marijuana; and health costs associated with various forms of the component chemical compounds in marijuana and other pharmacotherapies for special medical conditions.

The report contains six specific recommendations that address:

1. Continued research into the physiological effects of cannabinoids;
2. Clinical trials of cannabinoid drugs for symptom management;
3. Evaluation of psychological effects of cannabinoids in clinical trials;
4. Studies of individual health risks in smoking marijuana;
5. Clinical trials of marijuana use under limited circumstances for medical purposes;
6. Short-term use of smoked marijuana under strict conditions for patients with debilitating symptoms;

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PRESERVATION**

These IOM recommendations are supported by the following observations:

- Scientific data indicate a potential therapeutic value of cannabinoids for pain relief, control of nausea and vomiting, and appetite stimulation. This value would be enhanced by a rapid onset of drug effect.
- The psychological effects of cannabinoids may contribute to their potential therapeutic value. They can influence symptoms indirectly, which could create false impressions of the drug effect or be beneficial as a form of adjunctive therapy.
- Numerous studies suggest that marijuana smoke is an important risk factor in the development of respiratory diseases, but the data that could conclusively establish or refute this suspected link have not been collected.
- Because marijuana is a crude THC delivery system that also delivers harmful substances, smoked marijuana generally should not be recommended for medical use. Nonetheless, marijuana is widely used by certain patient groups, which raises both safety and efficacy concerns.
- If there is any future for marijuana as medicine, it lies in its isolated components -- the cannabinoids and their synthetic derivatives. Isolated cannabinoids will produce more reliable results than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, nonsmoked cannabinoid delivery systems.

ONDCP will carefully study the conclusions and recommendations contained in this report. We will continue to rely on the professional judgement of the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Surgeon General on all issues related to the medical value of marijuana and its constituent cannabinoids. We note the report's conclusion that "the future of cannabinoid drugs lies not in smoked marijuana, but in chemically-defined drugs that act on the cannabinoid systems that are a natural component of human physiology."

In an accompanying editorial in the March 18 *JAMA*, Joseph D. Zuckerman, M.D., from the New York University-Hospital for Joint Diseases, N.Y., writes: "The question remains whether the use of intensive inpatient rehabilitation units improve patient care outcome beyond standard acute hospital care. The study by Munin et al does not help answer this question because of the absence of a 'discharge to home' group. Unfortunately, the information available in the orthopedic literature does not help answer this question."

Dr. Zuckerman concludes: "It is reasonable to state that the primary goal of today's health care is to obtain the best possible patient outcomes using the most cost-effective approach. The use of inpatient rehabilitation programs has been proposed as one method to achieve this goal. It is critically important that clinicians and health care organizations continue efforts to evaluate the benefits, costs, and the cost-benefit of this approach. With this information available, physicians will be able to respond effectively to changes in health care and, more important, to initiate the changes that will most benefit our patients."  
(*JAMA*. 1998;279:880)

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## **DESPITE LITTLE SUCCESS, PUBLIC STILL SUPPORTS WAR ON DRUGS**

### **Surveys find opposition to drug legalization, support for medical use of marijuana**

CHICAGO—Even though the majority of Americans do not feel the "War on Drugs" has succeeded, they are not willing to give up on drug-fighting efforts, according to an article in the March 18 issue of *The Journal of the American Medical Association (JAMA)*.

Robert J. Blendon, Sc.D., and John T. Young, M.Phil., of the Harvard School of Public Health, in Boston, Mass., reviewed 47 national surveys conducted between 1978 and 1997. They looked at four areas important to health professionals interested in America's drug policy:

- Where do Americans get their information about the extent of the nation's illegal drug problem, and what are their experiences with it?
- What worries Americans most about the country's illicit drug problems?
- Why do Americans think individuals use illegal drugs?
- What are the public's views on various policy proposals to respond to the nation's drug problems, and what are their implications for the future?

On the final question, the researchers found a paradox: "Most Americans (58 percent) do not see the nation's illegal drug problem getting better after years of increases in national spending, and they see the War on Drugs as having failed thus far (78 percent). Yet, despite this assessment, they continue to support greater resources being expended in generally the same policy direction as has been followed in the past."

They go on to write: "Not only do Americans say that more money should be spent dealing with addiction, they report that they are willing to pay more in taxes (66 percent) to support increased antidrug-related spending."

When choosing among 19 options for reducing the use and effects of illegal drugs, the largest share of strong support is found for more severe penalties for drug sale and possession. The second choice is antidrug education in schools. The third choice is increased funding for police.

A majority of Americans believe drugs are one of the most important causes of crime. Only 14 percent of the public supports legalization of illicit drugs. The researchers write: "The majority of the public (52 percent) believes that drug-related crime would actually increase if drugs were legalized."

But a majority of Americans support legalized use of marijuana for medical purposes: "In early 1997, separate surveys reported that 62 percent and 60 percent of the American public supported a policy where physicians should be able to prescribe marijuana to their seriously and terminally ill patients."

Among other findings of the study:

- Most people rely on mass media for information about the scope of drug abuse in America.
- Although 82 percent of the public thinks illegal drug use is a big problem for society, only 27 percent see it as a major problem in their local communities. Eighty-one percent say drug abuse has never caused problems in their own families.
- Seventy-two percent see drug use as changing the national character; 64 percent of adults describe it as morally wrong.
- Seventy-three percent of adults are very concerned about the possibility of themselves or a family member being the victim of a crime committed by a drug user.
- The majority of Americans believe individuals might begin using illegal drugs because of peer pressure, poor parenting, or because drug dealers are trying to expand their markets.

Illicit drugs lead to approximately 11,000 deaths each year, according to information in the article. Over half a million drug-related episodes are reported in hospital emergency departments. Direct government expenditures linked to illicit drugs total \$27 billion annually.

(JAMA. 1998;279:827-832)<sup>5</sup>

**Note:** This work was supported by the Robert Wood Johnson Foundation.

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## **BOTULINUM TOXIN EFFECTIVE AGAINST EXCESSIVE SWEATING DISORDER**

### **Treatment could offer alternative to surgery**



**JAMA**<sup>®</sup>  
The Journal of the American Medical Association

Medical News & Perspectives - March 19, 1997

## NIH Panel Says More Study Is Needed to Assess Marijuana's Medicinal Use

IN 1988, Paul Palmberg, MD, PhD, was treating a glaucoma patient who did not respond to any of the conventional treatments. So his patient, Elvy Mussika, obtained marijuana from a federal government compassionate use program in hopes that it would lower her intraocular pressure.

Last month, Palmberg told his fellow members of a panel specially convened by the National Institutes of Health (NIH) in Bethesda, Md, that marijuana was the only agent that helped Mussika, who spoke during an activist-sponsored news conference at the meeting. "There may be a residual group of people for whom marijuana is essential. We ought to find out," Palmberg, professor of ophthalmology at the University of Miami School of Medicine in Miami, Fla, told the panel.

After a day and a half of hearing expert testimony and patients' testimonials, panel members said they believe sufficient rationale exists to conduct additional studies on the therapeutic use of marijuana. "For at least some of the potential indications, we feel that it looks promising," said William Beaver, MD, professor of pharmacology and anesthesia at Georgetown University School of Medicine in Washington, DC, and panel moderator.

### Political Issue

Leaders from 10 centers of the NIH organized the 2-day workshop and nonpartisan panel in response to last fall's voter initiatives in California and Arizona that supported medicinal use of marijuana. The initiatives, said National Institute on Drug Abuse Director Alan Leshner, PhD, launched a public debate about which the NIH feels a "strong obligation" to provide information.

Leshner said the NIH is "quite open" to supporting further research on inhaled marijuana. However, activists at the workshop charged that the meeting was little more than a Clinton administration stalling tactic aimed at keeping the 2 new state initiatives in limbo. Steve Michael of ACT UP Washington, an AIDS activist group, called the meeting "a politically motivated dog and pony show."

Activists and patients with various medical conditions that marijuana is reported to benefit--glaucoma, wasting syndrome from human immunodeficiency virus (HIV) infection, multiple sclerosis, and nausea from cancer chemotherapy--gave brief comments during a public comment period. They asked the federal government to expedite marijuana research by moving the drug to schedule II of the Controlled Substances Act from schedule I, which indicates no therapeutic benefit. They also asked that the Investigational New Drug compassionate access program that was closed to new applicants in 1992 be reopened.

**JAMA'**

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"Let [treatment] decisions be made in doctors' offices, not by federal bureaucrats," said Chuck Thomas, communications director of the Marijuana Policy Project in Washington, DC.

A formal report from the panel is expected this month. It will attempt to answer several basic questions concerning research that already has been done, questions that still need to be answered, medical conditions for which marijuana may be beneficial, and special issues in designing clinical trials.

Following testimony by experts in several specialty areas, the panelists said the drug warrants further study in the treatment of AIDS wasting syndrome, glaucoma, neuropathic pain, and nausea from cancer chemotherapy.

## **Appetite Stimulation**

Richard Mattes, PhD, MPH, associate professor of foods and nutrition at Purdue University, West Lafayette, Ind, cited several studies showing that marijuana boosts food consumption. In a study of 131 people, 91% said they ate every time they smoked marijuana, 67% reported eating after smoking even if they weren't hungry, and 64% said smoking marijuana enhanced the sensory appeal of food (*Br J Addict.* 1970;65:347).

Additional studies, Mattes said, show that people using marijuana ate more than those taking a placebo and that marijuana smokers also ate more in social settings with other people than when they were alone. Studies of dronabinol (Marinol, Roxane Laboratories Inc, Columbus, Ohio), the synthesized form of marijuana's active ingredient, Delta<sup>9</sup>-tetrahydrocannabinol (THC), show that the medication does not cause the same enhanced taste sensations that smoking marijuana does, Mattes said.

Even though many of the studies were conducted more than 2 decades ago, said Mattes, it still is not clear how smoked marijuana affects the appetite and food intake. It could be involved in a collapse of the satiety mechanism, he said, which is different from the process that causes hunger.

"Intoxication and subjective sensations contribute to the therapeutic effect in food intake," Mattes said.

The topic is an important one for future research because, as new drug combinations improve survival for people with HIV infection, the proportion of people who have wasting syndrome as an AIDS-defining event is increasing. The proportion is up to 31% in some studies, said Kathleen Mulligan, PhD, assistant professor of medicine at the University of California, San Francisco, School of Medicine.

Mulligan said currently approved medications and investigational therapies such as anabolic hormones and cytokine suppressors have provided "no satisfactory solution" for patients with wasting syndrome. In placebo-controlled studies of megestrol acetate, Mulligan said, patients gain weight, but it is predominantly fat.

Studies of dronabinol show the drug increases appetite, but findings on weight increase are inconsistent, Mulligan said. Dronabinol also is associated with delayed onset of effectiveness, prolonged duration, and patients' complaints of getting "too stoned." Adding dronabinol to megestrol produces no benefit, Mulligan noted.

Questions that further research might answer, Mulligan said, include whether marijuana helps to increase total energy intake in patients with catabolic illnesses, whether snacking increases but consumption of full meals decreases, and what the composition is of weight gained.

## **Nausea From Chemotherapy**

New therapies developed in the last 15 years have substantially improved nausea and vomiting control for cancer patients receiving chemotherapy, Richard Gralla, MD, director of the Ochsner Cancer Institute in New Orleans, La, told the NIH panel.

Gralla said the list of effective antiemetics includes corticosteroids and serotonin antagonists such as the highly effective ondansetron and granisetron. Standards for efficacy have also improved. Gralla said clinicians today "focus on complete control--no vomiting whatsoever." Some patients consider 3 or more chemotherapy-related episodes of nausea to be severe, he said, because emesis can be so well controlled with the newer drugs.

Even so, Gralla called smoked marijuana "a strategy that needs to be investigated," mainly because patients ask about it. He said several studies conducted in the 1970s with small numbers of patients showed dronabinol to be more effective than placebo in the control of nausea and vomiting, so "THC clearly has antiemetic effects." However, in a double-blind randomized study he conducted in the 1980s, Gralla said, metoclopramide hydrochloride was "significantly more effective than dronabinol."

Gralla said the medical literature contains just a single study comparing the efficacy of inhaled marijuana with dronabinol and a cannabinoid-containing placebo as an antiemetic (*Proc 20th Annu Mtg Amer Soc Clin Oncol.* 1984;3:91). The prospective randomized, double-blind comparison--a crossover design trial--of 20 patients showed that only 5 (25%) were free of vomiting and 3 (15%) had no nausea. "The overwhelming number had both vomiting and nausea regardless of whether they got THC or inhaled marijuana," Gralla said. The main end point of the study was patient preference, he said, and the result was that 45% of patients stated no preference, 35% preferred dronabinol, and 20% preferred marijuana.

Because of the recent state initiatives, Gralla said, patients are asking about marijuana, but there currently isn't enough evidence to tell them whether it should be used as a frontline therapy or in conjunction with other drugs. Without further study, he said, lingering questions may never be resolved.

## **What About Glaucoma?**

Currently, manipulation of intraocular pressure is the only effective treatment for glaucoma, said Paul Kaufman, MD, professor of ophthalmology and director of glaucoma services at the University of Wisconsin Medical School, Madison.

Currently used treatments include beta2 adrenergic agonists and antagonists, prostaglandin analogues, and laser surgery. But after reviewing the medical literature, Kaufman said, "there is very little question in my mind that marijuana lowers the intraocular pressure." Kaufman said the original study at the University of California at Los Angeles in the 1970s showed that inhaled marijuana could decrease intraocular pressure by 24%. Other studies have shown decreases of 7 mm Hg to 9 mm Hg, he noted.

But marijuana and orally administered THC were not widely used because the therapeutic effect was not long-lasting. "You would have to pretty much use it around the clock to treat this disease," Kaufman said.

He also expressed concern that marijuana constricts the pupils and causes hyperemia of the conjunctiva. Some reports also indicate that marijuana lowers blood pressure, which could affect optic nerve blood flow. However, during a discussion among panel members, Palmberg said his patient has experienced no change in blood pressure during long-term use. "Acute administration might be different," he said. "It should be studied."

Kaufman also pointed out that many of the drugs now used to treat glaucoma didn't exist when the initial studies on marijuana's effects were done. "It's almost like we have to start all over again to see where the place of marijuana is with all of these other drugs."

## **Movement Disorders and Analgesia**

Marijuana use has been associated with decreased spasticity in multiple sclerosis patients, but the data are scant, said Paul Consroe, PhD, professor of pharmacology and toxicology at the University of Arizona College of Pharmacy in Tucson, Ariz.

Clinical studies contain very small numbers of patients, and findings are conflicting, Consroe said. Some patients experience decreased spasticity and ataxia; others find it difficult to maintain their balance. Dronabinol reduces tremors in some patients but causes overwhelming dysphoria in others.

For conditions such as dystonia, Huntington disease, and Tourette syndrome, Consroe said there are few or no clinical data, but animal studies show potential benefit. However, he said clinical studies, anecdotal evidence, and case studies dating back to the 1800s show that marijuana and oral THC can reduce seizures in patients with epilepsy. Overall, Consroe concluded that more studies are needed. "Show me the money," he said, using the quip popularized by the film *Jerry Maguire*.

Data indicating whether marijuana has analgesic properties also are weak, said Richard Payne, MD, chief of pain and symptoms management at M. D. Anderson Cancer Center in Houston, Tex. "The evidence we have for [producing an analgesic effect] in animal models is confusing," he said.

In some studies using rats, THC was as potent as morphine in delaying the animals' response to a painful stimulus. But in mice THC appeared more effective than morphine in delaying the response. In other studies, however, THC appeared less potent than morphine in both species. In humans, Payne said, the 20-mg dose of THC needed to produce an analgesic effect causes severe adverse effects of delirium and dysphoria.

In rat models of neuropathic pain, cannabinoid analogues decrease hyperalgesia and allodynia and can reverse them, Payne said. In humans, he added, marijuana may have a role in easing neuropathic pain because even though opioids are effective, they are needed at very high doses. Payne said the question of whether smoked marijuana or oral THC has true analgesic properties in doses that don't cause adverse effects remains unanswered.

## **Additional Hurdles**

Questions about how to design clinical trials of smoked marijuana that will produce valid results have dogged researchers for years and continue to do so.

Because of its unique smell when smoked, maintaining blinded studies is difficult at best. Individuals also inhale different amounts during the beginning, middle, and end stages of smoking, and puff volume can differ from one smoking episode to another. Some people simply cannot tolerate smoking, and it presents a risk for pulmonary disease.

For some patients in clinical studies, Beaver suggested that the use of an inhaler or vaporizer would be beneficial. He noted that one of smoked marijuana's most appealing aspects for patients with nausea from cancer chemotherapy is that it doesn't require swallowing a pill.

In addition to the possibility of laying to rest a host of unanswered questions about smoked marijuana's therapeutic properties, members of the NIH panel and experts who testified said further research will be valuable in uncovering basic information about human physiology and disease processes.

Palmberg said additional research into the use of marijuana for glaucoma could reveal whether and to what extent THC receptors are located in the eye. Mulligan pointed out that further study may determine whether continued wasting in patients with AIDS contributes to the disease process independent of opportunistic infections.

To date, Mulligan said, there are no studies to demonstrate that reversal of wasting can improve survival in patients with AIDS.

--by *Rebecca Voelker*

(JAMA. 1997;277:867-868)

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The New England Journal of Medicine -- April 17, 1997 -- Volume 336, Number 16

**CORRESPONDENCE****Medicinal Marijuana?**

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**To the Editor:**

With respect to your editorial on the medicinal use of marijuana (Jan. 30 issue), (<sup>1</sup>) I made it a priority, as the first director of the National Institute on Drug Abuse (1973 to 1978), to investigate the health effects of smoking marijuana and to report on them regularly to the Congress and the public. Particular chemical constituents of smoked marijuana may have medical benefits, but it is unthinkable that in the closing decade of the 20th century, American medicine would return to prescribing smoked leaves for any condition. The history of the past hundred years in medicine has been to identify chemicals that offer benefits for specific problems and then to make those chemicals available in stable, known doses. The proper mechanism for sorting out claims of safety and efficacy was established by the Pure Food and Drug Act in 1906....

Robert L. DuPont, M.D.  
Institute for Behavior and Health  
Rockville, MD 20852

**References**

1. Kassirer JP. Federal foolishness and marijuana. *N Engl J Med* 1997;336:366-7.<sup>8</sup>  
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**To the Editor:**

... The image of smoking marijuana, even for "medicinal" purposes, is inextricably linked to images of illicit drug use in our culture and could send the powerful message to adolescents that marijuana use is OK. Although many adolescents who experiment with marijuana will later stop using illicit drugs, (<sup>1</sup>) a substantial minority will use this drug as a gateway to more serious forms of addiction. (<sup>2</sup>)

Data are not yet available on how the passage of the medical-legalization propositions in California and Arizona have influenced adolescents' perceptions of the harmfulness of marijuana or the likelihood that they will experiment with this drug. In the interim, the debate over medical legalization must consider not only the potential benefit to patients who may obtain relief from their symptoms but also the potential harm to the public at large, including the devastation of the lives of adolescents whose experimentation progresses to serious forms of drug abuse. Should the welfare of the many be compromised in an effort to meet the needs of the very few?

Philip D. Kanof, M.D., Ph.D.  
University of Arizona College of Medicine  
Tucson, AZ 85724

**References**

1. Kandel DB, Raveis VH. Cessation of illicit drug use in young adulthood. Arch Gen Psychiatry 1989;46:109-16.<sup>9</sup>  
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2. Dupre D, Miller NS, Gold MS, et al. Initiation and progression of alcohol, marijuana and cocaine use among adolescent users. Am J Addict 1995;4:43-8.  
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### To the Editor:

You are to be congratulated on your thoughtful editorial on marijuana. Your review of the available scientific evidence is straight to the point; there are no data to support the current proscription of medical marijuana use. Still, I do not foresee a reversal by the attorney general or the secretary of health and human services any time soon. I base this prediction on my belief that emotion and symbolism govern the debate over marijuana, not science.

Drug abuse is an enormous problem in our country. As the parent of two teenagers, I worry about the messages society is sending them. Certainly, I am worried about "street drugs," but I am equally worried about tobacco, alcohol, and a cornucopia of prescription and nonprescription medications that seem to promise a discomfort-free life through pharmaceuticals.

I am not particularly worried about marijuana. In 1995, the American Medical News reported that almost 70 million Americans older than 12 years had tried marijuana at least once. (1<sup>7</sup>) Not all these 70 million lives were ruined. Although I hope my children will not try marijuana, I believe they are likely to lead normal lives even if they do experiment with it.

With all the other drug problems in our society, I am frankly dumbfounded as to why marijuana has become such an important symbol in our national psyche, but it has.

William A. Hensel, M.D.  
Moses Cone Health System  
Greensboro, NC 27401

### References

1. Hearn W. Considering cannabis: does marijuana have medicinal value? Recent developments are reigniting a longstanding debate. American Medical News. October 2, 1995:19, 21-3.  
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### To the Editor:

In the 16th century, Juan de Cardenas, a Spanish physician, wrote, "To seek to tell the virtues and greatness of this holy herb, the ailments which can be cured by it, and have been, the evils from which it has saved thousands would be to go on to infinity... this precious herb [tobacco] is so general a human need not only for the sick but for the healthy." (1<sup>7</sup>) Just as this 16th-century physician cited anecdotal evidence in support of his statement about tobacco, in your editorial, "Federal Foolishness and Marijuana," you advocate the use of marijuana on the basis of anecdotes and the testimony of "thousands of patients." One might reflect on the medical foolishness that might be seen in the future by those looking back at this episode in our history.

Laurence Domino, M.D.  
St. Lawrence Hospital  
Lansing, MI 48915

### References

1. Goodman J. Tobacco in history: the cultures of dependence. New York: Routledge, 1993:44.  
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**To the Editor:**

It is very disturbing to realize that Giovanni Polli (1812 to 1880), the father of laboratory medicine in Italy, was more compassionate 130 years ago than many government authorities today. In 1861 he reported that he had treated a patient with rabies, who eventually died, with "haschisch" and that it provided excellent palliation. He advocated its use in terminally ill patients, (17) saying, "Very often most therapy, or even the entire therapy, is no more than palliative; therefore, the physician who finds a convenient and effective palliative treatment is lucky.... It is obvious that haschisch, which we tried, can always be called on for help as the most benign and sure sedative when there is no hope of a definitive cure."

Romolo M. Dorizzi, M.D.  
Azienda Ospedaliera di Verona  
37124 Verona, Italy

**References**

1. Polli G. Risultato di un esperimento terapeutico dell'haschisch. Ann Univers Med 1861;155:632-7.  
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**To the Editor:**

... It would be incorrect to transfer Schedule 1 agents to Schedule 2, permitting physicians to prescribe them. Physicians would be pressed into a state of continual vigilance with respect to the drug culture. Despite their best efforts, a substantial diversion of medically prescribed agents to the general population for personal use and sale would be unpreventable. A demand for such diversion within families would arise uncontrollably. The corruption of physicians, already a problem, would inevitably increase. The adverse medical and behavioral effects of marijuana as a schedule I agent would create social problems, as well as major problems, hitherto unstudied, in patient care. Medicolegal complications for families, physicians, and the institutions that employ physicians would multiply, and the costs of care would escalate.

Arthur Taub, M.D., Ph.D.  
Yale University School of Medicine  
New Haven, CT 06519

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**To the Editor:**

... Should hospitals waive their no-smoking rules for patients smoking marijuana cigarettes, while cracking down on those who smoke tobacco products?

Marshall E. Deutsch, Ph.D.  
41 Concord Rd.  
Sudbury, MA 01776-2328

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**To the Editor:**

In your fine editorial, you did not point out an ironic contradiction in federal policy. In December the Health Care Financing Administration issued a directive that Medicare beneficiaries in health maintenance organizations (HMOs) are entitled to information from physicians on all options for medically necessary treatments. HMOs are forbidden to "gag" doctors. Yet the attorney general has threatened sanctions and criminal prosecution for a doctor who prescribes marijuana.

David Grant, M.D.  
602 West French Pl.  
San Antonio, TX 78212

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**To the Editor:**

... The recent legislation in California and Arizona is sloppy, irresponsible lawmaking. In California, marijuana can now be recommended for anyone, of any age, for any ailment. In Arizona, all Schedule 1 drugs can be prescribed, without provisions governing quality, dosage control, supervision, or compliance. These drugs are still produced by an unregulated, criminal black market.

James E. Copple, M.Div.  
Community Anti-Drug Coalitions of America  
Alexandria, VA 22306

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**To the Editor:**

Your judgment that proscribing the use of marijuana is hypocritical, given the acceptance of narcotic analgesics for the relief of pain, does not withstand scrutiny. The latter are reproducibly effective for their primary use, to provide analgesia. Their pharmacologic and pharmacodynamic characteristics have been well studied, as have their toxicity and relative merits. I see no reason why marijuana should be exempt from such considerations. The hypocrisy, in my opinion, is in those who dismiss demonstrably effective therapies for nausea, glaucoma, headaches, fatigue, or depression, while neglecting to admit that the preference for marijuana rests on its principal effect, euphoria....

John A. Tilelli, M.D.  
Arnold Palmer Hospital for Children and Women  
Orlando, FL 32806

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**To the Editor:**

As a person with AIDS who has to use medicinal marijuana in my fight to stay alive, I thank you for your support. I do not drink, nor do I use drugs, and I would not use marijuana if I did not have to. There is little hope for me after 16 years of infection with the human immunodeficiency virus (HIV). The medicinal use of marijuana is one of the only things that makes me feel generally better, and it helps me eat.

Gary Allen Johnson  
San Francisco, CA 94123-1861

---

**To the Editor:**

I was the care giver for a dear friend who died of AIDS. In his final months, he asked me to obtain marijuana for his nausea. The marijuana eased his suffering.

But this issue goes beyond marijuana. As my friend's care giver, I had to struggle with his doctor over pain control. My friend was in constant, severe pain, and it was a never-ending battle to convince the doctor to prescribe Demerol (meperidine). There was always much ado over the triplicate forms and the suspicions of government drug regulators. Everyone knew the end was near. Still, I had to battle for every drop of meperidine. The war on drugs has become the war on patients.

Richard Mays, M.A.  
P.O. Box 2764  
Guerneville, CA 95446

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### To the Editor:

You point to largely experiential evidence of the medicinal benefits of marijuana and the apparent absence of serious short-term toxicity. However, a note of caution is warranted. Although it is true that smoking marijuana carries no immediate risk of death, there may be serious adverse effects in the very patients for whom medicinal marijuana is most commonly considered (i.e., those whose immune defenses are already compromised by AIDS or cancer plus chemotherapy). For example, in patients with AIDS, marijuana use has been associated with the development of both fungal and bacterial pneumonias. (1,2) Moreover, among HIV-positive persons, marijuana use has been shown to be a risk factor for rapid progression from HIV infection to AIDS and the acquisition of opportunistic infections or Kaposi's sarcoma, or both. (3)

Cellular studies and studies in animals lend support to these potential health consequences of marijuana. For example, delta-9-tetrahydrocannabinol has been shown to have immunosuppressive effects on macrophages, natural killer cells, and T cells, as well as on the response of mice to opportunistic infection. (4) In our own studies, (5) (and unpublished data) we recovered alveolar macrophages from the lungs of habitual marijuana smokers and found a significant reduction in their ability to kill fungi, bacteria, and tumor cells, as well as a deficiency in their ability to produce protective inflammatory cytokines, such as tumor necrosis factor (alpha).

Donald P. Tashkin, M.D.  
Michael D. Roth, M.D.  
Steven M. Dubinett, M.D.  
UCLA School of Medicine  
Los Angeles, CA 90095-1690

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**Dr. Kassirer replies:**

Let's set the record straight. I recommend that only desperately ill patients be allowed to use marijuana, that only physicians prescribe it, and that the government regulate it. Like some of the writers, I am opposed to the referendums in California and Arizona, and I stated publicly on several occasions that I would have voted against them. My argument for prescribing marijuana for seriously ill patients without requiring further research was based on compassion for these suffering people and on the grounds that short-term use of the agent is virtually harmless. If the only effect in these patients is to produce euphoria, so what? In fact, I did support more research on the effectiveness of marijuana in comparison with available agents, but I made two points: first, that such research is extremely difficult because the outcomes that are evaluated are entirely subjective, and second, that the government -- despite nearly a century of mechanisms for assessing safety and efficacy -- almost never permits clinical research on marijuana.

Reasonable people differ on the possible consequences of my proposal. I disagree that the compassionate provision of marijuana to very sick people would lead to more widespread abuse of marijuana; such abuse is a function of the availability of street drugs, not prescription drugs. There is no comparable epidemic of morphine or meperidine use. Similarly, though putting physicians in charge of prescribing marijuana would increase their burden somewhat, making decisions about who should receive which drugs (and how often) is precisely what doctors do well. It is hard to imagine why malpractice claims and costs would increase if physicians were made responsible for prescribing just one more controlled substance.

It is true that smoking is not a traditional means of delivering a medication, yet inhalers are used for many conditions, and the pulmonary route of absorption is extremely effective for many agents. I am sure that we could find some way of dealing with smoking in hospitals, maybe by allowing patients to use marijuana in other forms.

Finally, I believe that the influence of marijuana on immunity in humans requires far more confirmation. The scattered anecdotal reports of an association of marijuana with aspergillus infections in patients with HIV infection are worrisome, but an association alone does not prove causality. Aspergillus species are also found in the air, the soil, and plant matter such as tobacco. In addition, all the patients in the Journal article who were infected with aspergillus must have been severely immunosuppressed, because they had already had serious infections with other opportunistic organisms. Needless to say, claiming cause and effect in such patients is treacherous.

Jerome P. Kassirer, M.D.

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The New England Journal of Medicine -- January 30, 1997 -- Volume 336, Number 5

**EDITORIAL****Federal Foolishness and Marijuana**

The advanced stages of many illnesses and their treatments are often accompanied by intractable nausea, vomiting, or pain. Thousands of patients with cancer, AIDS, and other diseases report they have obtained striking relief from these devastating symptoms by smoking marijuana. (1<sup>7</sup>) The alleviation of distress can be so striking that some patients and their families have been willing to risk a jail term to obtain or grow the marijuana.

Despite the desperation of these patients, within weeks after voters in Arizona and California approved propositions allowing physicians in their states to prescribe marijuana for medical indications, federal officials, including the President, the secretary of Health and Human Services, and the attorney general sprang into action. At a news conference, Secretary Donna E. Shalala gave an organ recital of the parts of the body that she asserted could be harmed by marijuana and warned of the evils of its spreading use. Attorney General Janet Reno announced that physicians in any state who prescribed the drug could lose the privilege of writing prescriptions, be excluded from Medicare and Medicaid reimbursement, and even be prosecuted for a federal crime. General Barry R. McCaffrey, director of the Office of National Drug Control Policy, reiterated his agency's position that marijuana is a dangerous drug and implied that voters in Arizona and California had been duped into voting for these propositions. He indicated that it is always possible to study the effects of any drug, including marijuana, but that the use of marijuana by seriously ill patients would require, at the least, scientifically valid research.

I believe that a federal policy that prohibits physicians from alleviating suffering by prescribing marijuana for seriously ill patients is misguided, heavy-handed, and inhumane. Marijuana may have long-term adverse effects and its use may presage serious addictions, but neither long-term side effects nor addiction is a relevant issue in such patients. It is also hypocritical to forbid physicians to prescribe marijuana while permitting them to use morphine and meperidine to relieve extreme dyspnea and pain. With both these drugs the difference between the dose that relieves symptoms and the dose that hastens death is very narrow; by contrast, there is no risk of death from smoking marijuana. To demand evidence of therapeutic efficacy is equally hypocritical. The noxious sensations that patients experience are extremely difficult to quantify in controlled experiments. What really counts for a therapy with this kind of safety margin is whether a seriously ill patient feels relief as a result of the intervention, not whether a controlled trial "proves" its efficacy.

Paradoxically, dronabinol, a drug that contains one of the active ingredients in marijuana (tetrahydrocannabinol), has been available by prescription for more than a decade. But it is difficult to titrate the therapeutic dose of this drug, and it is not widely prescribed. By contrast, smoking marijuana produces a rapid increase in the blood level of the active ingredients and is thus more likely to be therapeutic. Needless to say, new drugs such as those that inhibit the nausea associated with chemotherapy may well be more beneficial than smoking marijuana, but their comparative efficacy has never been studied.

Whatever their reasons, federal officials are out of step with the public. Dozens of states have passed laws that ease restrictions on the prescribing of marijuana by physicians, and polls consistently show that the public favors the use of marijuana for such purposes. (1<sup>7</sup>) Federal

authorities should rescind their prohibition of the medicinal use of marijuana for seriously ill patients and allow physicians to decide which patients to treat. The government should change marijuana's status from that of a Schedule 1 drug (considered to be potentially addictive and with no current medical use) to that of a Schedule 2 drug (potentially addictive but with some accepted medical use) and regulate it accordingly. To ensure its proper distribution and use, the government could declare itself the only agency sanctioned to provide the marijuana. I believe that such a change in policy would have no adverse effects. The argument that it would be a signal to the young that "marijuana is OK" is, I believe, specious.

This proposal is not new. In 1986, after years of legal wrangling, the Drug Enforcement Administration (DEA) held extensive hearings on the transfer of marijuana to Schedule 2. In 1988, the DEA's own administrative-law judge concluded, "It would be unreasonable, arbitrary, and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record." (17) Nonetheless, the DEA overruled the judge's order to transfer marijuana to Schedule 2, and in 1992 it issued a final rejection of all requests for reclassification. (27)

Some physicians will have the courage to challenge the continued proscription of marijuana for the sick. Eventually, their actions will force the courts to adjudicate between the rights of those at death's door and the absolute power of bureaucrats whose decisions are based more on reflexive ideology and political correctness than on compassion.

Jerome P. Kassirer, M.D.

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The New England Journal of Medicine -- September 7, 1995 -- Volume 333, Number 10  
**CORRESPONDENCE**

## Marijuana, the AIDS Wasting Syndrome, and the U.S. Government

### To the Editor:

Evidence of the therapeutic value and limited toxicity of marijuana in the treatment of various symptoms and syndromes is rapidly accumulating. Patients with glaucoma, migraine, epilepsy, multiple sclerosis, paraplegia, quadriplegia, the AIDS wasting syndrome, or nausea and vomiting due to chemotherapy for cancer have risked severe penalties to acquire cannabis, because they find it more useful than legally available medicines. (1<sup>7</sup>,2<sup>7</sup>) The U.S. government has consistently refused to permit prescription sales of marijuana, insisting that the evidence of its safety and efficacy is inadequate.

In response to a lawsuit brought by advocates of the medical use of marijuana, an administrative law judge with the Drug Enforcement Administration (DEA) recommended in 1988 that the federal legal classification of marijuana be changed so that physicians can prescribe it. (3<sup>7</sup>) The DEA did not implement the recommendation. In 1992, Richard Bonner, then DEA administrator, offered this suggestion: "Those who insist that marihuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money, and rhetoric into lobbying, public relations campaigns, and perennial litigation." (4<sup>7</sup>)

Encouraged by this declaration, Donald Abrams, of the University of California, San Francisco, sought permission to conduct a privately financed pilot study comparing three potencies of inhaled marijuana (high, medium, and low) with oral delta-9-tetrahydrocannabinol (dronabinol) capsules, which are available by prescription in the United States, for the treatment of weight loss associated with the AIDS wasting syndrome. Dr. Abrams's protocol (Investigational New Drug No. 43,542) was designed in consultation with the Food and Drug Administration (FDA) and approved by the FDA, the University of California, San Francisco, institutional review board, the California Research Advisory Panel, and the scientific advisory committee of the San Francisco Community Consortium.

Unfortunately, the U.S. government will not allow Dr. Abrams to obtain a legal supply of marijuana. The DEA refused to permit him to import marijuana from Hortapharm, a company licensed by the government of the Netherlands to cultivate cannabis for botanical and pharmaceutical research. The National Institute on Drug Abuse (NIDA), which controls the domestic supply of marijuana for clinical research, rejected Dr. Abrams's request in April 1995. The letter of rejection, from NIDA director Alan I. Leshner, was sent nine months after Dr. Abrams had submitted his request.

Given the limited sources of support for research on marijuana (pharmaceutical companies, for example, are not interested in supporting such research), the U.S. government by now should have taken note of the increasingly persuasive therapeutic claims and sponsored its own clinical trials through the National Institutes of Health. Instead, as Dr. Bonner's remark and the handling of Dr. Abrams's protocol indicate, the government has responded by urging others to investigate the medical potential of marijuana and then creating obstacles that make the research impossible to pursue.

Lester Grinspoon, M.D.  
James B. Bakalar  
Harvard Medical School  
Boston, MA 02115

Rick Doblin  
John F. Kennedy School of Government  
Cambridge, MA 02138

## References

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2. Grinspoon L, Bakalar JB. Marihuana as medicine: a plea for reconsideration. JAMA 1995;273:1875-6.<sup>8</sup>

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3. Young FL. Opinion and recommended ruling, marijuana rescheduling petition. Department of Justice, Drug Enforcement Administration. Docket 86-22. Washington, D.C.: Drug Enforcement Administration, September 1988.

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Editor's note: Drs. Leshner and Abrams were offered the opportunity to respond. Dr. Leshner declined to do so. Dr. Abrams's reply follows.

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## To the Editor:

The San Francisco Community Consortium is an association of providers of care for patients infected with the human immunodeficiency virus (HIV) in the San Francisco Bay area. The consortium conducts community-based clinical trials of therapies of potential benefit to our patients. Inhaled marijuana is being used increasingly by people with HIV infection, especially for its purported benefit as an antiemetic agent and an appetite stimulant in those with the AIDS wasting syndrome. Up to 2000 people infected with HIV are reported to be obtaining marijuana at a cannabis buyer's club in our area. The California State Assembly has recently endorsed legislation to make medicinal marijuana available to patients with life-threatening illnesses.

In an effort to determine whether inhaled marijuana is truly of any potential benefit and, more important, to evaluate its safety in people with AIDS, the Community Consortium designed a pilot study. We thought it would be appropriate to conduct a small study of the overall feasibility of investigating inhaled marijuana use by such patients, before embarking on a full-scale trial of its efficacy. The pilot-drug-evaluation staff at the FDA provided valuable comments on the design of the protocol. Pulmonary-function tests, lymphocyte-subgroup analyses, and measurements of viral burden by the branched-DNA technique were to be performed serially for safety. Body composition was to be measured by state-of-the-art techniques to assess potential trends in the amelioration of wasting.

The FDA and the institutional review board supported the study. Unfortunately, the DEA and the NIDA opposed it. Most disturbing was the absence of a response from either agency for an unacceptably long period, followed by the NIDA's outright rejection of the proposal without any opportunity for dialogue or compromise. Such behavior is offensive not only to the investigators but to the patients for whom we seek to find safe and effective treatments.

Donald I. Abrams, M.D.  
Carroll C. Child, R.N., M.S.  
Thomas F. Mitchell, M.P.H.  
University of California, San Francisco  
San Francisco, CA 94143

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**The New England Journal of Medicine -- January 26, 1995 -- Volume 332, Number 4****CORRESPONDENCE**

## Marihuana and Its Reviews

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**To the Editor:**

Dr. Robert Swift (Sept. 15 issue) (1<sup>7</sup>) gives a very supportive account of Grinspoon and Bakalar's book *Marihuana: The Forbidden Medicine*. (2<sup>7</sup>) Swift considers the book to present "cogent and convincing arguments for the legalization of marijuana."

As I pointed out in my review of the book in the *Annals of Internal Medicine*, (3<sup>7</sup>) Grinspoon and Bakalar have only assembled anecdotes that they use to justify the rescheduling of marijuana. Like the members of the pro-marijuana lobby during hearings held by the Drug Enforcement Agency to consider rescheduling marijuana, these authors believe that marijuana should be used to treat nausea associated with cancer chemotherapy, glaucoma, wasting in AIDS, depression, menstrual cramps, pain, and virtually limitless ailments. (3<sup>7</sup>) In their anecdotes there are no controls, no standardization of the dose, no quality control, and no independent medical evaluation for efficacy or toxicity.

According to Grinspoon and Bakalar, the Chinese used marijuana to "quicken the mind, induce sleep, cure dysentery, stimulate appetite, relieve headaches, and cure venereal disease." One of the references from 1860 states purported beneficial effects "without interfering with the actions of the internal organs" (a statement known to be inaccurate). Potions and remedies were common in those earlier years. Many were absolutely useless, or conversely were harmful to unsuspecting subjects.

The medical issue surrounding the smoking of marijuana can best be summarized by an opinion from Dr. Philip Lee in a letter to Congress after the "medical marijuana" issue was submitted to the National Institutes of Health. He states,

Scientists at the National Institutes of Health indicate that, after carefully examining the existing preclinical and human data, there is no evidence to suggest that smoked marijuana might be superior to currently available therapies for glaucoma, weight loss associated with AIDS, nausea and vomiting associated with cancer chemotherapy, muscle spasticity associated with multiple sclerosis, or intractable pain. (4<sup>7</sup>)

We do not smoke medicine anywhere in our society. We should turn to truly medical solutions to solve our medical problems.

Eric A. Voth, M.D.  
International Drug Strategy Institute  
Topeka, KS 66606

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## Dr. Swift replies:

### To the Editor:

It is amazing to me how strong the emotions are that always emerge with regard to issues of drug legalization. Dr. Voth certainly conveys his strong negative feelings about the medical use of marijuana and its biologically active components. He takes issue with my review of *Marihuana: The Forbidden Medicine*, which he sees as giving "a very supportive account" of the book. Obviously, he has not been convinced by the arguments of Dr. Grinspoon and Mr. Bakalar. I respect Dr. Voth's opinions, as I respect those of Grinspoon and Bakalar. However, I am concerned that opinions like Dr. Voth's about drug legalization are clouding rational, scientific thinking on this issue of the therapeutic value of marijuana and its components.

I agree with Dr. Voth that some of the evidence presented in support of the medical use of marijuana and its components is anecdotal, with "no controls, no standardization of dose, no quality control, and no independent medical evaluation for efficacy or toxicity." Grinspoon and Bakalar point out that this situation has occurred because of the strict controls on marijuana research, which have prevented an objective evaluation of the drug in controlled clinical trials.

The one analogue of tetrahydrocannabinol that is approved and marketed as a pharmaceutical agent, dronabinol, has well-documented antiemetic, analgesic, and appetite-stimulating properties. Yet, despite the availability of this legal agent, a substantial proportion of patients with cancer use illicit marijuana as part of their treatment, and almost half of the oncologists surveyed support this use of marijuana for their patients. (1<sup>7</sup>) So it seems that at least some patients do "smoke medicine" in our society. As clinicians and scientists, we should endeavor to find out why this is the case.

Our goal should be to provide the best treatment for our patients. I agree with Dr. Voth that therapeutic decisions should be made on an objective, medical basis. I also agree with Grinspoon and Bakalar that policy decisions, rather than objective medical decisions, have controlled research on the therapeutic use of marijuana and its components.

Robert M. Swift, M.D., Ph.D.  
Brown University  
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Providence, RI 02912

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American Journal of Public Health, March 1996, Vol. 86<sup>#3</sup> pp. 441-442  
(endorsement of medical marijuana); Journal of Clinical Oncology  
Vol. 9 #7, July 1991 pp. 1314-19) (marijuana as an anti-emetic medicine)

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## Editorials

## FEDERAL FOOLISHNESS AND MARIJUANA

THE advanced stages of many illnesses and their treatments are often accompanied by intractable nausea, vomiting, or pain. Thousands of patients with cancer, AIDS, and other diseases report they have obtained striking relief from these devastating symptoms by smoking marijuana.<sup>1</sup> The alleviation of distress can be so striking that some patients and their families have been willing to risk a jail term to obtain or grow the marijuana.

Despite the desperation of these patients, within weeks after voters in Arizona and California approved propositions allowing physicians in their states to prescribe marijuana for medical indications, federal officials, including the President, the secretary of Health and Human Services, and the attorney general sprang into action. At a news conference, Secretary Donna E. Shalala gave an organ recital of the parts of the body that she asserted could be harmed by marijuana and warned of the evils of its spreading use. Attorney General Janet Reno announced that physicians in any state who prescribed the drug could lose the privilege of writing prescriptions, be excluded from Medicare and Medicaid reimbursement, and even be prosecuted for a federal crime. General Barry R. McCaffrey, director of the Office of National Drug Control Policy, reiterated his agency's position that marijuana is a dangerous drug and implied that voters in Arizona and California had been duped into voting for these propositions. He indicated that it is always possible to study the effects of any drug, including marijuana, but that the use of marijuana by seriously ill patients would require, at the least, scientifically valid research.

I believe that a federal policy that prohibits physicians from alleviating suffering by prescribing marijuana for seriously ill patients is misguided, heavy-handed, and inhumane. Marijuana may have long-term adverse effects and its use may presage serious addictions, but neither long-term side effects nor addiction is a relevant issue in such patients. It is also hypocritical to forbid physicians to prescribe marijuana while permitting them to use morphine and meperidine to relieve extreme dyspnea and pain. With both these drugs the difference between the dose that relieves symptoms and the dose that hastens death is very narrow; by contrast, there is no risk of death from smoking marijuana. To demand evidence of therapeutic efficacy is equally hypocritical. The noxious sensations that patients experience

are extremely difficult to quantify in controlled experiments. What really counts for a therapy with this kind of safety margin is whether a seriously ill patient feels relief as a result of the intervention, not whether a controlled trial "proves" its efficacy.

Paradoxically, dronabinol, a drug that contains one of the active ingredients in marijuana (tetrahydrocannabinol), has been available by prescription for more than a decade. But it is difficult to titrate the therapeutic dose of this drug, and it is not widely prescribed. By contrast, smoking marijuana produces a rapid increase in the blood level of the active ingredients and is thus more likely to be therapeutic. Needless to say, new drugs such as those that inhibit the nausea associated with chemotherapy may well be more beneficial than smoking marijuana, but their comparative efficacy has never been studied.

Whatever their reasons, federal officials are out of step with the public. Dozens of states have passed laws that ease restrictions on the prescribing of marijuana by physicians, and polls consistently show that the public favors the use of marijuana for such purposes.<sup>1</sup> Federal authorities should rescind their prohibition of the medicinal use of marijuana for seriously ill patients and allow physicians to decide which patients to treat. The government should change marijuana's status from that of a Schedule 1 drug (considered to be potentially addictive and with no current medical use) to that of a Schedule 2 drug (potentially addictive but with some accepted medical use) and regulate it accordingly. To ensure its proper distribution and use, the government could declare itself the only agency sanctioned to provide the marijuana. I believe that such a change in policy would have no adverse effects. The argument that it would be a signal to the young that "marijuana is OK" is, I believe, specious.

This proposal is not new. In 1986, after years of legal wrangling, the Drug Enforcement Administration (DEA) held extensive hearings on the transfer of marijuana to Schedule 2. In 1988, the DEA's own administrative-law judge concluded, "It would be unreasonable, arbitrary, and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record."<sup>1</sup> Nonetheless, the DEA overruled the judge's order to transfer marijuana to Schedule 2, and in 1992 it issued a final rejection of all requests for reclassification.<sup>2</sup>

Some physicians will have the courage to challenge the continued proscription of marijuana for the sick. Eventually, their actions will force the courts to adjudicate between the rights of those at death's door and the absolute power of bureaucrats whose decisions are based more on reflexive ideology and political correctness than on compassion.

JEROME P. KASSIRER, M.D.

## Reefer Madness -- The Federal Response to California's Medical-Marijuana Law

George J. Annas

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Marijuana is unique among illegal drugs in its political symbolism, its safety, and its wide use. More than 65 million Americans have tried marijuana, the use of which is not associated with increased mortality. (1) Since the federal government first tried to tax it out of existence in 1937, at least partly in response to the 1936 film *Reefer Madness*, marijuana has remained at the center of controversy. Now physicians are becoming more actively involved. Most recently, the federal drug policy against any use of marijuana has been challenged by California's attempt to legalize its use by certain patients on the recommendation of their physicians. The federal government responded by threatening California physicians who recommend marijuana to their sick patients with investigation and the loss of their prescription privileges under Drug Enforcement Administration (DEA) regulations. (2)

The editor-in-chief of the Journal suggested that prohibiting physicians from helping their suffering patients by suggesting that they use marijuana is "misguided, heavy-handed, and inhumane." (3) He recommended that marijuana be reclassified as a Schedule II drug and made available by prescription without the usual requirement of controlled clinical trials. Many states, including Massachusetts, had previously passed laws that permitted their citizens to use marijuana for medicinal purposes under some circumstances. (4) California's law seems to have engendered a uniquely harsh federal response because California is a large, trend-setting state; because its new marijuana law is very broad as compared with others; and because the law was passed by popular referendum. In this article I will discuss the new California law and its implications for physicians.

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### The California Proposition

In the fall of 1996, California voters approved the Medical Marijuana Initiative (Proposition 215) by a vote of 56 to 44 percent. The act is entitled the Compassionate Use Act of 1996, and its purpose is to give Californians the right to possess and cultivate marijuana for medical purposes "where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief." (5) Nothing in the act permits persons using marijuana for medical purposes to engage in conduct that endangers others (such as driving while under its influence), condones "the diversion of marijuana for nonmedical purposes," or permits the buying or selling of marijuana. (5) The two operative sections of the law are as follows:

Notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes.

[Existing California law] relating to the possession of marijuana [and the] cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver [the person who has consistently assumed responsibility for the patient's housing, health, or safety] who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician. (5)

The primary purpose of this law is to provide a specified group of patients with an affirmative defense to the charge of possession or cultivation of marijuana, the defense of medical necessity. To use this defense, the patient must be able to show that his or her physician recommended or

approved of the use of marijuana, either orally or in writing. Obviously, a note from a physician is better evidence than a simple assertion that "my doctor said this would be good for me," and most patients will want a written statement to help protect them from problems with the police. Nothing in this law changes current law against buying or selling marijuana or affects federal law; it merely provides that qualified patients and their primary care givers can possess and cultivate their own marijuana for personal medicinal purposes, without violating state drug laws.

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## Compassion and the Use of Unapproved Drugs

The federal government has been in the business of regulating drugs for almost a century, and few exceptions have ever been made to the basic rules of the Food and Drug Administration (FDA), even for patients with cancer or AIDS. In 1979, for example, the FDA was successful in convincing a unanimous U.S. Supreme Court that Congress intended no exception for terminally ill patients who sought to take laetrile, an unapproved drug, for cancer. The FDA's primary rationale was that the use of this unapproved and useless drug could prevent patients from seeking conventional treatments for cancer that offered them at least some chance of a cure. (6) Under President Ronald Reagan, however, the FDA responded with a great deal more flexibility to the AIDS epidemic and permitted the use and sale of drugs not yet approved (but in use in ongoing clinical trials) if, among other things, "the drug [was] intended to treat a serious or immediately life-threatening disease." (7) More surprisingly, the FDA also permitted individual patients to import unapproved drugs from other countries for their personal, medical use. (8) These regulations were almost purely political, had no scientific basis, and tended to conflate treatment and research and to undermine the very purpose of clinical trials. (8) The theory used to justify these exceptions to federal drug laws was the very one rejected by the Supreme Court: terminally ill patients have "nothing to lose" and should not be deprived of the hope (even the false hope) that they might escape death. (6,8)

Given this history, it is not surprising that the advocates of the medicinal use of marijuana concentrate their reform efforts on helping patients with cancer ameliorate the adverse effects of chemotherapy and helping patients with AIDS counteract weight loss and fight their disease. Virtually no one thinks it is reasonable to initiate criminal prosecution of patients with cancer or AIDS who use marijuana on the advice of their physicians to help them through conventional medical treatment for their disease. Anecdotal evidence of the effectiveness of smoked marijuana abounds. (9) Perhaps the most convincing is the account of Harvard professor and author Stephen Jay Gould, one of the world's first survivors of abdominal mesothelioma. When Gould started intravenous chemotherapy, he writes:

Absolutely nothing in the available arsenal of anti-emetics worked at all. I was miserable and came to dread the frequent treatments with an almost perverse intensity. I had heard that marijuana 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 marijuana twice [in the 1960s]... and had hated it.... Marijuana worked like a charm.... The 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, and surely the most important effect upon my eventual cure. (10)

Similarly, in patients with AIDS, marijuana has been credited with counteracting such side effects of treatment as severe nausea, vomiting, loss of appetite, and fatigue, as well as with stimulating the appetite to help prevent weight loss.

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## The White House Press Conference

Had the California proposition been limited to the use of marijuana for terminal illnesses such as cancer and AIDS, it would probably have caused much less concern. Arizona passed a much broader initiative that permitted physicians to prescribe any drug on Schedule I, but in April 1997, the Arizona legislature amended the law to apply only to drugs approved by the FDA, thus

effectively repealing it. (11) The California law applies only to marijuana but makes it available for a wide range of medical conditions, including anorexia, pain, spasticity, glaucoma, arthritis, migraine, "or any other illness for which marijuana provides relief." (5) This very broad definition of the potential medicinal uses of marijuana seemed an explicit endorsement of the drug itself, which the Clinton administration and others believed to be sending the wrong message to America's youth. After thinking about the issue for approximately two months, the Clinton administration announced that it would vigorously oppose the implementation of the California proposition and the Arizona law. (2)

Barry McCaffrey, director of the Office of National Drug Control Policy, announced at a White House news conference on December 30, 1996, that "nothing has changed. Federal law is unaffected by these propositions." (2) McCaffrey expressed concern about marijuana as a "gateway drug" and about the potential impact of the law on children. As for the potential medicinal uses of marijuana, he said:

This is not a medical proposition. This is the legalization of drugs that we're concerned about. Here's what the medical advisor in the state of California saw as the potential uses of marijuana. [Here McCaffrey showed a slide.]... It includes recalling forgotten memories, cough suppressants, Parkinson's disease, writer's cramp. This is not medicine. This is a Cheech and Chong show. And now what we are committed to doing is to look in a scientific way at any proposition that would bring a new medicine to the assistance of the American medical establishment. (2)

Secretary of Health and Human Services Donna Shalala said that the initiatives reinforced the growing belief among Americans that marijuana is not harmful, whereas the administration remained "opposed to the legalization of marijuana [because] all available research has concluded that marijuana is dangerous to our health." (2) Nonetheless, she did say that the National Institutes of Health (NIH) would continue to support and review "peer-reviewed" and "scientifically valid" research on "the possible usefulness of smoked marijuana in the limited circumstances where available medications have failed to provide relief for individual patients." (2)

Finally, Attorney General Janet Reno announced that physicians who followed the terms of the California law would be the new targets of federal law enforcement (instead of drug dealers) and threatened physicians with loss of their registrations with the DEA and with exclusion from participation in Medicare and Medicaid. She stated:

Federal law still applies.... U.S. attorneys in both states will continue to review 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 controlled substances. We will not turn a blind eye toward our responsibility to enforce federal law and to preserve the integrity of medical and scientific process to determine if drugs have medical value before allowing them to be used. (2)

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## **Doctor-Patient Conversations**

Two basic issues are raised by the administration's position. One involves government regulation of doctor-patient conversations, and the other the quality of evidence necessary to make marijuana available by prescription. A group of California physicians filed suit against McCaffrey, Reno, and Shalala, arguing that the threats of prosecution against physicians for talking to their patients violate their First Amendment rights and interfere with their ability as physicians to use "their best medical judgment in the context of a bona fide physician-patient relationship." (12)

In the only comparable case to reach the U.S. Supreme Court, the Court narrowly upheld a gag rule related to discussing abortion in a federally funded Title X family-planning clinic. (13) The Court upheld the gag rule because Congress could reasonably limit the types of medical services available at a federally funded facility. (14) The Court was able to sidestep the First Amendment issue because patients (at least in theory) had access to other doctors who had an obligation to furnish

them with full information, and the doctor-patient relationship in a Title X clinic was characterized as not "all-encompassing" but, rather, as limited only to preconception counseling:

The Title X program regulations do not significantly impinge upon the doctor-patient relationship. Nothing in them requires a doctor to represent as [his or her] own any opinion that [he or she] does not in fact hold. Nor is the doctor-patient relationship established by expectation on the part of the patient of comprehensive medical advice. The program does not provide post-conception medical care, and therefore a doctor's silence with regard to abortion cannot reasonably be thought to mislead a client into thinking that the doctor does not consider abortion an appropriate option for her. (13)

Even if one accepts this unconvincing rationale, it is impossible to apply it to California physicians who believe that marijuana would be beneficial for their patients and who are providing their overall health care. Patients receiving care for cancer or AIDS rightfully and reasonably expect and are entitled to full disclosure and discussion of available treatment options. The California physicians are on strong legal ground with their lawsuit, and they should prevail. In early April, U.S. District Court judge Fern M. Smith granted a preliminary injunction prohibiting the DEA from carrying out its threats against California physicians and encouraged the litigants to try to work out a settlement of the dispute. (15)

In response to the lawsuit and the growing opposition to its threats to physicians, the administration issued a clarifying letter, essentially stating that physicians may discuss marijuana with their patients so long as they do not recommend its use. (16) This provides no guidance at all. Of course doctors can talk to patients; the question is what they can tell them. The real subject of dispute remains whether physicians can "recommend" marijuana (and thereby grant their patients immunity from state prosecution), as the California proposition provides. Would, for example, telling a patient with cancer that other physicians have reported that marijuana has given their patients relief from nausea constitute a "recommendation"?

Judge Smith made it clear that the First Amendment protects physician-patient communications and that the government has no authority to determine the content of physicians' speech. (15) She also concluded that the federal statements regarding threatened prosecution were vague and thus could lead to physicians' censoring their own speech to avoid possible federal prosecution. On the other hand, she noted (correctly) that the First Amendment does not protect "speech that is itself criminal because [the speech is] too intertwined with illegal activity." (15) Under federal drug laws, which cannot be affected by legislation in California, it remains a crime for physicians to aid, abet, or conspire -- by speech or action -- to violate federal criminal statutes. Thus, it is not a violation of the First Amendment for the federal government to prosecute or threaten to prosecute physicians who specifically intend to aid, abet, or conspire with their patients to violate federal drug laws.

Judge Smith could have added that to prevail in such a case the government will have to prove more than simply that the physician recommended marijuana as worth trying for a medical condition. The "more" will include evidence that the physician "associated himself with the venture" of illegally purchasing marijuana "as something he wished to bring about and sought by his actions to make succeed." (17) This should require at least that the physician identify a source of the marijuana, and some connection between that source and the physician. (18) It is only speech short of this that the injunction covers. Of course, this formulation still leaves it uncertain exactly how far physicians may go in recommending marijuana use before the federal government is justified in prosecuting them for criminal behavior. Judge Smith concluded with an understatement: "This injunction does not provide physicians with the level of certainty for which they had hoped." (15)

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## **Marijuana as Medicine**

Attempts to have marijuana reassigned from Schedule I to Schedule II began almost immediately after Congress passed the Uniform Controlled Substances Act of 1970, which established the current system of drug classification. The following findings must be made to place a drug on Schedule I: "(A) The drug... has a high potential for abuse; (B) The drug... has no currently

accepted medical use in treatment in the United States; and (C) there is a lack of accepted safety for use of the drug under medical supervision." Part A for Schedule II drugs is identical; the other requirements are "(B) The drug... has a currently accepted medical use in treatment in the United States... and (C) Abuse of the drug... may lead to severe psychological or physical dependence."

In 1988, after two years of hearings, DEA administrative-law judge Francis Young recommended shifting marijuana to Schedule II on the grounds that it was safe and had a "currently accepted medical use in treatment." (19) Specifically, Judge Young found that "marijuana, in its natural form, is one of the safest therapeutically active substances known to man.... At present it is estimated that marijuana's LD-50 [median lethal dose] is around 1:20,000 or 1:40,000. In layman's terms... a smoker would theoretically have to consume 20,000 to 40,000 times as much marijuana as is contained in one marijuana cigarette... nearly 1500 pounds of marijuana within about fifteen minutes to induce a lethal response." As for medical use, the judge concluded, among other things, that marijuana "has a currently accepted medical use in treatment in the United States for nausea and vomiting resulting from chemotherapy treatments." (19) The administrator of the DEA rejected Young's recommendation, on the basis that there was no scientific evidence showing that marijuana was better than other approved drugs for any specific medical condition. Further attempts to get the courts to reclassify marijuana have been unsuccessful.

Reacting to a DEA suggestion that only a "fringe group" of oncologists accepted marijuana as an antiemetic agent, a survey of a random sample of the members of the American Society of Clinical Oncology was undertaken in 1990. (20) More than 1000 oncologists responded to the survey, and 44 percent of them reported that they had recommended marijuana to at least one patient. (20) Marijuana was believed to be more effective than oral dronabinol (Marinol) by the respondents: of those who believed they had sufficient information to compare the two drugs directly, 44 percent believed marijuana was more effective, and only 13 percent believed dronabinol was more effective. (20) Of course, nothing in the FDA regulations requires a drug to be more effective than an existing one for it to be approved. Nonetheless, in the current anti-marijuana climate, the NIH has consistently refused to fund research on marijuana. In the wake of the California proposition, this position is no longer tenable.

An NIH panel, after a two-day workshop in February, recommended research on marijuana in the areas of wasting associated with AIDS, nausea due to cancer chemotherapy, glaucoma, and neuropathic pain. (21) This list seems reasonable, especially since objective criteria such as weight gain, intraocular pressure, and the frequency of vomiting can be used to determine the drug's effectiveness.

Such research may be difficult to do, but it is possible to compare orally administered dronabinol with smoked marijuana. Some argue that because the symptoms of nausea are so subjective and "extremely difficult to quantify in controlled experiments," marijuana should be available as a prescription drug on a compassionate basis. (3) In fact, current FDA regulations provide the authority for making marijuana available on a compassionate basis while such studies are proceeding. Other support for its compassionate use would appear to come from the Clinton administration's solicitor general, Walter Dellinger, who argued before the Supreme Court less than two weeks after the McCaffrey-Reno press conference that the administration believed that Americans had a weak constitutional right "not to suffer." Although Dellinger said he did not believe this right was broad enough to prohibit the states from making physician-assisted suicide for terminally ill patients a crime, it should certainly be broad enough to prohibit the federal government from denying patients with cancer and AIDS access to drugs that could help them withstand potentially life-saving treatments.

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## What About the Children?

The final argument that the administration makes against any medical use of marijuana is that this would send the "wrong message" to children, who would then use this "gateway drug" and get hooked on much more harmful substances, such as cocaine and heroin. There are two responses to this argument. The first is provided by Boston Globe columnist Ellen Goodman, who asks, "What

is the infamous signal being sent to [children]?... If you hurry up and get cancer, you, too, can get high?" (22)

The second response relates to the "gateway" issue itself. A 1994 survey found that 17 percent of current marijuana users said they had tried cocaine and only 0.2 percent of those who had not used marijuana had tried cocaine. (23) One way to interpret these data is that children who smoke marijuana are 85 times as likely as others to try cocaine; another is that 83 percent of pot smokers, or five out of six, never try cocaine. (23) Honesty is likely to make a greater and more lasting impression on our children than political posturing and hysteria. Many people want to make marijuana legal for everyone. But opposition to the legalization of marijuana generally is not a good reason to keep it from patients who are suffering. Making marijuana a Schedule II drug does not make it widely acceptable or available any more than classifying medicinal cocaine as a Schedule II drug made it acceptable or available.

## Conclusions

Doctors are not the enemy in the "war" on drugs; ignorance and hypocrisy are. Research should go on, and while it does, marijuana should be available to all patients who need it to help them undergo treatment for life-threatening illnesses. There is certainly sufficient evidence to reclassify marijuana as a Schedule II drug. Unlike quack remedies such as laetrile, marijuana is not claimed to be a treatment in itself; instead, it is used to help patients withstand the effect of accepted treatment that can lead to a cure or amelioration of their condition. As long as a therapy is safe and has not been proved ineffective, seriously ill patients (and their physicians) should have access to whatever they need to fight for their lives.

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## Dangerous habits

3 years ago, a *Lancet* editorial began, "The smoking of cannabis, even long term, is not harmful to health" (Nov 11, 1995); an assertion criticised by many readers as encouraging an indulgence that is illegal in many countries. Predictably, the legalise-cannabis lobby seized on *The Lancet*'s apparent endorsement of this substance's safety. This week we publish a seminar on the adverse effects of cannabis (p 1611). Wayne Hall and Nadia Solowij conclude that the most likely adverse effects of smoking cannabis are bronchial irritation, the risk of accidents when intoxicated, dependence, and possible cognitive impairment with heavy, long-term use. The evidence summarised in this seminar was considered by a committee of the UK House of Lords which reported on Nov 11. The committee recommended that clinical trials be done on the effects of cannabis in multiple sclerosis and in chronic pain, and that the UK Government should reclassify cannabis so that it can be prescribed by doctors under certain circumstances.

The debate about whether or not cannabis, taken for recreational rather than medical reasons, should be legalised in countries where it is banned will rumble on, and further complicate scientific assessment of the therapeutic effects of cannabinoids. The arguments advanced by each side are well-rehearsed, but usually fail to consider the problems presented by cannabis in a wider perspective. We would, perhaps, have been wiser to have begun our editorial 3 years ago with a less provocative statement; but, on the evidence summarised by Hall and Solowij, it would be reasonable to judge cannabis less of a threat to health than alcohol or tobacco, products that in many countries are not only tolerated and advertised but are also a useful source of tax revenue. The desire to take mood-altering substances is an enduring feature of human societies worldwide and even the most draconian legislation has failed to extinguish this desire--for every substance banned another will be discovered, and all are likely to have some ill-effect on health. This should be borne in mind by social legislators who, disapproving of other people's indulgences, seek to make them illegal. Such legislation does not get rid of the problem; it merely shifts it elsewhere.

One aspect of taking mood-altering substances may require legislation: the protection of others from annoyance and harm. Whether or not a person's indulgence poses a threat to others has been used as a guide to define the limits of socially acceptable behaviour; although to do so begs the question of people's responsibility for themselves. Should it be, for example, permissible for people deliberately to put their lives or health at risk through participating in dangerous sports such as boxing or motor racing? Do people have the right to decide for themselves what risks to take, irrespective of any expense and inconvenience to others when the risks come home? Is it reasonable to say "It is my life, I shall do as I choose", when almost everyone shares their lives with friends or family who would be damaged by their illness or death? Whatever the answers to these questions, there is one aspect that is indisputable: people have the right to know what are the risks to themselves and to others.

2 weeks ago, we published evidence that the sustained use of 3,4-methylenedioxymethamphetamine ("Ecstasy") was associated with a decrease in serotonin neurons in the brain (Oct 31, p 1433). This is information that any user of Ecstasy has a right to know; just as users of cannabis should be aware of its possible hazards. Because the debate about use of cannabis arouses strong emotions, there is, as Hall and Solowij note, no "consensus on what health information the medical profession should give to patients who are users or potential users of cannabis." Doctors called upon for advice about use of cannabis will find the authors' last paragraph a useful source of dispassionate information. The advice is little different from that appropriate for many other mood-altering substances: do not drive motor vehicles whilst intoxicated and do not overindulge.

We will qualify our opinion of 3 years ago and say that, on the medical evidence available, moderate indulgence in cannabis has little ill-effect on health, and that decisions to ban or to legalise cannabis should be based on other considerations.

## **Israeli Government to Give Marijuana Guidelines**

**January 30, 1999**

**by Rachelle H B Fishman**

**The Lancet (email)**

On Jan 20, the Israeli Health Ministry established a committee to provide doctors with guidelines for prescribing marijuana. Until now marijuana may only be given by special permit with the drug being provided by the police from confiscated supplies.

Boaz Lev, an internist and the ministry's deputy director-general for medical affairs, has asked the six-member committee of physicians, jurists, and public officials to define the medical conditions under which physicians will be permitted to prescribe marijuana, rather than continue on an ad hoc basis. "We want to establish the general guidelines and the optimum mechanism to provide marijuana to those who need it, but also to supervise distribution so the drug is not abused for non-medicinal use."

Marijuana can provide relief from severe chronic pain, muscular spasms, nausea, and loss of appetite caused, for example, by chemotherapy or AIDS. But Lev says "we don't want people to have to break the law to get treatment when no other drug is effective." Possession or trade in even the smallest quantities of the drug in Israel is punishable by a jail sentence.

Calls for a committee to examine the medicinal use of marijuana have been made in the last few years. In 1995, at a meeting held at the Hebrew University of Jerusalem, Rafi Mechoulam, a pharmacologist and a pioneer in marijuana research, suggested that an expert committee should look at the medicinal properties of the drug.

Earlier this year, a Knesset subcommittee, chaired by MK Naomi Chazan (Meretz) strongly recommended the Health Ministry establish an expert group. The committee also suggested that the safety and efficacy of the drug be tested in clinical trials. Chazan made it clear that "we do not expect the drug to be widely prescribed, and want to make it clear that it is being considered as a totally different issue from whether it should be legalized or decriminalized" the committee said.

No change in the general policy about marijuana use is planned or expected.

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from:

[Http://www.hemp.net/news/9902/01/israels\\_marijuana\\_guidelines.html](http://www.hemp.net/news/9902/01/israels_marijuana_guidelines.html)

**Select Committee on Science and Technology Report**

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# HOUSE of LORDS

## PRESS INFORMATION

EMBARGO 0001 HOURS  
WEDNESDAY 11th NOVEMBER 1998

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### LORDS SAY, LEGALISE CANNABIS FOR MEDICAL USE

The Government should allow doctors to prescribe cannabis for medical use: this is the conclusion of a report by the House of Lords Science and Technology Committee, published today.

Lord Perry of Walton, chairman of the inquiry said: "We have seen enough evidence to convince us that a doctor might legitimately want to prescribe cannabis to relieve pain, or the symptoms of multiple sclerosis (MS), and that the criminal law ought not to stand in the way. Far from being a step towards general legalisation, our recommendation would make the ban on recreational use easier to enforce. Above all, it would show compassion to patients who currently risk prosecution to get help."

#### MEDICAL USE

Cannabis is a "Schedule 1" drug, and cannot be used at all in medicine, except for research under special Home Office licence. **The Lords recommend that it should be moved to "Schedule 2".** This would allow doctors to prescribe it, subject to certain special regulations, and it would allow doctors and pharmacists to supply it in accordance with a prescription.

The report sets out evidence that cannabis can be effective in some patients to relieve the symptoms of MS, and against certain forms of pain. The Lords say, this evidence is enough to justify a change in the law. They are less convinced about its effectiveness in other conditions, including epilepsy, glaucoma and asthma.

The Lords welcome the fact that clinical trials of cannabis are currently being launched, by the Royal Pharmaceutical Society, and by Dr Geoffrey Guy of GW Pharmaceuticals, with a view to the eventual licensing of cannabis as a medicine. The Lords say, however, that cannabis should be rescheduled now, rather than waiting several years for the results of these trials.

If cannabis ever becomes a licensed medicine, the Lords do not envisage it being licensed for smoking; they call for research into alternative delivery systems.

At present, people who use cannabis for medical reasons risk prosecution; and juries sometimes refuse to convict such people, which brings the law into disrepute. If prescription were legalised, then someone using cannabis for medical reasons who was accused of recreational use could clear himself at once by producing the prescription. [More]

#### RECREATIONAL USE

The Lords find enough evidence of toxic effects of cannabis to justify maintaining the present ban on recreational use. Besides being intoxicating, they report that:

- regular heavy use can lead to psychological dependence, and even in some cases to physical dependence, involving withdrawal symptoms;
- cannabis can pose a risk to people with a heart condition;
- cannabis can exacerbate pre-existing mental illness;
- smoking cannabis is as bad for the lungs as smoking tobacco, and may cause cancer.

#### NOTES FOR EDITORS

1. The report follows an inquiry which began in April, and included 12 public hearings. A list of the Lords who took part in the study is attached :
2. The report is published by The Stationery Office: *Cannabis*, HL Paper 151, ISBN 0 10 4151986, £9.50.
3. The evidence taken by the Committee is published separately as HL Paper 151-I, ISBN 0 10 4792981, £22.60.
4. The full text will be on the Internet on publication, accessible via the UK Parliament home page at [www.parliament.uk](http://www.parliament.uk)
4. The Government are required to respond in writing to the report; and the report will be debated in the House of Lords.

#### Further information from Elaine Morgan/Tessa Perfect

##### House of Lords Committee Office

'Phone 0171-219 6075; Fax 0171-219 4931 [Ends]

#### CHAIRMAN

Lord Perry of Walton FRS (Lib Dem): former Professor of Pharmacology; founding Vice-Chancellor of the Open University 1969-81.

#### MEMBERS

Lord Butterfield (Cons): Vice-Chancellor of Nottingham University 1970-75; Regius Professor of Physic (ie medicine), Cambridge, 1975-87; Vice-Chancellor of Cambridge University 1983-85.

Lord Butterworth (Cons): Vice-Chancellor of the University of Warwick 1963-85.

Lord Carmichael of Kelvingrove (Lab): MP 1962-83; former junior Minister in various departments.

Lord Dixon-Smith (Cons): former Chairman, Association of County Councils.

Lord Kirkwood (Lib Dem): metallurgist; former lecturer, Sheffield University.

Lord Nathan (cross-bench): solicitor; former member of Royal Commission on Environmental Pollution.

Lord Porter of Luddenham (cross-bench): Nobel Prize for Chemistry 1967; President of the Royal Society 1985-90.

**Lord Rea (Lab):** former GP.

**Lord Soulsby of Swaffham Prior (Cons):** Emeritus Professor of Animal Pathology, Cambridge; President of the Royal Society of Medicine.

**Lord Walton of Detchant (cross-bench):** former professor of Neurology and Dean of Medicine, Newcastle University; former President of the General Medical Council, the British Medical Association, and the World Federation of Neurology.

**Lord Winston (Lab):** Dean of the Institute of Obstetrics and Gynaecology.

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# BIGGER, BETTER BEAM ME UP

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## Marijuana Special Report:

### Let's chill out

**Despite pressure to let sick people use marijuana, governments are wary**

The strength of President Clinton's revival at the ballot box last week surprised everyone. But then, so did the number of votes cast in favour of the drug Clinton famously never inhaled.

In Alaska, Nevada, Washington and Arizona, voters all approved ballot paper motions asking that the smoking of marijuana should be made legal for people with certain illnesses. And in Britain this week, an inquiry launched by the House of Lords said that doctors should be allowed to prescribe cannabis on a named-patient basis. So is the tide of opinion finally turning for the evil weed?

Not yet. The British government has not changed its view that relaxing the law on prescribing marijuana will require rigorous evidence of its effectiveness from clinical trials. Of course, scientific studies, long stifled by both British and US governments, should be carried out. But the Lords point out reasonably that anecdotal evidence of its value in relieving the symptoms of multiple sclerosis and other conditions argues for a more immediate, compassionate approach.

The objection that prescription marijuana might end up being sold on the black market seems implausible. Allowing doctors to prescribe marijuana would actually make it easier to distinguish between medical and recreational users. And as the report rightly points out, doctors in Britain have been allowed to prescribe heroin for people in chronic pain, yet there is no evidence that this heroin ends up on the black market.

## ARTICLES:

- **Let's chill out**  
(14 November 1998)
- **Lords reckon it's high time for a change**  
(14 November 1998)
- **High Hazards**  
(27 June 1998)
- **Smoke in strokes**  
(11 July 1998)
- **Newswire: From on high**  
(25 April 1998)
- **Decriminalisation. Yes. Totally safe. No**  
(21 February 1998)
- **The report the WHO tried to hide**  
(21 February 1998)
- **What is left after smoking 10 joints a day for 30 years?**  
(21 February 1998)

• Does marijuana  
press the same  
chemical buttons as  
heroin and cocaine?  
(21 February 1998)

• Are athletes better  
off smoking  
marijuana or  
tobacco?  
(21 February 1998)

• Which is most  
addictive: coffee,  
alcohol, marijuana  
or shopping?  
(21 February 1998)

• Aerosols: the  
future of the spliff?  
(21 February 1998)

• What happens to  
Dutch dope  
smokers at the age  
of 26?  
(21 February 1998)

• Drop in with Dr  
Dave  
(21 February 1998)

• Is there such a  
thing as a cannabis  
addict?  
(21 February 1998)

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• READERS  
LETTERS

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• MARIJUANA CHAT

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• REFERENCES

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• MAIN PAGE

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The biggest obstacles everywhere are political. In California, the state voted in favour of legalising marijuana for certain illnesses two years ago. And what happened? Federal law enforcers moved in to close down the growers' clubs that sprang up to supply patients. The US drugs tsar, Barry McCaffrey, continues to argue that the medical use of marijuana will send the wrong message to teenagers and encourage drug abuse.

In the US, proponents of medical marijuana are now full of talk about a new era. And in Britain, the Lords report is being welcomed. But there is a way to go before either country can really be rational about the issue.

From New Scientist, 14 November 1998



BIGGER

HOME • NEW SCIENTIST • NS+ • JOBS



## Marijuana Special Report:

### High hazards

A FRENCH government study has heaped fuel on the debate over the safety of cannabis by listing it as the least dangerous of all potentially addictive drugs. It also concludes that alcohol is among the most dangerous.

The study, commissioned by French health minister Bernard Kouchner, was carried out by a panel of 10 French and foreign scientists headed by Bernard-Pierre Roques of the René Descartes University of Paris. The panel searched the scientific literature for information about psychological and physical dependence, neural and general toxicity and social hazards such as aggressive behaviour caused by various legal and illegal drugs. The team then grouped the substances into three categories of dangerousness.

Cannabis was the only drug put in the least dangerous category. While cautioning that no drug they assessed was "completely free of danger", the researchers gave cannabis a rating of "weak" for social hazard and addictiveness, "very weak" for general toxicity and zero for neurotoxicity.

In the most dangerous category, they included heroin and other opiates, and cocaine. Alcohol was also placed in this category because of its strong toxicity, its potential as a social hazard and its "very strong" addictiveness. In the middle category they placed stimulants such as amphetamines, hallucinogens and tobacco—largely because of its "very strong" addictiveness and toxicity.

The authors point out that governments base their decisions whether or not to criminalise a drug on its ability to induce dependence. They conclude that the official classification for some drugs is incorrect.

#### ARTICLES:

- Let's chill out  
(14 November 1998)
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- The report the WHO tried to hide  
(21 February 1998)
- What is left after smoking 10 joints a day for 30 years?  
(21 February 1998)
- Does marijuana press the same



## BIGGER BETTER

HOME • NEW SCIENTIST • NS+ • JOBS

### Marijuana Special Report:

## Lords reckon it's high time for a change

British law should be altered to allow doctors to prescribe marijuana and pharmacists to supply it, according to an influential House of Lords committee.

At present, doctors in Britain are not permitted to prescribe cannabis, and patients who want it to relieve the symptoms of diseases such as multiple sclerosis must turn to the black market for supplies. In an unexpectedly forthright report, the House of Lords Select Committee on Science and Technology concludes that this "exposes patients and in some cases their carers to all the distress of criminal proceedings".

In recommending that doctors be allowed to prescribe herbal cannabis, rather than merely chemicals extracted from the plant, the Lords go further than other expert groups. This is bound to provoke opposition from ministers and the medical establishment. Last year, the British Medical Association called for more research into the main active ingredients of cannabis and recommended that these cannabinoids be made available to a wider range of patients. Pointedly, however, the BMA did not advocate prescribing cannabis in herbal or resin form. Several scientific witnesses who testified to the Lords committee agreed, given the absence of conclusive evidence that smoking cannabis offers patients more relief than taking individual cannabinoids. And the British government has repeatedly said it will only consider changing the law if such evidence emerges.

"The problem with this policy is that it will take several years at least for this to happen," concludes the report. "In the meantime, 85 000 people in this country will continue to suffer the very unpleasant symptoms of multiple sclerosis."

David Concar

From New Scientist, 14 November 1998

### ARTICLES:

- Let's chill out  
(14 November 1998)
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- What is left after smoking 10 joints a day for 30 years?  
(21 February 1998)
- Does marijuana press the same chemical buttons as heroin and cocaine?

## **Marihuana as Medicine**

### **A Plea for Reconsideration**

From the Department of Psychiatry, Harvard Medical School,  
and the Massachusetts Mental Health Center, Boston.

Reprint requests to Harvard Medical School, 74 Fenwood Road,  
Boston, MA 02115 (Dr Grinspoon).

JAMA, June 21, 1995 -- Vol. 273, No. 23 1875

#### **Commentary**

BETWEEN 1840 and 1900, European and American medical journals published more than 100 articles on the therapeutic use of the drug known then as *Cannabis indica* (or Indian hemp) and now as marihuana. It was recommended as an appetite stimulant, muscle relaxant, analgesic, hypnotic, and anticonvulsant. As late as 1913 Sir William Osler recommended it as the most satisfactory remedy for migraine.

Today the 5000-year medical history of cannabis has been almost forgotten. Its use declined in the early 20th century because the potency of preparations was variable, responses to oral ingestion were erratic, and alternatives became available -- injectable opiates and, later, synthetic drugs such as aspirin and barbiturates. In the United States, the final blow was struck by the Marihuana Tax Act of 1937. Designed to prevent nonmedical use, this law made cannabis so difficult to obtain for medical purposes that it was removed from the pharmacopeia. It is now confined to Schedule I under the Controlled Substances Act as a drug that has a high potential for abuse, lacks an accepted medical use, and is unsafe for use under medical supervision.

In 1972 the National Organization for the Reform of Marijuana Laws petitioned the Bureau of Narcotics and Dangerous Drugs, later renamed the Drug Enforcement Administration (DEA), to transfer marihuana to Schedule II so that it could be legally prescribed. As the proceedings continued, other parties joined, including the Physicians Association for AIDS [acquired immunodeficiency syndrome] Care. It was only in 1986, after many years of legal maneuvering, that the DEA acceded to the demand for the public hearings required by law. During the hearings, which lasted 2 years, many patients and physicians testified, and thousands of pages of documentation were introduced. In 1988 the DEA's own administrative law judge, Francis L. Young, declared that marihuana in its natural form fulfilled the legal requirement of currently accepted medical use in treatment in the United States. He added that it was "one of the safest therapeutically active substances known to man."<sup>(1)</sup> His order that the marihuana plant be transferred to Schedule II was overruled, not by any medical authority, but by the DEA itself, which issued a final rejection of all pleas for reclassification in March 1992.

Meanwhile, a few patients have been able to obtain marihuana legally for therapeutic purposes. Since 1978, legislation permitting patients with certain disorders to use marihuana with a physician's approval has been enacted in 36 states. Although federal regulations and procedures made the laws difficult to implement, 10 states eventually established formal marihuana research programs to seek Food and Drug Administration (FDA) approval for Investigational New Drug (IND) applications. These programs were later abandoned, mainly because the bureaucratic burden on physicians and patients became intolerable.

Growing demand also forced the FDA to Institute an Individual Treatment IND (commonly referred to as a Compassionate IND) for the use of physicians whose patients needed marihuana because no other drug would produce the same therapeutic effect. The application process was made enormously complicated, and most physicians did not want to become involved, especially since many believed there was some stigma attached to prescribing cannabis. Between 1976 and 1988 the government reluctantly awarded about a half dozen Compassionate INDs for the use of marihuana. In 1989 the FDA was deluged with new applications from people with AIDS, and the number granted rose to 34 within a year. In June 1991, the Public Health Service announced that the program would be suspended because it undercut the administration's opposition to the use of illegal drugs. After that no new Compassionate INDs were granted, and the program was discontinued in March 1992. Eight patients are

still receiving marihuana under the original program; for everyone else it is officially a forbidden medicine.

And yet physicians and patients in increasing numbers continue to relearn through personal experience the lessons of the 19th century. Many people know that marihuana is now being used illegally for the nausea and vomiting induced by chemotherapy. Some know that it lowers intraocular pressure in glaucoma. Patients have found it useful as an anticonvulsant, as a muscle relaxant in spastic disorders, and as an appetite stimulant in the wasting syndrome of human immunodeficiency virus infection. It is also being used to relieve phantom limb pain, menstrual cramps, and other types of chronic pain, including (as Osler might have predicted) migraine. (2) Polls and voter referenda have repeatedly indicated that the vast majority of Americans think marihuana should be medically available.

One of marihuana's greatest advantages as a medicine is its remarkable safety. It has little effect on major physiological functions. There is no known case of a lethal overdose; on the basis of animal models, the ratio of lethal to effective dose is estimated as 40,000 to 1. By comparison, the ratio is between 3 and 50 to 1 for secobarbital and between 4 and 10 to 1 for ethanol. Marihuana is also far less addictive and far less subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics. The chief legitimate concern is the effect of smoking on the lungs. Cannabis smoke carries even more tars and other particulate matter than tobacco smoke. But the amount smoked is much less, especially in medical use, and once marihuana is an openly recognized medicine, solutions may be found. Water pipes are a partial answer; ultimately a technology for the inhalation of cannabinoid vapors could be developed. Even if smoking continued, legal availability would make it easier to take precautions against aspergilli and other pathogens. At present, the greatest danger in medical use of marihuana is its illegality, which imposes much anxiety and expense on suffering people, forces them to bargain with illicit drug dealers, and exposes them to the threat of criminal prosecution.

The main active substance in cannabis, [ $\delta$ -9]-tetrahydrocannabinol ([ $\delta$ -9]-THC), has been available for limited purposes as a Schedule II synthetic drug since 1985. This medicine, dronabinol (Marinol), taken orally in capsule form, is sometimes said to obviate the need for medical marihuana. Patients and physicians who have tried both disagree. The dosage and duration of action of marihuana are easier to control, and other cannabinoids in the marihuana plant may modify the action of [ $\delta$ -9]-THC. The development of cannabinoids in pure form should certainly be encouraged, but the time and resources required are great and at present unavailable. In these circumstances, further isolation, testing, and development of individual cannabinoids should not be considered a substitute for meeting the immediate needs of suffering people.

Although it is often objected that the medical usefulness of marihuana has not been demonstrated by controlled studies, several informal experiments involving large numbers of subjects suggest an advantage for marihuana over oral [ $\delta$ -9]-THC and other medicines. For example, from 1978 through 1986 the state research program in New Mexico provided marihuana or synthetic [ $\delta$ -9]-THC to about 250 cancer patients receiving chemotherapy after conventional medications failed to control their nausea and vomiting. A physician who worked with the program testified at a DEA hearing that for these patients marihuana was clearly superior to both chlorpromazine and synthetic [ $\delta$ -9]-THC. (3) It is true that we do not have studies controlled according to the standards required by the FDA — chiefly because legal, bureaucratic, and financial obstacles are constantly put in the way. The situation is ironical, since so much research has been done on marihuana, often in unsuccessful attempts to prove its dangerous and addictive character, that we know more about it than about most prescription drugs.

Physicians should offer more encouragement to controlled research, but it too has limitations. Individual therapeutic responses can be obscured by the statistical results of group experiments in which there is little effort to identify the specific features of a patient that affect the drug response. Furthermore, much of our knowledge of synthetic medicines as well as plant derivatives comes from anecdotal evidence. For example, as early as 1976 several small, methodologically imperfect, and relatively obscure studies had shown that taking an aspirin a day could prevent a second heart attack. In 1988 a large-scale experiment demonstrated dramatic effects. This story is suggestive, because marihuana, like aspirin, is a substance known to be unusually safe and to have enormous potential health benefits.

Cannabis can also bring about immediate relief of suffering measurable in a study with only one subject. In the experimental method known as the single patient randomized trial, active and placebo treatments are administered randomly in alternation or succession to a patient. The method is often useful when large scale controlled studies are impossible or inappropriate because the disorder is rare, the patient is atypical, or the response to the treatment is idiosyncratic. Many patients, either deliberately or because of unreliable supplies, have informally carried out somewhat similar experiments by alternating periods of cannabis use with periods of no use in the treatment of various disorders. (2) (pp.133-135)

The American Medical Association was one of the few organizations that raised a voice in opposition to the Marihuana Tax Act of 1937, yet today most physicians seem to take little active interest in the subject, and their silence is often cited by those who are determined that marihuana shall remain a forbidden medicine. Meanwhile, many physicians pretend to ignore the fact that their patients with cancer, AIDS, or multiple sclerosis are smoking marihuana for relief; some quietly encourage them. In a 1990 survey, 44% of oncologists said they had suggested that a patient smoke marihuana for relief of the nausea induced by chemotherapy. (4) If marihuana were actually unsafe for use even under medical supervision, as its Schedule I status explicitly affirms, this recommendation would be unthinkable. It is time for physicians to acknowledge more openly that the present classification is scientifically, legally, and morally wrong.

Physicians have both a right and a duty to be skeptical about therapeutic claims for any substance, but only after putting aside fears and doubts connected with the stigma of illicit nonmedical drug use. Advocates of medical use of marihuana are sometimes charged with using medicine as a wedge to open a way for "recreational" use. The accusation is false as applied to its target, but expresses in a distorted form a truth about some opponents of medical marihuana; they will not admit that it can be a safe and effective medicine largely because they are stubbornly committed to exaggerating its dangers when used for nonmedical purposes.

We are not asking readers for immediate agreement with our affirmation that marihuana is medically useful, but we hope they will do more to encourage open and legal exploration of its potential. The ostensible indifference of physicians should no longer be used as a justification for keeping this medicine in the shadows.

Lester Grinspoon, MD  
James B. Bakalar, JD

1. *In the Matter of Marijuana Rescheduling Petition, Docket 86-22, Opinion, Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of Administrative Law Judge, September 6, 1988.* Washington, DC: Drug Enforcement Agency; 1988.

2. Grinspoon L., Bakalar J. *Marihuana, the Forbidden Medicine.* New Haven, Conn.: Yale University Press; 1993.

3. *In the Matter of Marijuana Rescheduling Petition, Docket 86-22, Affidavit of Daniel Dansac, M.D.* Washington, DC: Drug Enforcement Agency; 1987.

4. Doblin R, Kleiman MAR. Marihuana as anti-emetic medicine: a survey of oncologists' attitudes and experiences. *J Clin Oncol.* 1991;9:1275-1290.

pp. 1875-1876 JAMA, June 21, 1995 -- Vol. 273, No. 23

[End]

To: Todd Summers

From: Cornelius

Per Conversation.

9 pages

# The 1999 National Conference on African-Americans and AIDS

*A National Forum on HIV/AIDS for Health Professionals Who Provide Care for African-Americans*

---

## Organizing Committee

John G. Bartlett, M.D.  
*The Johns Hopkins University*

February 4, 1999

Elaine M. Daniels, M.D., Ph.D.  
*OXO Chem, Inc.*

Dear Distinguished Guest:

Robert C. Gallo, M.D.  
*Institute of Human Virology  
at University of Maryland*

Thank you for participating in the Expert Roundtable Consensus meeting to be held on Wednesday, February 24. Below is the day's agenda. A summary of discussion topics is also attached.

Eric Gossby, M.D.  
*U.S. Department of Health  
and Human Services*

Date: February 24, 1999

K. Mary Hess  
*Bristol-Myers Squibb  
Immunology*

Time: 4 p.m. to 6 p.m.

Rick Marlink, M.D.  
*The Harvard AIDS Institute*

Place: Renaissance Hotel, Washington, D.C.  
Meeting Room 12, 13, 14

Celia Maxwell, M.D.  
*Howard University*

Press  
Conference: 6 to 6:30 p.m.

Stephen B. Thomas, Ph.D.  
*Rollins School of Public  
Health of Emory University*

Dinner: 7 p.m.  
Renaissance Hotel  
Meeting Room 5

---

February 25-26, 1999

I look forward to seeing you then.

Renaissance  
Washington, D.C. Hotel

Sincerely,

999 Ninth Street, N.W.  
Washington, D.C. 20001

*K. Mary Hess*

K. Mary Hess  
Conference Committee Member

---

**Johns Hopkins Continuing Medical Education**

720 Rutland Avenue, Turner 20 • Baltimore, Maryland 21205-2195 • Phone (410) 955-2959 • Fax (410) 955-0807

# The 1999 National Conference on African-Americans and AIDS

*A National Forum on HIV/AIDS for Health Professionals Who Provide Care for African-Americans*

## Agenda

### Organizing Committee

John G. Bartlett, M.D.  
*The Johns Hopkins University*

4:00 p.m.

#### Welcome to the Roundtable:

Eric Goosby, M.D., DHHS

John G. Bartlett, M.D., Johns Hopkins Medical Institutions

Elaine M. Daniels, M.D., Ph.D.  
*OXO Chemi, Inc.*

4:10 p.m.

#### What are the main objectives the Nation needs to meet to vanquish HIV/AIDS epidemic in the African-American community?

Robert C. Gallo, M.D.  
*Institute of Human Virology  
at University of Maryland*

Eric Goosby, M.D.  
*U.S. Department of Health  
and Human Services*

K. Mary Hess  
*Bristol-Myers Squibb  
Immunology*

Rick Marlink, M.D.  
*The Harvard AIDS Institute*

Celia Maxwell, M.D.  
*Howard University*

5:10 p.m.

#### What are the major obstacles to successfully containing the epidemic in the African-American community?

Stephen B. Thomas, Ph.D.  
*Rollins School of Public  
Health of Emory University*

February 25-26, 1999

Renaissance  
Washington, D.C. Hotel

999 Ninth Street, N.W.  
Washington, D.C. 20001

- Access to expert care
- Access to treatment for drug abuse
- Access to high potency antiretroviral drug therapy
- Creation of a community supported, culturally sensitive HIV prevention education program
- A greater degree of support and involvement with HIV/AIDS prevention and health education outreach by the church leadership
- Leadership from all walks of life must embrace the goal of de-stigmatizing HIV/AIDS
- African American Women in particular need better prevention and treatment education, as well as outreach programs especially designed for them
- Continued funding of critical treatment and social programs

6:00 p.m. -

6:30 p.m.

Press Conference

7:00 p.m.

Adjourn for dinner

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**The 1999 National Conference on  
African-Americans and AIDS**  
*A National Forum on HIV/AIDS for Health Professionals Who Provide Care for African-Americans*

---

Cornelius Baker  
By Fax  
202-898-0435

Dear Mr. Baker:

In an effort to increase awareness on Capitol Hill, the Conference Committee for the 1999 National Conference on African-Americans and AIDS has identified four important topics related to HIV that must be further explored and developed to positively affect the HIV community.

- Prevention
- Testing
- Counseling
- Treatment

These topics, detailed on the attached pages, are suggested for discussion during the Roundtable Consensus Meeting to be held on February 24, 1999.

We hope that you echo these messages throughout the Conference. The momentum generated by the Conference will help carry forth our Call to Action to effectively create policy initiatives.

I welcome any comments you may have. I can be reached via fax at 410-995-0610 or by page at 888-971-6109. I look forward to working with you in our continued efforts against the HIV/AIDS epidemic in the African-American community.

Sincerely,

*K. Mary Hess*

K. Mary Hess

**Draft: 2/18/99**

**Embargo: February 25, 1999 /8:00 a.m.**

**Contact: Peter Steinberg  
Medisphere Communications  
212-213-4211  
917-593-9824 / Pager**

**Brian Vastag  
Johns Hopkins University  
410-955-8665  
410-283-4981 / Pager**

**HIV EXPERTS CONVENE IN WASHINGTON FOR FIRST NATIONAL FORUM ON  
HIV/AIDS IN THE AFRICAN-AMERICAN COMMUNITY**

**-- HIV/AIDS Experts Representing Public Health, Government, and the Medical  
Community to Join Together for Inaugural Conference --**

(Washington, DC, February 25, 1999) AIDS is the leading killer of African-American males between the ages of 25 and 44 and is the second leading killer of African-American women in the same group. Alarmingly, while the overall number of deaths from AIDS fell in the U.S. in 1997 by 47 percent, the same dramatic decrease was not seen in the African American community. In order to address this important health issue, experts will convene in Washington, D.C. today for the inaugural National Conference on African-Americans and AIDS.

"This conference is taking place against the backdrop of what has become a nationwide health crisis in the African-American community," said John Bartlett, M.D., chief of the Division of Infectious Diseases at Johns Hopkins University School of Medicine, and a member of the conference organizing committee. "African-Americans account for 40% of the nation's AIDS cases but comprise only 13% of the U.S. population. Moreover, there are some major obstacles to successfully containing the epidemic in the African-American community. These obstacles include the stigma attached to HIV/AIDS, which prevents many African-Americans from seeking treatment or engaging in prevention-oriented behaviors. In order to address this situation, we must begin to help African-Americans to understand that, with proper treatment, AIDS patients are able to live longer and can look forward to a future that will allow them to return to work, to take care of their families, and to contribute to society."

Discussions at the conference will focus on such issues as the epidemiology of HIV in the U.S., the disconnect between the American healthcare system and the African-American community, and HIV in women. The two-day conference will feature presentations by several prominent clinicians who are on the front lines of treating HIV/AIDS in the African-American community, as well as by public health experts such as U.S. Health and Human Services Secretary Donna Shalala and Phill Wilson, Founder, AIDS Foundation Los Angeles.

"Conquering the HIV/AIDS epidemic in the African-American community is all about access," commented Eric Goosby, M.D., director of the Office of HIV/AIDS Policy in the U.S. Department of Health and Human Services. "Expanding access among African-Americans will demand the creation of improved programs which focus on prevention, testing, counseling, and treatment. These programs will also require the support of leaders from all walks of African-American life: the church, civic, fraternal and corporate organizations, working in tandem with government, AIDS service organizations and medical providers who treat African-Americans."

The 1999 National Conference on African-Americans and AIDS will be held February 25-26, 1999 at Renaissance Hotel in Washington, DC. The co-sponsors of the 1999 National Conference on African-Americans and AIDS include: The Johns Hopkins Medical Institutions, the Rollins School of Public Health at Emory University, Howard University, the Harvard AIDS Institute, and the Institute of Human Virology at the University of Maryland.

The conference is being supported through an unrestricted educational grant from Bristol-Myers Squibb Immunology. Full audio and slide presentations of the conference will be available on [www.hopkins-sids.edu](http://www.hopkins-sids.edu) beginning March 2, 1999.

####

### **Expanded Access for HIV Positive Individuals**

**Last year, the death rate from AIDS was nearly cut in half – the biggest single-year drop in history for a major cause of death in the United States, but so much more needs to happen:**

- **Nearly two-thirds of persons with HIV are not getting regular care**
- **Even fewer are getting the new multi-drug regimens**

**With proper treatment, AIDS patients are not only living longer, they are going back to work, taking care of their families, contributing to society and looking forward to a future they didn't think they had.**

***So why are so many HIV positive individuals not under a physician's care? Programs must be expanded to stress the benefits associated with Prevention, Testing, Counseling and Treatment.***

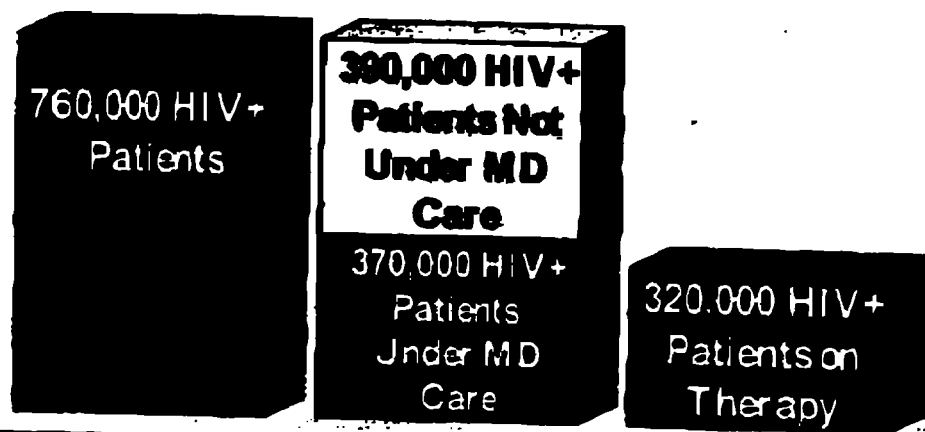
**Prevention is a message that can never be lost. It is very important to deliver timely and informative messages stressing prevention and testing because of the wide cultural diversities of the patient populations. Increased testing will drive HIV positive individuals to treatment centers where benefits of counseling and drug therapy can make a dramatic impact on extending and enhancing human life.**

**There are several studies that highlight the cost-effectiveness of AIDS medicines for example:**

- **A Los Angeles medical practice treating about 450 people with AIDS reported that each dollar of increased spending on drug therapy saved twice that amount in overall treatment costs.**
- **A study of AIDS treatment costs at St. Vincent's Hospital in New York City found that, due to new drug treatments, the monthly average of hospitalized patients declined by 45 percent between February 1995 and September 1996.**
- **French researchers reported that aggressive treatment with triple-drug therapy saved \$650,000 a month in avoided hospitalizations in four treatment centers.**
- **According to a study presented at the 12<sup>th</sup> World AIDS Conference in 1998, the Department of Veterans Affairs found that giving patients full access to new AIDS drugs helped realize a net savings of \$18 million in treatment costs in 1997.**

**Despite the overwhelming evidence that AIDS medicines are cost-effective, society must still solve the problem of getting individuals who are HIV positive to a physician for treatment.**

## Why are so many HIV positive individuals not under a physician's care?



Source: Center for Disease Control

## SOLUTIONS

Programs must be expanded:

- Prevention
- Testing
- Counseling
- Treatment

- AIDS is now the leading cause of death of African American men & women ages 25 - 44.
- African American women account for 56% of women living with AIDS.
- African American children account for 58% of children living with AIDS.



COMMUNICATION W O R K S

Carmelino  
898-0639

## FAX TRANSMITTAL

Date:

2/15

Pages to follow:

7

To:

JEFF JACOBS

Organization:

ARDC ACTION Council

Fax:

202-986-1345

Phone:

From:

N. PARKER

Note:

2017 Mission Street, Suite 304, San Francisco, California 94110  
415.255.1946 • fax 415.255.1947 • www.communicationworks.org • a.mail works@igc.org



## COMMUNICATION W O R K S

February 15, 1999

Dear friends,

Thanks you for signing on to the letter regarding legal and immediate access to medical marijuana for people with AIDS.

We are forwarding to you the final copy of the letter with all the signatories. We plan to send the letter to the drug czar, Barry McCaffrey, et al and release it to the media on Wednesday, February 17th.

And to those who have agreed to serve as spokespersons, we thank you for taking a stance on this issue. We are sending you a list of suggested talking points should the media contact you for comment. Please feel to refer to this when talking with reporters. We think this could be a helpful resource if you choose to use them.

Should you have any further questions, please do not hesitate to give us a call. We can be reached at (415) 255-1946. We will be delighted to answer whatever queries you might have.

We salute you for all your hard work on this issue. Thanks to your commitment, lives are being saved, and burdens eased. Hopefully, our work around this letter will bring people who are living with AIDS one step closer to safe, legal access to medical marijuana.

Sincerely,

Rachel Swain/Tommy McDonald  
Communication Works

Dave Fratello  
Americans for Medical Rights

2017 Mission Street, Suite 204, San Francisco, California 94110  
tel 415.255.1946 • fax 415.255.1947 • [www.communicationworks.org](http://www.communicationworks.org) • [mail.works@igc.org](mailto:mail.works@igc.org)

February 17, 1999

General Harry McCaffrey  
Director  
Office of National Drug Control Policy

Dear General McCaffrey;

As advocates and care givers for people living with HIV disease and AIDS, we are writing to urge you to help break the bureaucratic logjam that is keeping a potentially life-saving medicine virtually inaccessible to thousands of people living with AIDS and other debilitating illnesses.

That medicine is marijuana. Marijuana's therapeutic uses are well documented in scientific literature. Recent scientific studies have confirmed what has been reported to us by hundreds of people living with HIV - that marijuana can be safely used to reduce nausea and vomiting, stimulate appetite, and promote weight gain. Marijuana is widely recognized by physicians specializing in AIDS care as an important component of treatment for some patients who suffer from symptoms of advanced-stage HIV disease and the multiple-drug therapies used to manage HIV.

Today, thanks to one federally approved clinical study of marijuana for people living with AIDS, sixty-four patients receive marijuana legally from supplies grown by the federal government. However, thousands of Americans, many of them people living with HIV, use marijuana as a medicine illegally, putting themselves at risk of arrest and prosecution. Because the practice is illegal, most patients use marijuana without medical supervision. Marijuana's illegality means that patients cannot be sure of obtaining standardized products that are free of contaminants. People should not have to risk their health or jail to receive needed medical care.

For this reason, thirty-five state legislatures have passed laws supporting the use of marijuana as a medicine. In addition, voters in six states (Alaska, Arizona, California, Nevada, Oregon, and Washington) and the District of Columbia have recently approved ballot measures legalizing the medical use of marijuana within their borders - nearly one in five Americans lives in a state whose voters have approved medical marijuana. Now, the nation is looking to the federal government to begin to show compassion and flexibility on this issue.

You may be aware that the standard Food and Drug Administration approval process has been streamlined for several medications important to people living with HIV disease and AIDS. Drugs shown to fall within an acceptable standard of safety have been made available to patients before completion of all scientific trials proving effectiveness. This special procedure has helped thousands of

patients to obtain life-extending benefits from new medications, and has contributed directly to building the science base for such new drugs.

Our request is simple. Just as other promising AIDS medications have been made available prior to final FDA approval, so too should marijuana, when recommended by a physician, be made available to patients who choose to use it.

There is not much question about the relative safety of marijuana - it has been heavily studied around the world. These studies have revealed an important fact: there is no lethal dose of marijuana. Besides this finding, occasional marijuana smoking under controlled circumstances has not been proved to be dangerous. In sum, the known risks of marijuana are clearly within a range of acceptability sufficient to allow individual physicians and patients to monitor its use, and its results. Under these circumstances, making marijuana immediately available on a quasi-experimental basis to people living with AIDS, when their physicians request it, is a moderate step that can add to the federal government's responsiveness to the epidemic.

We appeal to you, General McCaffrey, because you are in a unique position to provide leadership on this issue. Science and compassion should dictate our nation's policy regarding medical treatment. However, politics has stood in the way of the approval of marijuana as a legal medication, and the full development of a science base leading to FDA approval could still be years away. We call upon you to be a part of the political solution. We ask that you publicly encourage your colleagues in the administration to respond positively to the scientific and public support for making marijuana medically available.

Sincerely,

cc: Donna Shalala, Secretary of Health and Human Services  
Jane Henney, director, Food and Drug Administration  
Sandra Thurman, director, Office of National AIDS Policy  
Sen. Trent Lott (R-MS) Senate Majority Leader  
Sen. Tom Daschle (D-SD) Senate Minority Leader  
Rep. J. Dennis Hastert (R-IL), Speaker of the House  
Rep. Dick Armey (R-TX) House Majority Leader  
Rep. Richard Gephardt (D-MO) House Minority Leader

**AIDS / Marijuana letter to McCaffrey**

- Daniel Zingale/Jeff Jacobs  
Executive Director/Legislative Director  
AIDS Action Council
- Regina Aragón  
Public Policy Director  
San Francisco AIDS Foundation
- Herb K. Schultz  
Director of Government Affairs  
AIDS Project Los Angeles
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**Washington, DC**
- **Steven B. Johnson**  
**Director of Public Policy and Communications**  
**Northwest AIDS Foundation**  
**Seattle, WA**
- **Mark D. Garvey**  
**Being Alive Program Specialist**  
**AIDS Project Arizona**  
**Phoenix AZ**



COMMUNICATION W O R K S

## Talking points

### Why is this letter coming out now?

- Almost 250,000 U.S. residents are living with AIDS, and as many as 900,000 are HIV positive. Marijuana helps relieve pain, control nausea and combat the life-threatening 'wasting syndrome' associated with AIDS. Marijuana can save lives now, and should be available now.
- General McCaffrey released this year's national drug control strategy on February 9. Six states have approved medical marijuana ballot initiatives, but McCaffrey has not addressed the needs of patients in those states and nationwide. We're calling on his office to take humanitarian action now.
- After California passed Proposition 215 in 1996, McCaffrey promised to base his marijuana policy on science. He commissioned an Institute of Medicine review of the science on medical marijuana. That study is due out March 15, and we are urging McCaffrey to make good on his promise and respect the evidence showing medical marijuana works.

### Who's behind this effort?

- Twenty AIDS organizations from around the country have signed on to this letter, and support the need for people with AIDS to have immediate access to medical marijuana.

### Don't we need more research before we approve marijuana as a medicine?

- We want, and need more research. But there's already a mound of solid evidence supporting medical marijuana. *Lancet*, the *New England Journal of Medicine*, the *Journal of the American Medical Association*, President Nixon's commission on medical marijuana, Britain's House of Lords – all have found that medical marijuana's benefits outweigh its risks. We want to learn more about marijuana, but AIDS patients cannot afford to wait for years of research to prove what they and their doctors already know: medical marijuana works.

### Isn't smoking marijuana bad for your health?

- Many AIDS patients use smoked marijuana to control the nausea caused by multiple drug therapies. Marijuana enables them to swallow the medicines that keep them alive. Patients say they can't take anti-emetic pills because they can't keep them down. For these people, the life-saving benefits of smoked marijuana outweigh any risks associated with its use.

2017 Mission Street, Suite 304, San Francisco, California 94110

415.233.1946 • fax 415.233.1947 • [www.communicationworks.org](http://www.communicationworks.org) • [s.mail.works@igc.org](mailto:s.mail.works@igc.org)

- Safer delivery systems, like inhaler devices, may be developed in years to come. But people with AIDS can't afford to wait out years of research and development. They need access to medical marijuana now.

**Doesn't it Send a Dangerous Message to Kids?**

- We're asking that marijuana be prescribed under controlled conditions – like any other medicine. We allow valium to be prescribed by doctors to people who need it. That doesn't send a bad message or encourage kids to try it. What does send a bad message is being dishonest about marijuana's benefits, and denying treatment to people who need it.

**What does fast-track mean?**

- The federal government has streamlined the approval process for experimental AIDS drugs like protease inhibitors before the completion of all scientific trials. We're asking that marijuana get the same treatment – compassionate, emergency approval while we wait for new research.

**Isn't this a pipe-dream?**

- We don't think so. Six U.S. states have approved medical marijuana. It's registering seventy percent approval nationwide. Britain and Israel just provisionally approved medical use of marijuana. The major scientific and medical journals agree that marijuana has medical benefits. It's just a matter of time before U.S. federal policy catches up with the rest of the world and recognizes this as an critical health issue.

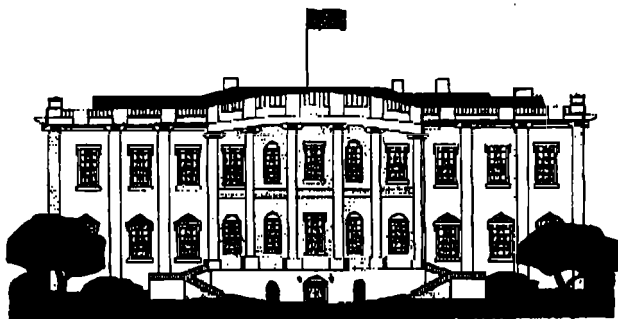
**Don't alternatives to smoked marijuana already exist?**

Not alternatives that really work. Marinol is a synthetic drug

- There is no way to control the dosage. Some patients complain that marinol leaves them feeling stoned – whereas with smoked marijuana, patients can titrate the dosage to meet their specific needs.
- Many AIDS patients suffer from extreme nausea related to other treatments and have a hard time keeping a Marinol pill down.

**EXECUTIVE OFFICE OF THE PRESIDENT**

Office of National Drug Control Policy  
Washington, DC 20503



Office of National Drug Control Policy

**FACSIMILE MESSAGE**

**TO:** Ms. Sandra Thurman

**FAX:** 6-2438

**DATE:** 2/18/99 **TIME:** 8:30 AM **PAGES:** 11 + Cover

---

**FROM:** Janet Crist, Chief of Staff, Office of National Drug Control Policy

**FAX NUMBER:** (202) 395-6708

**OFFICE NO:** (202) 395-6732

---

**COMMENTS:** Following are copies of the press release we discussed at this morning's White House meeting and the advance fax ONDCP received on 2/15.

IDM Study



COMMUNICATION W O R K S

February 15, 1999

General Barry McCaffrey  
Director  
Office of National Drug Control Policy

Dear General McCaffrey;

This is a courtesy letter to inform you that the following letter will be sent to your office on Wednesday, February 17, 1999. It is possible you will receive calls from the media or from AIDS organizations and we want to be sure you have a copy in advance.

The final copy of the letter will arrive on Wednesday morning.

If you have any questions, please do not hesitate to contact us at (415) 255-1946.

Respectfully

Rachel Swain and Tommy McDonald  
Communication Works

**EMBARGOED FOR RELEASE UNTIL: 06:00 A.M. EST, THURSDAY,  
FEBRUARY 18, 1999**

February 17, 1999

General Barry McCaffrey  
Director  
Office of National Drug Control Policy

Dear General McCaffrey;

As advocates and care givers for people living with HIV disease and AIDS, we are writing to urge you to help break the bureaucratic logjam that is keeping a potentially life-saving medicine virtually inaccessible to thousands of people living with AIDS and other debilitating illnesses.

That medicine is marijuana. Marijuana's therapeutic uses are well documented in scientific literature. Recent scientific studies have confirmed what has been reported to us by hundreds of people living with HIV - that marijuana can be safely used to reduce nausea and vomiting, stimulate appetite, and promote weight gain. Marijuana is widely recognized by physicians specializing in AIDS care as an important component of treatment for some patients who suffer from symptoms of advanced-stage HIV disease and the multiple-drug therapies used to manage HIV.

Today, thanks to one federally approved clinical study of marijuana for people living with AIDS, sixty-four patients receive marijuana legally from supplies grown by the federal government. However, thousands of Americans, many of them people living with HIV, use marijuana as a medicine illegally, putting themselves at risk of arrest and prosecution. Because the practice is illegal, most patients use marijuana without medical supervision. Marijuana's illegality means that patients cannot be sure of obtaining standardized products that are free of contaminants. People should not have to risk their health or jail to receive needed medical care.

For this reason, thirty-five state legislatures have passed laws supporting the use of marijuana as a medicine. In addition, voters in six states (Alaska, Arizona, California, Nevada, Oregon, and Washington) and the District of Columbia have recently approved ballot measures legalizing the medical use of marijuana within their borders - nearly one in five Americans lives in a state whose voters have approved medical marijuana. Now, the nation is looking to the federal government to begin to show compassion and flexibility on this issue.

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Sincerely,

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Jane Henney, director, Food and Drug Administration  
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## **SIGNATORIES**

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Executive Director / Legislative Director  
AIDS Action Council
- Regina Aragón  
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**Being Alive Program Specialist**  
**AIDS Project Arizona**  
**Phoenix AZ**

## **AIDS Groups Issue First Call for Drug Czar to Approve Medical Marijuana on Fast Track for People with AIDS**

PRNewswire  
16-FEB-99

**/CAUTION -- ADVANCE FOR RELEASE AT 6:00 A.M. EST THURSDAY, FEB. 18/ Unprecedented Statement Comes as Institute of Medicine Prepares to Publish**

**Full Review of Medical Marijuana Science /ADVANCE/ WASHINGTON, Feb. 18 /PRNewswire/ -- Physicians should be allowed to prescribe marijuana as an emergency measure to people with HIV/AIDS without further research, says a letter to be sent February 17th from the heads of seventeen AIDS organizations to General Barry McCaffrey, director of the Office for National Drug Control Policy. This is the first time that AIDS groups have come together to call for legal, immediate access to marijuana.**

Citing a fast-track system that has allowed physicians to prescribe protease inhibitors and other AIDS medications before the completion of clinical trials, the letter calls on McCaffrey to give immediate approval to what they say is another life-saving drug -- marijuana.

"(W)e urge you to help break the bureaucratic logjam that is keeping a potentially life-saving medicine, marijuana, virtually inaccessible to thousands of people living with AIDS," says the letter, signed by AIDS Action Council, San Francisco AIDS Foundation, Latino Commission on AIDS, National Native American AIDS Prevention Center, AIDS National Interfaith Network, Mothers' Voices to End AIDS, AIDS Project Los Angeles, and other organizations around the country.

Copies of the letter were also sent to the Secretary of Health and Human Services, the Director of the U.S. Food and Drug Administration, the Office of National AIDS Policy and the U.S. House and Senate Majority and Minority leaders.

The AIDS organizations are urging McCaffrey to make good on an October, 1997 statement to Congress, which said: "If sound medical research demonstrates that there are medical uses for smoked marijuana, there are appropriate and responsive procedures for rescheduling this mind-influencing drug through the time-tested process.

"The FDA has already demonstrated flexibility in accelerating procedures for allowing the use of emerging AIDS-related drugs without jeopardizing science or the public health."

Thousands of Americans with HIV/AIDS use marijuana to relieve the nausea caused by

multiple-drug therapies, and to combat the "wasting syndrome" associated with the late, often fatal, stages of AIDS by stimulating appetite. But, with marijuana classed as a highly-controlled Schedule I substance under federal law, most patients use the medicine illegally, risking prosecution and exposure to contaminated products.

Recent studies and editorials in prestigious scientific journals Lancet, New Scientist, New England Journal of Medicine and the Journal of the American Medical Association have concluded that marijuana's medical benefits outweigh its risks. Convinced by existing research, Britain and Israel recently sanctioned the compassionate use of marijuana on a provisional basis, and six U.S. states have passed ballot initiatives to legalize medical marijuana -- throwing state policies into conflict with federal law.

In 1996, McCaffrey commissioned the Institute of Medicine at the National Academy of Sciences to conduct a full review of the science surrounding medical marijuana. That study is expected to be released next month, and may lead to calls for new research into medical marijuana. Just one clinical trial has been approved by the federal government since 1985.

AIDS organizations say terminally-ill patients cannot afford to wait for years of research to prove something they already know: medical marijuana works.

"Science and compassion should dictate our nation's policy regarding medical treatment," says the letter. "However, politics has stood in the way of the approval of marijuana as a legal medication, and the full development of a science base leading to FDA approval could still be years away.

"Under these circumstances, making marijuana immediately available on a quasi-experimental basis to people living with AIDS [...], is a moderate step that can add to the federal government's responsiveness to the epidemic."

(The full text of the letter follows:) February 17, 1999

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Director  
Office of National Drug Control Policy  
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We ask that you publicly encourage your colleagues in the administration to respond positively to the scientific and public support for making marijuana medically available. Sincerely,

cc: Donna Shalala, Secretary of Health and Human Services

Jane Henney, director, Food and Drug Administration

Sandra Thurman, director, Office of National AIDS Policy  
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Executive Director  
Boulder County AIDS Project  
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**Statement by General Barry R. McCaffrey  
Director, Office of National Drug Control Policy  
Submitted for the Record to the House Judiciary  
Committee,  
Subcommittee on Crime,  
Medical Marijuana Referenda in America,  
October 1, 1997**

Chairman McCollum, members of the subcommittee, thank you for the opportunity to address the issue of medical marijuana referenda in the United States. The Office of National Drug Control Policy is pleased to work with the 105th Congress to dramatically reduce drug use and its consequences. In particular, Chairman McCollum, the Office of National Drug Control Policy appreciates your longstanding support, as well as that of this committee's members. Indeed, the Office of National Drug Control Policy Reauthorization Act of 1997, which is now before the Congress reflects a continuing and constructive dialogue between committed Senators and Representatives, their expert staff, and ONDCP. Over the past 17 years, bipartisan partnership has contributed to a 50 percent overall reduction in drug use and a 75 percent reduction in casual cocaine use. Nevertheless, America's drug abuse problem will kill another 140,000 Americans and cost our society \$700 billion over the coming decade if unchecked. My commitment to the Congress when you considered my appointment in February of last year remains constant -- to forge a coherent counter drug strategy that will reduce illegal drug use and protect our youth and society in general from the terrible damage caused by drug abuse and drug trafficking.

Today, it is my purpose to update you on developments since early December 1996, when we addressed the issue of medical marijuana referenda before the Senate Committee on the Judiciary. The ballot initiatives passed in November of 1996 in Arizona and California bypassed the rigorous scientific approval process required of all medicines and allowed for the use of marijuana as a "medicine." The President directed ONDCP to lead an interagency task force responsible for developing a sound federal response. Members of this task force included: ONDCP and the departments of Justice, Treasury, Defense, Health and Human Services, Transportation, Labor, Education, and the Postal Service, and the Nuclear Regulatory Commission. ONDCP also sought input from prominent medical experts, elected state and local officials, Congressional delegations, drug prevention and treatment groups, law enforcement officials, community leaders, and concerned citizens. On December 30, 1996, the federal response was announced at a press conference with Attorney General Reno, Health and Human Services Secretary Shalala, Director of the National Institute on Drug Abuse, Dr. Alan Leshner, and myself.

**I. A Federal Response Based on Science, Not Ideology**

The logic of the federal response is simple: federal law remains in effect, and science must prevail over ideology. At the heart of the federal response is the preservation of the longstanding, established medical-scientific process for ensuring that any substance purporting to be a medicine must undergo the rigorous evaluation of the scientific process. This process has protected American citizens from snake oils, dangerous drugs, unproven substances and ineffective treatments for over fifty years. Because of this process, American citizens have faith that the drugs they take are both safe and effective. The government's position is that any substance provided or sold to the American public as a medicine must withstand the scrutiny of the same medical-scientific process to which all other potential medicines are subject. To exempt any substance from this time-honored procedure will undermine the established process that has long protected the American public so well.

The federal response on medical marijuana has four goals: 1) preserving the established scientific medical process for determining safe and effective medicines; 2) protecting our youth; 3) upholding existing federal law; and, 4) preserving drug-free workplaces. Attached is a copy of the federal response. (Tab A) All of the agencies listed in the response are undertaking the outlined activities to achieve these four goals.

#### **A. What Constitutes Good Medicine Should Not be Determined at the Ballot Box**

Referenda cannot protect American citizens from fraudulent claims and dangerous drugs. Nor can they ensure that potential medicines are subjected to a process of evaluation by both the Food and Drug Administration (FDA) and the National Institute of Health (NIH) based on sound science. A fundamental role of the FDA is to protect the public's health and safety by testing every potential medicine to ensure both their safety and efficacy. For a purely medical and scientific issue to be decided by popular referendum undercuts the safeguards established over the years by the Congress through the federal Pure Food and Drug Laws. Subverting the public health process and declaring smoked marijuana a "medicine" threatens the integrity of our established medical safeguards.

This issue has nothing to do with marijuana specifically; rather, it has everything to do with protecting the public health and safety of our citizens. Avram Goldstein, M.D., Professor Emeritus of Pharmacology at Stanford University, offers the following analogy: Imagine a ballot initiative to change the rules by which the Federal Aeronautics and Aviation (FAA)'s Air Traffic Control System manages commercial aircraft in California. It is disturbing to think that a well-funded activists in one state could establish different procedures from the rest of the country on a matter that clearly affects the well-being of all of us. If *sound* medical research demonstrates that there are medical uses for smoked marijuana, there are appropriate and responsive procedures for rescheduling this mind-influencing drug through the time-tested process. The FDA has already demonstrated flexibility in accelerating procedures for allowing the use of

emerging AIDS-related drugs without jeopardizing science or the public health.

### **B. Protecting the American Public from Unproven Substances Is Our Shared Responsibility**

The medical process for establishing substances as medications is well established and clear: the FDA evaluates clinical and laboratory data developed and submitted by outside scientists and clinicians to determine if the scientific evidence demonstrates that the benefits of the intended use of a particular drug outweigh the associated risks for that use. This process protects the public by ensuring that adequate scientific studies have been performed to provide a rational basis from which to conclude that the benefits of a drug outweighs its risks and by assuring that the product is accompanied by sufficient information to the physician and patient to permit its accurate prescription and use. Allowing any drug to bypass the federal approval process does a grave disservice to the public. Further, allowing any potential medication to bypass this process establishes a loophole that threatens to undermine the imperative for rigorous science as the basis for determining what constitutes good medicine.

### **C. Marijuana Remains a Controlled Substance**

Marijuana has not been approved by the FDA to treat any disease or condition. Because marijuana has a high potential for abuse and no currently accepted medical use in the United States, it remains a Schedule I drug under the provisions of the Controlled Substance Act, Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Moreover, the FDA, as reported by Associate Commissioner for Health Affairs Dr. Stuart Nightingale, has not been provided sufficient studies on smoked marijuana to permit the agency to determine if the potential benefits of smoking marijuana for specific indications outweigh the known risks associated with the drug. Absent sufficient scientific evidence, there is no rational basis for a change in the classification of marijuana. It is in the interest of every American to ensure the continued application of the medical-scientific process to determine the safety and efficacy of drugs for therapeutic uses.

### **D. No Rational Basis Exists for Exempting Marijuana From the Standard Approval Process -- Anecdotes Should Not Drive Public Health Policy**

We must ensure that all patients receive compassionate treatment using medicines proven to be safe and effective. However, the tragic lessons of history serve to remind us that hope and hearsay are not enough. Drug legalization proponents play on the sympathies all Americans share for those suffering from serious illnesses. We must do all that we can to minimize human suffering and to treat these tragic diseases. However, anecdotal claims about the medical benefits of smoked marijuana are insufficient grounds to subvert the protections Americans rely upon and deserve. In short, science provides no reason to exempt smoked marijuana from meeting the same rigorous standards

required by all substances purporting to yield medical benefit.

### **1. Smoked Marijuana Poses Risks for the Individual User**

The preponderance of scientific evidence to date demonstrates that marijuana is a dangerous drug. Marijuana is a contributing cause in the injury and death to users and non-users alike. Research shows that smoked marijuana, in addition to impairing normal brain function, also damages the heart, lungs, reproductive and immune systems. Recent studies show that regular, heavy marijuana use compromises the ability to learn and remember information primarily by impairing an individual's ability to focus, sustain, and shift attention. The PET scan, attached at Tab B, demonstrates the effects of marijuana on the normal neurochemical activity of the human brain. The four images at the top of the slide show normal brain activity. The four at the bottom show the brain activity of a marijuana abuser. The color red indicates the highest level of activity. Yellow, green, and lastly blue, show respectively diminishing levels of brain activity. Compared to the normal slides, the brain slides of the marijuana abuser clearly show diminished activity in all cross sections, particularly in the cerebellum. Lower cerebellar metabolism explains not only defects in motor coordination, but also seems to account for some of the reported learning disturbances found in chronic marijuana users. These effects are alarming among adults; they are extremely dangerous for adolescents.

### **2. Smoked Marijuana is a Significant Risk to America's 68 Million Children**

Medical marijuana initiatives present even greater risks to our young people. Drug use, in particular marijuana use, among our young people is already too high. The rate of drug use among our children is linked to their perceptions of risks related to drugs. Referenda that tell our children that marijuana is a "medicine" send them the wrong signal about the dangers of illegal drugs -- increasing the likelihood that more children will turn to drugs. Moreover, marijuana is a "gateway" drug, leading children into more harmful drug use and eventually addictions.

#### **a. Drug Use is Up Among Young People**

The results from the National Household Survey on Drug Abuse (NHSDA) over the past few years suggest that the general decline in drug use from the peak of the late 1970s may have ended. No significant changes -- either up or down -- in illicit drug use or in the total numbers of casual and hardcore users were reported in 1996, compared with 1992, 1993, 1994, or 1995. Current drug use appears to have stabilized at about 6 percent of the general population. However, illicit drug use by adolescents has been increasing steadily since 1992.

The rate of current drug use of any illicit drug among youth ages 12 to 17 was 10.9 percent in 1995. Although that figure dropped to 9 percent in 1996, the rate remains markedly higher over 1992's low of 5.3 percent. Marijuana represents the bulk of this

increase in drug abuse among children. According to the 1996 NHSDA, the rate of past-month marijuana use among children ages 12 to 17 was 7.1 percent, more than double the 3.4 percent long-term low for 1992. The consequences of youth marijuana use are devastating; over half (55 percent) of all youths ages 15-17 admitted to drug treatment, were seeking treatment for marijuana. (SAMHSA Office of Applied Studies.)

The 1997 *Back to School Survey* conducted by the Center on Addiction and Substance Abuse (CASA) at Columbia University also found that drug use is becoming more commonplace for our young people. The study found that an increasing number of children had been exposed to: deaths from substance abuse-related incidents, kids coming to school drunk or high, smoking, drinking and drug sales on school grounds, students expelled or suspended for possessing, using or selling drugs, and parties where marijuana is available. The study further found that teens are more likely to see drugs sold at school than in the neighborhood -- 41 percent of high school students have seen drugs sold at their schools, while only 25 percent have seen them sold in their neighborhoods. The 1997 CASA study also found that 74 percent of high school students and 52 percent of middle school students say a student has been expelled or suspended for possessing, using, or selling drugs in the past year. 56 percent of high school students and 24 percent of middle school students have attended a party in the past six months where marijuana was available.

#### **b. Attitudes Determine Behaviors**

The University of Michigan's annual *Monitoring The Future* (MTF) survey of drug use among youth, the preeminent report on juvenile attitudes and drug use rates, shows that as our children become more accepting of drug use and less fearful of its consequences, they increasingly use marijuana and other drugs of abuse.

- According to the MTF Survey, youth attitudes about drugs began to soften in 1989. These changes were reflected by lowered rates of disapproval and diminished perceptions of drug use as risky. Two years later, marijuana use by our children began to increase. The MTF reports that marijuana use among 8th graders was 3.2 percent in 1991, and increased each year thereafter to a rate of 11.3 percent in 1996.
- The MTF also reports that the rate of marijuana use among 10th and 12th graders began to increase in 1992. Twelfth graders' use increased from 11.9 percent in 1992 to 21.9 percent by 1996; 10th grade use increased from 8.1 percent in 1992 to 20.4 percent by 1996.

Dr. Lloyd Johnston, who has directed the MTF survey since the 1970s, suggests "generational forgetting" as a major factor contributing to the five-year trend (1991-1996) of increased drug use among our children. His theory holds that as new generations have less direct experience with the negative consequences of

drug use, the likelihood that they will begin using drugs increases. Dr. David Musto of Yale University has also documented this phenomenon of learned experience informing decisions to use drugs since the turn of the century. Clearly, when people see firsthand the pernicious effects of illegal drugs, they tend to reject them. This may be one of the reasons past-month marijuana usage rates declined from 10.9 percent to 9 percent in 1996 among those ages 12 to 17 (NHSDA).

Changing youth attitudes toward marijuana and other drugs is the key to reducing drug use among our children. We cannot afford any further erosion of youth attitudes towards drugs by allowing marijuana to be falsely depicted as a safe and effective medicine. When Americans think of smoking marijuana, erroneously the image they remember is "Cheech and Chong." Whether intended or not, permitting the "medical" use of smoked marijuana will send the a false and powerful message to our adolescents that marijuana use is beneficial. If pot is medicine, teenagers rightfully will reason, how can it hurt you? At a time when we need to be reaching out to our young people and explaining the dangers of drug use, we can ill afford to send our children a mixed -- or more accurately a mixed up -- message on marijuana. No one should make the mistake of believing that increased societal acceptance of marijuana will not cause drug abuse to increase among our children.

### **c. Marijuana is a "Gateway" Drug**

The danger of sending the wrong message to our children about marijuana is compounded by the fact that smoking marijuana can often be the first step down a slippery path that leads to the use of drugs like cocaine, heroin, LSD, and methamphetamine. Most young people who smoke marijuana do not end up addicted to drugs. However, NHSDA reports and research by the Center on Addiction and Substance Abuse at Columbia University (CASA) both establish a strong correlation between marijuana use and cocaine use. Among those young people who have tried cocaine, virtually all used marijuana first.

CASA's October 1994 report on *Cigarettes, Alcohol, Marijuana: Gateways to Illicit Drug Use*, concluded that a 12 to 17-year old who uses marijuana is 85 times more likely to use cocaine than one who does not. This statistical correlation is 8 times stronger than the link between smoking and lung cancer, 17 times stronger than the link between exposure to asbestos and lung cancer and, 20 times stronger than that between high cholesterol and heart disease. The report also found that the earlier children begin to smoke marijuana, the more likely they are to subsequently use cocaine. Sixty percent of children who used marijuana before the age of 15 progressed to cocaine use, while only 20 percent of those who began smoking marijuana after the age of 17 did so.

These strong statistical correlations should inform both individual behavior and public policy. Parents, mentors, and children should conclude that smoking marijuana is not innocuous. All of us should understand that anything that directly

or indirectly causes increased marijuana use by our children also paves the way for increased "hard" drug use and addiction.

### **3. Drug Availability Leads to More Abuse and Addiction**

Allowing the medical use of smoked marijuana would also likely increase the availability of marijuana, thereby increasing the risks of widespread drug use. As drugs become more available, abuse and addiction rise. By allowing marijuana to be legally grown, and used, medical marijuana initiatives are likely to increase the amount of marijuana that is available on our streets and in our schools for illegal use. The burgeoning number of cannabis clubs creates a huge potential for diversion to the streets, where teenagers comprise a lucrative target market. The potential for black market spillover is heightened because the referenda that are at issue provide little or no effective medical or law enforcement supervision of the use of marijuana. For example:

- California Proposition 215 fails to define both what constitutes a "caregiver" and the "conditions" for which marijuana could be used. Given that some advocates claim marijuana can be used to help everything from writer's cramp to diarrhea, virtually anyone possessing marijuana could claim some "caregivers" relationship to someone with some form of "condition." Because 215 contains no age limitation, a child could legally use marijuana on a verbal -- or even Internet -- recommendation of any physician, even without an examination.
- District of Columbia initiative, "Measure 57," provides that up to 20 people would be allowed to cultivate and sell unlimited quantities of marijuana for an individual with a condition drawn from a similarly amorphous range of conditions. If this initiative were to become law, drug traffickers would be basically shielded from successful prosecution.

The law of supply and demand suggests that increasing the supply of marijuana available in the United States will cause the price of marijuana to drop even more and the psychoactive properties of the drug to further increase.

### **4. Science Documents the Risks of Marijuana Use to Individuals and Society**

For decades, U.S. policy-makers have opposed the legalization of marijuana based on the weight of the available scientific evidence. Marijuana advocates have mounted a well-financed and sophisticated public relations campaign to persuade Americans of their point of view. These deceptive public relations efforts have relied almost exclusively on personal anecdotes to support their position. Anecdotes aside, the scientific data currently available paint a strikingly different picture from the image those who support legalization would have the American public see.

For example, two recent research studies, published this past

June in *Science*, have demonstrated disturbing similarities between marijuana's effects on the brain and those produced by highly addictive drugs like cocaine, heroin, alcohol, and nicotine. According to David Friedman, M.D., a neurobiologist at Bowman Gray School of Medicine, these studies "send a powerful message that should raise everyone's awareness about the dangers of marijuana use."

Meanwhile, misconceptions about marijuana continue to abound. Confused by conflicting messages, it is no wonder that many Americans, especially our youth, do not understand what current scientific research is teaching us about the damaging effects of smoked marijuana. Current research points to serious risks for society. Marijuana smoke contains cancer-causing compounds, reduces workplace productivity, and is increasingly prevalent in automobile accidents and youth fatalities. Examples of recent findings include:

- A roadside study, conducted in Memphis, Tennessee, of reckless drivers not believed to be impaired by alcohol, found that 45 percent tested positive for marijuana. (Brookoff D et al., *Testing Reckless Drivers for Cocaine and Marijuana*, New Eng J Med 320:762-768, 1994.)
- Marijuana impairs coordination, perception, and judgment, causing many accidents. A study of 1023 trauma victims revealed that marijuana had been used by 34.7 percent. (Soderstrom CA et al., *Marijuana and Alcohol Use Among 1,023 Trauma Patients*, Archives of Surg 123:733-737, 1988.)
- One study conducted at the R Adams Cowley Shock Trauma Center, University of Maryland Medical Center, Baltimore, found that 34 (32.1 percent) of the 106 motorcyclists treated for injuries tested positive for marijuana. (Soderstrom CA et. al., *Psychoactive Substance Use Disorders Among Seriously Injured Trauma Center Patients*, JAMA. 277 (22): 1769-74, 1997 Jun 11.)
- A study of 182 fatal truck accidents revealed that 12.5 percent of the drivers had used marijuana, in comparison to 12.5 percent for alcohol, 8.5 percent for cocaine, 7.9 percent for stimulants. (Department of Transportation. National Transportation Safety Board Report, Washington, D.C., February 5, 1990.)
- The most consistent finding from the literature on employee marijuana use is its association with increased absenteeism. It is also associated with increased accidents, higher turnover, low job satisfaction, counterproductive behavior, withdrawal and antagonistic behavior, and higher use of employee assistance programs and medical benefits. (NIDA National Conference on Marijuana Use: Prevention, Treatment and Research, 1995.)
- Treatment figures show that 141,000 Americans were admitted in 1995 to drug treatment programs for marijuana

addiction. Over half (55 percent) of all youths ages 15-17 admitted to drug treatment, were seeking treatment for marijuana. (SAMHSA Office of Applied Studies.)

## **II. Safeguarding the Public Health**

### **A. ONDCP's Efforts to Inform Decision-makers and the Public**

In order to preserve the protections enjoyed by our citizens, ONDCP will continue to provide assistance to state legislatures and urge them to support the federal response based on science. Our efforts to date include the widespread dissemination of the *ONDCP Policy Statements on Marijuana for Medical Purposes* and on *Industrial Hemp*. These policy statements have been sent to the governors of all the states, law enforcement agencies, and numerous nongovernmental organizations. (Copies of these statements can be found under Tab D (Medical Marijuana), and Tab E (Industrial Hemp).) In addition, ONDCP has also focused further efforts to inform the public and decision-makers as to the dangers of medical marijuana referenda in those states where such initiatives are under strong consideration. (States that are currently considering initiatives to allow the medical use of marijuana are outlined in map format under Tab F.)

### **B. ONDCP's Efforts Demonstrate the Federal Commitment to Science Over Ideology**

#### **1. Scientific Studies**

The efforts of the Department of Health and Human Services and ONDCP demonstrate the federal government's commitment to and reliance upon the scientific process as the appropriate means to determine the potential medical use, if any, for smoked marijuana. To that end, we have supported the following actions:

- ☐ **Institute of Medicine (IOM) Study:** In January 1997, ONDCP commissioned the IOM of the National Academy of Science (NAS) to conduct a comprehensive review of the known health effects and potential medical use of smoked marijuana. This evaluation is now assessing the current state of scientific knowledge; identify gaps in the knowledge base about marijuana; and will include clinical, medical, and scientific evidence on the following topics:
  - ☐ the neurological mechanism of action of marijuana;
  - ☐ the effects of marijuana on health and behavior;
  - ☐ marijuana's possible "gateway" characteristics;
  - ☐ the efficacy of therapeutic use of marijuana for specific medical conditions; and,
  - ☐ the effects of marijuana use compared with approved alternative psychotherapies.

The IOM has selected two "Principal Investigators" to conduct the study. These Investigators will now solicit additional expertise from universities, health professional schools, medical centers, hospices, state and local health departments, and other resources as appropriate. There will be three public meetings, at least one will be held on each coast, to foster maximum input. The final report will be released to the public upon completion in December 1998. We look forward to sharing these results with the subcommittee and the other members of Congress as they become available.

- **The National Institutes of Health (NIH) Workshop on Medical Utility of Marijuana:** In February, 1997, the NIH convened a 2-day meeting to review the scientific data concerning the potential therapeutic uses for marijuana and the need for and feasibility of additional research. The Ad Hoc Group of Experts received testimony from recognized experts in the field as well as public testimony. In August 1997, this group of experts released their report to the NIH, which is currently reviewing its substance and conclusions.

The panel concluded that the risks associated with marijuana, especially smoked marijuana, must be considered not only in terms of immediate adverse effects on the lungs, but also the long-term effects in patients with chronic diseases. The experts also were concerned about the possibility that frequent and prolonged marijuana use might lead to clinically significant impairments of immune system function is great enough that studies on immune function should be part of any research project on the medical uses of marijuana. This is especially true in studies involving patients with compromised immune systems. Members of the group also were concerned about the effects of the dangerous combustion byproducts of smoked marijuana on patients with chronic diseases. Based on these risks, they favored the development of a smoke-free inhaled delivery system that could provide to the patient purer forms of marijuana's most active ingredient, delta-9-tetrahydrocannabinol (THC), or its related compounds known as cannabinoids.

According to Dr. Harold Varmus, the NIH is open to receiving research grant applications for studies of the medical efficacy of marijuana. Applications will undergo the normal scientific review process. NIH is prepared to fund applications that meet the accepted standards of scientific design and that, on the basis of peer review, are competitive with other applications that qualify for funding.

- **Development of Alternative Delivery Systems for THC:** THC, the major psychoactive ingredient in the marijuana plant, is already available as a synthetic FDA-approved medication known as "Marinol," which is taken by mouth. Like all drugs authorized by the FDA, Marinol has proved itself safe and effective in valid clinical trials for the control of nausea and for wasting due to AIDS. THC has not been shown to be safe and effective for any other

condition. Like almost all drugs used in modern medicine -- for reasons of quality control and safety -- THC is a pure substance, not a crude and variable mixture in a plant.

ONDCP has met with pharmaceutical representatives to determine their time-table for the development of alternative delivery systems such as inhalers, skin patches, and/or suppositories. Development of these alternative delivery systems over the next 2-5 years will provide a safer means of delivering THC. Efforts are now underway to educate physicians regarding the efficacy and availability of Marinol as well as proper dosing strategies to achieve maximum therapeutic effect.

## **2. Recent Advances Have Increased the Availability of Effective Medications**

In addition to the scientific efforts being undertaken by the government, medical research in general is increasing the availability of other effective treatments that stand to render any potential need for medical marijuana as obsolete. Philip Kanof, M.D., Ph.D., a distinguished psychiatrist and pharmacologist at the VA Medical Center in Tucson, raises an important question: How many individuals truly are unable to obtain relief with appropriate use of existing FDA-approved medications? According to Dr. Kanof, newer 5HT<sub>3</sub> receptor antagonists such as ondansetron and granisetron have been very successful in managing nausea and vomiting in most chemotherapy patients. Drugs such as baclofen, benzodiazepines, and the newly approved tizanidine often produce significant relief from spasticity due to multiple sclerosis. And, as previously mentioned, Marinol is often effective in stimulating appetite in those AIDS patients suffering from a wasting syndrome.

To the extent that patients are suffering, it is important to question the degree to which their suffering is caused by their inability to obtain relief from existing medications, or because their physicians may not be as well informed as they might be about existing therapeutic options. Dr. Kanof urges that the first step towards alleviating the suffering of these patients should be the dissemination of algorithms for appropriate pharmacological management of these conditions -- not encouraging the use of a carcinogenic drug with no accepted medical uses and significant abuse potential.

## **C. ONDCP is Working to Change Perceptions of Drug Use Among Our Nation's Youth**

Regardless of whether smoked marijuana eventually demonstrates scientific merit for medical use, the number one goal of the *National Drug Control Strategy* remains that of educating and enabling youth to reject illegal drugs. ONDCP has developed a clear and powerful objective to meet that goal: the proposed Anti-drug Abuse Youth-Oriented Media Campaign. We recognize the tremendous power of the media in driving public opinion. Young people are particularly susceptible to the influences of television, the Internet and radio. Unfortunately, in recent years the number of drug-related public service

announcements (PSAs) carried by television, radio, and print media have decreased markedly.

At the same time, there has been an increase in music, TV, movies, Internet web sites, fashion, humor, and other forms of communication that normalize or glamorize illegal drugs. Advertising experts believe targeted, high-impact paid media ads are the most cost-effective, quickest means of changing patterns of drug-use behavior by altering adolescent perceptions of danger and social disapproval of drugs. It is also the most effective means of reaching baby-boomer parents who may be ambivalent about sending strong anti-drug messages to their kids.

America needs to reverse the trends of youth drug use and diminishing PSAs by developing a public education campaign that supplements anti-drug announcements already offered by dedicated organizations like the Partnership for a Drug-Free America and the National Center for Advancement and Prevention. Youth will be warned about the hazards of illegal drugs and shown the advantages of a drug-free lifestyle. Information-based material will be repeated with sufficient frequency to reinforce learning and motivate youth to reject illegal drugs.

### **III. A Shared Commitment**

Addressing the problem of drug use in America will only be possible through a shared commitment to progress. The bipartisan support of Congress has been instrumental to the work of the Office of National Drug Control Policy. We welcome and look forward to your continued help on a range of initiatives, including, but not limited to:

- ☐ Passage of ONDCP's reauthorization;
- ☐ Protection of the time-proven system that shields Americans from bad medicine;
- ☐ Approval of the Anti-drug Youth-Oriented Media Campaign; and,
- ☐ Assistance with restoring the Administration's budget request in drug-related areas, particularly with respect to the Safe and Drug Free Schools Program.

Your support for these and other initiatives is vital to continued progress in decreasing the use of illegal drugs in America.

Thank you for this opportunity to testify on the issue of medical marijuana referenda in America. ONDCP remains committed to addressing this issue on the basis of sound science. The American public has the right to expect that our medicines are both safe and effective. It is our job -- Congress and the Administration working together -- to protect our citizens, in particular America's children. We look forward to a continued bipartisan effort to uphold the highest standards of American medicine while ensuring that our youth are equally protected.

**To:** Sarah for Sandy Thurman and Todd Summers  
**Fax #:** 632-1096  
**Re:** Testimony  
**Date:** March 11, 1998  
**Pages:** 14, including this cover sheet.

**FACSIMILE**

From the desk of...

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## Marijuana Policy: Then and Now

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criminal issue. It is also a medical issue."

#### **MANDATORY MINIMUMS TOO EXPENSIVE, SAYS RAND**

On May 13, the Rand Corporation announced findings of a quantitative research study comparing the cost effectiveness of mandatory minimum sentences with other drug policy sanctions, including conventional law enforcement methods and drug treatment programs for hard-core users. *Mandatory Minimum Drug Sentences: Throwing Away the Key or the Taxpayers' Money?* concludes that the most cost-effective way of dealing with the cocaine trade is to treat hard-core users rather than threatening distributors with mandatory minimum sentences.

Rand's research model was designed to answer the question: What would happen to overall cocaine consumption if an additional \$1 million were spent on different approaches? Spending the extra \$1 million on mandatory sentences for cocaine dealers, who otherwise would have been sentenced to non-mandatory sentences, would reduce cocaine consumption by 28.6 pounds annually. If the \$1 million is spent to arrest, confiscate the assets of, prosecute, and incarcerate more cocaine dealers for conventional prison terms, the resulting reduction in cocaine consumption would be just over 59.4 pounds. If the \$1 million is spent to treat heavy users of cocaine, Rand calculated that cocaine consumption would be decreased by a little over 220 pounds. Rand estimated that current cocaine consumption is 321 tons a year.

The researchers point out that placing hard-core users into treatment can reduce overall demand, thereby making the market less profitable. Rand assumes that lower profits will attract fewer dealers because the possible risks will outweigh the possible benefits.

To get the report, contact Rand at 1700 Main St., P.O. Box 2138, Santa Monica, CA 90407-2138; tel. (310) 451-6915; email: [order@rand.org](mailto:order@rand.org); Web: [www.rand.org](http://www.rand.org).

#### **NEW ENGLAND JOURNAL ARTICLE DEFENDS PROP. 215**

Writing in the August 7 edition of the *New England Journal of Medicine*, Boston University Professor George Annas endorsed more research into marijuana's medical potential, without making patients wait for the drug. "Research should go on," Annas wrote, "and while it does, marijuana should be available to all patients who need it to help them undergo treatment for life-threatening illnesses."

Annas's article examines the California medical marijuana law enacted by voters last November and discusses its implications for physicians. "[O]pposition to the legalization of marijuana generally is not a good reason to keep it from patients who are suffering," Annas concluded.

The article, "Reefer Madness: The Federal Response to California's Medical-Marijuana Law," is in vol. 337, no. 6 of the *Journal*, and is available online: <http://www.nejm.org:80/public/1997/0337/0006/0435/1.htm>. The *Journal's* editor-in-chief endorsed moving marijuana to Schedule II in a January 30 editorial ["Federal Foolishness & Marijuana," *DPL*, Winter/Spring 1997].

#### **INSIDE THE BELTWAY**

##### **NIH PANEL SUPPORTS MEDICAL MARIJUANA RESEARCH**

A panel of experts convened by the National Institutes of Health acknowledged marijuana's medical potential in an August 8 report, but called for "more and better studies" to measure the potential. The report summarizes a two-day meeting last February ["NIH Urges Research into Marijuana," *DPL*, Winter/Spring 1997, p. 14], which was convened to review marijuana research, in response to the medical marijuana-related initiatives that were passed in Arizona and California last November.

Panel chair Dr. William Beaver, professor of Pharmacology and Anesthesia at Georgetown University's School of Medicine, summed up the panel's conclusions thus: "[M]arijuana looks promising enough to recommend that there be new controlled studies done" for specific medical indications, including appetite stimulation, nausea and vomiting following anticancer therapy, neurological and movement disorders, analgesia, and glaucoma.

The panel said one of the reasons that better research studies are needed is because human studies of marijuana's pharmacology have been limited and inconsistent. The panel found that much of what is known about the effects of smoked marijuana on people is inferred from studying only one of marijuana's active ingredients, delta-9-THC.

Although not asked to address marijuana's legal classification, the panel attached an appendix noting that marijuana's Schedule I status adds "regulatory burden and time delays," which means that "many researchers have been discouraged from pursuing research" on marijuana.

Reform advocacy groups hailed the report as proof that the government had been ignoring marijuana's medical potential. The Marijuana Policy Project circulated positive comments made by most panelists during its closed-door roundtable meeting in February (see [www.mpp.org](http://www.mpp.org)).

Copies of the panel's report are available from NIH at (301) 496-5787 and is online at <http://www.nih.gov/news/medmarijuana/MedicalMarijuana.htm>.

##### **NEEDLE EXCHANGE UPDATE: NEW BILL SEEKS TO LIFT THE BAN; AMA AND ABA EXPRESS SUPPORT; NEW COALITION PLANS RALLY**

On August 4, U.S. Representatives Elijah Cummings (D-Md.) and Nancy Pelosi (D-Calif.) introduced H.R. 2212, "The HIV Prevention Outreach Act," which would allow states to use federal AIDS prevention funds to support needle exchange programs (NEPs). This bill, if enacted, would lift the ban on federal funding of NEPs.

Both representatives are pushing for hearings and they are seeking needle exchange clients to testify. According to Cummings, "The bottom line is that giving clean needles to addicts saves lives."

Cummings held up Baltimore's NEP, which is in his district, as a successful program based on an evaluation by Johns Hopkins University. But, he added, "I am fully aware that the idea of exchanging ... needles makes some of my colleagues in Washington uncomfortable. But, as successful as the Baltimore needle exchange program has been,

people are still dying everyday needlessly because the federal government will not financially support ... these programs."

Both the American Medical Association and the American Bar Association have recently supported increased access to and funding for clean needles and syringes nationwide.

In June, the American Medical Association's policy-making House of Delegates voted in favor of ending the ban on federal support for NEPs. The AMA resolution called for the encouragement of "extensive application of needle and syringe exchange and distribution programs and the modification of restrictive laws and regulations concerning the sale and possession ... to maximize the availability of needles and syringes." The AMA's resolution was released in conjunction with their "Physician's Guide to HIV Prevention," which calls on doctors to help patients reduce the likelihood of acquiring HIV.

In San Francisco on August 5, the American Bar Association adopted a resolution stating that the ABA supports "the removal of legal barriers to the establishment and operation of approved needle exchange programs that include a component of drug counseling and drug treatment referrals."

Frustrated by the Clinton administration's refusal to lift the ban on federal funding of needle exchanges, the National Coalition to Save Lives Now, a network of NEP support groups, is organizing a demonstration in front of the U.S. Department of Health and Human Services for noon on September 17. The demonstration will emphasize the public's growing anger at the administration's disregard for the large body of research indicating that exchanges are effective in saving lives and tax dollars. For more information or to become involved, contact Chris Lanier at the Coalition: phone: (212) 213-6376; fax: (212) 213-6582; email: ncsln@dti.net.

#### **CLINTON AND THE SENTENCING COMMISSION COMPROMISE ON THE CRACK/POWDER COCAINE SENTENCING DISPARITY**

In July, the Clinton administration recommended that the crack cocaine/powder cocaine sentencing disparity be reduced from a 100-to-1 to a 10-to-1 ratio. In a June 3 letter to President Clinton, Attorney General Janet Reno and White House drug policy advisor Barry McCaffrey agreed that there should be far less disparity between crack and powder cocaine under the sentencing guidelines.

Despite drug policy advisor McCaffrey's view that a "1-to-1 [ratio] made more sense," White House officials ultimately agreed with Attorney General Reno that crack cocaine must be punished more harshly due to its continued association with greater violence.

In April, the U.S. Sentencing Commission advised Congress to revise the "federal statutory penalty structure scheme for both crack and powder cocaine offenses." In 1995, the Sentencing Commission unanimously recom-

mended that Congress eliminate the disparity entirely.

However, Congress and the administration rejected the 1995 recommendations. The 1995 directive instructed the commission to consider its findings further and submit proposed changes to federal law and sentencing guidelines for cocaine offenses. For the next two years, the commission reviewed research and consulted law enforcement officials, drug abuse experts, and treatment providers. Following the review, commission officials provided specific recommendations for revising federal sentencing guidelines without eliminating the disparity.

Current guidelines impose a five-year mandatory minimum for those convicted of possessing five grams of crack or 500 grams of powder cocaine. The commission's April recommendation to Congress calls for five-year minimum sentences for possessing between 25 and 75 grams of crack or for having between 175 and 350 grams of powder cocaine. The Clinton administration chose a 10-to-1 ratio: 25 grams for crack, 250 grams for powder.

Both the president's and the Sentencing Commission's recommendations await congressional action.

#### **HOUSEHOLD SURVEY REPORTS DIPS IN YOUTH DRUG USE**

The National Household Survey on Drug Abuse (NHSDA) found that youth drug use dipped in 1996, ending a series of increases reported by teenagers since 1992. The decrease in youth drug use from 1995 to 1996 occurred among the younger part of the 12-17 year-old age group. The declines included a slight, but statistically insignificant, drop in reported past-month marijuana use by 12-17 year-olds.

The NHSDA is different from the University of Michigan's annual high school survey, which measured students' preferences in early 1996. NHSDA was conducted in each quarter of 1996. The University of Michigan survey found increases in youth drug use, including a 1.1 percent increase in past-year marijuana use by 12th graders and a 4.9 percent increase by 10th graders.

Clinton administration officials were guardedly optimistic about the survey results, the first measured decline in youth drug use since President Clinton took office.

The Household Survey is usually interpreted by politicians as a pass/fail test of drug policy, but it can demonstrate in other ways how practical the current drug policy is. For example, in 1996 the NHSDA estimated that 23.1 million people had used an illegal drug within the past year. The problem with a law-enforcement-dominated policy is that the number of yearly users in 1996 was 14.4 times greater than the number of people behind bars for all offenses (1.6 million), according to Justice Department statistics.

The Substance Abuse and Mental Health Services Administration conducts the survey, which interviewed approximately 18,269 people aged 12 and older as a representative sample of the civilian, noninstitutionalized population. The results of the survey can be viewed on the SAMHSA Web site at: [www.samhsa.gov](http://www.samhsa.gov).

## **INTERNATIONAL**

### **SWISS HEROIN MAINTENANCE PROVES SUCCESSFUL; AUSTRALIAN AND DUTCH EXPERIMENTS IN THE WORKS**

The Swiss Federal Office of Public Health declared its three-year heroin maintenance experiment a success when it released the final report on July 10. The researchers found that crime dropped by 60 percent, unemployment among participants fell by half, and significant public funds were saved due to a reduction in the costs of criminal procedures, imprisonment, and disease treatment.

In January 1994, the Swiss government began a multi-year, multi-city scientific trial to provide injectable and oral morphine, methadone, and heroin to long-term addicts to assess the effects on their health, social integration, and behavior. Some participants were able to use heroin-laced cigarettes, and one pilot study examined the use of cocaine-laced cigarettes. The program was not free for participants, who paid approximately \$13 a day for their drugs and other services [see *DPL*, Summer 1995, p. 12; *DPL*, Winter/Spring 1997, p. 16].

The program was directed by Prof. Dr. Ambros Uchtenhagen of the Institute for Social Psychiatry in Zürich. It was comprised of 1,146 patients in seven cities at 18 treatment centers. The study found that the retention rates were high for both six- and 18-month research periods. Patients in maintenance programs showed improvements in physical health, mental health, and social situations (e.g., housing, hygiene, employment) as well as a reduction in new HIV infections. The study additionally found that criminal activities by participants decreased, resulting in a "significant" decrease in court convictions. Findings also suggest that patients' income from criminal activity "decreased dramatically."

The researchers concluded that "the continuation of heroin-assisted treatment can be recommended for the indications described in this research as long as the general organizational and operational conditions set out in the research protocol are established."

The Swiss government report is available on the Lindesmith Center's Web site at: <http://www.lindesmith.org/presumm.html>.

Soon after the release of the Swiss report, the Australian government decided to move forward with its own heroin maintenance experiments. On July 31, the Ministerial Council on Drug Strategy approved the project, which plans to maintain 40 registered heroin addicts in the capital city of Canberra for the first phase of the project. If successful, Phase 2 will involve 250 Canberra addicts, and Phase 3 will include 1,000 addicts in Canberra and two cities in other territories.

Before the heroin maintenance trials can commence, approval must be obtained from the United Nations' International Narcotics Control Board. The earliest approval could be granted is February 1998, and the earliest the trials could begin is July 1998.

Though approved by the Australian government, the

## **HOT OFF OF THE PRESSES**

Craig Reinerman and Harry Levine, editors:  
***Crack in America: Demon Drugs and Social Justice***

Professors Reinerman and Levine present a collection of articles on the sociology of crack use, and recommend a harm reduction reform of crack policy. Sections include one devoted to international perspectives and one analyzing the effects of prohibition.

*Published by University of California Press: (800) 822-6657  
paperback, 388 pages (1997), \$17.95*

Lester Grinspoon, M.D., and James B. Bakalar:  
***Marihuana, the Forbidden Medicine (revised & expanded)***

This new edition features an expanded list of symptoms and disorders treatable with cannabis, new case studies, and an updated argument about making the drug available as a medicine. The authors provide a strong defense of the usefulness of anecdotal evidence.

*Published by Yale University Press: (800) 987-7323  
paperback, 296 pages (1997), \$16*

Lester Grinspoon, M.D., and James B. Bakalar:  
***Psychedelic Drugs Reconsidered (reprint)***

This book is the first Drug Policy Classic Reprint by the Lindesmith Center. This 1979 book surveys the history and use of hallucinogens and assesses their potential uses. Includes a new introduction by the authors and a preface by Lindesmith Director Ethan Nadelmann.

*Distributed by Bookworld Companies: (800) 444-2524, or visit  
[www.bookworld.com](http://www.bookworld.com)  
paperback, 385 pages (1997/1979), \$12.95*

heroin trials have met with the ire of U.S. State Department officials. According to the *Sydney Morning Herald* ("The Real Drug War: Why the U.S. Won't Let Australia Reform its Drug Laws," July 19), Robert Gelbard, assistant secretary of state for narcotics and law enforcement, was not happy with Australia's attempts to reform its drug policy when he visited that country in January 1996. He reportedly was "scathing" in his views of the Swiss heroin trials, and was quoted as saying, "The United States government viewed with concern any countries who appear to be or are actively considering liberalization of drug laws."

[EDITOR'S NOTE: At press time, Australia's federal Cabinet decided not to pass the necessary legislation to allow heroin to be imported for the trial or provide financial support for it. Michael Moore, an Independent member of the Australian Capital Territory Legislative Committee and a 1994 DPF awardee, said of the decision, "It was made on ignorance and it was built on fear...." See the next Letter for more details.]

The Dutch government's Central Commission on Heroin Maintenance has proposed that heroin maintenance experiments begin with 750 addicts in March 1998. The cities that may participate in the experiment are Amsterdam, Rotterdam, Utrecht, Groningen, The Hague, and Heerlen. ♦

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# Programme for a Medical Prescription of Narcotics:

Final Report of the Research Representatives  
*Ambros Uchtenhagen, Felix Gutzwiller and Anja Dobler-Mikola (Eds.)*

## Summary of the Synthesis Report

*Uchtenhagen, A. "Summary of the Synthesis Report." In Uchtenhagen, A., Gutzwiller, F., and A. Dobler-Mikola (Eds.), Programme for a Medical Prescription of Narcotics: Final Report of the Research Representatives (1997). Zurich: Institute for Social and Preventive Medicine at the University of Zurich.*

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*This synthesis report is available from the Swiss Federal Office of Public Health in Berne, and from the Addiction Research Institute in Zurich.*

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*To be presented at the media conference on 10 July, 1997, in Berne, Switzerland.*

The Medical Prescription of Narcotics Programme (PROVE) was designed according to scientific tenets and criteria. A detailed research protocol was drawn up to govern the threeyear collection of data for analysis. It also describes the methods and times of the data collection as well as the rules governing data transfer and data protection- Data collection began on 1 January 1994 and ended on 31 December 1996. The objectives of the study concern the effects of the prescribed narcotics--the effects on the health, social integration and dependent behaviour of the research participants; the suitability of this treatment for heroin dependents whose previous therapy had been unsuccessful, and the effectiveness of this treatment compared with that of other therapies currently available.

The general conditions for the conduct of the programme are described in the programme's research plan of 1 November 1993, based on the Swiss government decree of 21 October 1992. They set out the admission criteria for patients, the modalities of treatment and safety regulations. The admission criteria stipulated a minimum age of 20 years, a history of heroin dependency of at least 2 years, and participation in other treatments had to have failed on several occasions- An indication of the adverse affects of drug use on health and/or social relations also had to be present. The injections of prescribed narcotics had to be given under supervision and injectable narcotics could not be taken home. The treatment had to involve the provision of psychosocial care as well as the prescription of narcotics.

In accordance with the government decree, the narcotics to be tested in the programme were morphine, methadone and heroin for intravenous and oral use- In addition, use of the cigarette form of heroin was examined, and a pilot study was conducted based on the use of cocaine cigarettes.

The research issues which were to be analysed, therefore, span a wide range of topics relating to the pharmacology and toxicology of the prescribed substances: the participants' state of health lifestyle and dependent behaviour: the practicability of the study and its economic viability.

## Research plan and organisation

A research plan governing the distribution of the different narcotics amongst the patients was drawn up to deal with these issues. Two double-blind studies (the prescribed substance is not known to either the patient or the therapist), three randomised studies (treatment is allocated by randomisation) and eleven studies with individual indications (treatment is allocated after discussion with the patient) were set up. The feasibility of each was tested on three occasions in a methadone outpatient clinic and once in a penal institution. One treatment centre was allocated the prescription of intravenous and oral methadone only. On the basis of initial treatment findings, the original plan for the distribution of treatment places was modified; this, however, did not necessitate any amendments to the research protocol itself. A second series of additional treatment centres was approved in order to increase the scope of the research issues.

A total of 18 treatment centres were approved: one was in a penal institution, the others were all outpatient clinics. They were located in Basel, Bern, Biel, Fribourg, Geneva, Horgen, Lucerne, Olten, St Gallen, Solothurn, Thun, Wetzikon, Winterthur, Zug and Zurich. One application was withdrawn, one refused, and one approved treatment centre was not, in the event, set up.

In view of the large number of treatment centres involved and the range of research issues to be addressed, a clear organisation of the research, including uniform rules about powers and responsibilities as well as the flow of data, was needed. A particularly rigorous audit of the programme's research procedures was also required. An independent research team were mandated the tasks of devising the research protocol, data collection procedure and analysis, and the write-up of reports. Even before the start of the study, the programme's research protocol and research plan had been submitted to the supraregional Ethics Committee of the Swiss Academy of Medical Sciences for approval. Similarly each individual treatment centre had obtained the prior approval for its project from a regional or local ethics committee. The Federal Data Protection Officer checked that the relevant provisions were observed. In addition, a national specialist group was established to oversee and assess the activities of the research team. An additional specialist group (the Safety Assurance Group) was responsible for checking and analysing in detail any side-effects of the prescribed substances.

At the request of the INCB (international Narcotics Control Board), an international specialist group was appointed by the World Health Organisation to appraise the overall research programme and results.

## Overview of research studies and data sources

This summary report incorporates the results of a series of studies mentioned below.

The main study was primarily focused on the participants and their characteristics on admission, during and on leaving treatment or on switching to another treatment programme. The information was derived from periodic interviews with the patients, conducted by specially trained interviewers. It also includes the daily treatment data on all prescribed narcotics (recorded electronically at the treatment centres). In addition, the main study examines the Organisation of the treatment centres, narcotics dispensation, the professional background of the staff and the problems which arose during treatment. This information was obtained from periodic interviews with project managers.

Special medical studies examined trials carried out according to specific methodological designs (double-blind and randomised studies); side-effects of the prescribed substances; pregnancies which occurred during treatment; deaths, the pharmacological properties of the heroin injected and the trial of

non-injectable heroin products. The data were collected and analysed according to the terms outlined in the relevant research protocols. Special social science studies considered the changes in criminal behaviour, the incidence of offences and of convictions. For this, information from police records and the central criminal register were extracted and compared with information obtained from the patient. Another special study examined the prison-based heroin-by-prescription project. Special economic studies were commissioned to determine, firstly, the costs arising from treatment and, secondly, the economic benefit of treatment. Additional data were collected for these studies.

Comparison of treatment results are based on systematically recorded reference data from abstinence-based in-patient treatment institutions in Switzerland and from methadone substitution treatments in the canton of Zurich. This has enabled a comparative analysis of the findings after at least one year's treatment. The randomised study in Geneva provides the additional data needed to compare the participants' treatment results with those from other treatment programmes. In addition, a comparative study is being carried out for patients who have recently entered selected methadone maintenance clinics.

## Samples

The analysis of the overall programme is based on the data of the 1,146 patients admitted to the programme who effectively started treatment. For such cases where all admission data were recorded (n=1,035), 2 cohorts were formed (A admitted before the extension and B admitted after the extension of the study) in order to determine any differences between the two. By the end of 1996, 350 patients had dropped out of the study. Electronically recorded data on 403,402 treatment days were included in the analysis. The in-treatment study was based on the changes observed during 6, 12 and 18 months of treatment. The permanence of such changes, however, can only be ascertained after a longer period of time.

For the special studies, the analysis was based on data drawn from various samples, the size of which varied according to the characteristics of the study (e.g. according to the observation period and the prescribed substance). The smallest-sized samples were the pharmacological pilot studies (in accordance with their governing guidelines).

The summary of results below refers to the substance-related, patient-related and project-related research issues.

## Substance-related results

- Recruitment of patients, retention rate (the duration of continuing participation) and compliance (adherence to the treatment instructions) were better with the prescription of injectable heroin than with that of injectable morphine and methadone.
- Of the injectable narcotics used, morphine and methadone proved to be of limited use; heroin was also more suitable in therapeutic terms because of its fewer side-effects.
- There are as yet no apparent absolute contra-indications to the prescription of heroin; particular caution is necessary in cases of preexisting epilepsy.
- Heroin cigarettes are relatively ineffective (up to 90% of the heroin is destroyed) and may be replaced by other non-injectable forms (for example, slow-release tablets).

## Patient-related results

This summarises the extent to which the designated target group of heroin dependents could effectively be reached, what changes occurred in their state of health during treatment, how illicit drug use and social integration among patients in the programme developed, and what changes were observed in criminal behaviour.

## **Target group**

- The programme was able, to a greater extent than other treatments, to reach its designated target group: those with chronic heroin dependency, a history of failed attempts with other forms of treatment and marked deficiencies in terms of health and social integration.
- Those patients admitted to the project who had previously been following methadone substitution treatment had continued to use illicit heroin to a large extent during their methadone treatment.

## **Development of the state of health**

- The improvements in physical health which occurred during treatment with heroin also proved to be stable over the course of one and a half years and in some cases continued to increase (in physical terms, this relates especially to general and nutritional status and injection-related skin diseases).
- In the psychiatric area, depressive states in particular continued to regress, as well as anxiety states and delusional disorders.
- Pre-existing HIV infections were referred for suitable medical treatment in the majority of cases-, the same applied to other clinically apparent infectious diseases.
- Three new HIV infections, 4 hepatitis B infections and 5 hepatitis C infections occurred during the study (in a total of 11 people). This was very probably related to cocaine injected outside the programme.
- The pregnancies and births which occurred during treatment were adequately supervised and progressed normally (with the exception of one spontaneous miscarriage during heroin withdrawal); there were no indications of developmental defects in the neonates.

## **Dependent behaviour**

- Illicit heroin and cocaine use rapidly and markedly regressed, whereas benzodiazepine use decreased only slowly and alcohol and cannabis consumption hardly declined at all.
- In a minority of patients, the continued regular use of cocaine (5%) and benzodiazepines (9%) even after 18 months of treatment constituted a difficult therapeutic problem to manage.

## **Social integration**

- The participants' housing situation rapidly improved and stabilised (in particular, there were no longer any homeless),
- Fitness for work improved considerably, those with permanent employment more than doubled (from 14% to 32%), and the number of unemployed fell by more than a half (from 44% to 20%), - the remainder lived on benefits or irregular employment or were engaged in housework.
- Debts during the treatment period were constantly and substantially reduced.
- A third of patients who, on admission, were dependent on welfare required no further support; on the other hand, others turned to welfare support (as a result of the loss of illicit income).

- Contact with drug dependents and the drug scene declined massively, but was not adequately replaced by new social contacts during the observation period.

## **Criminal activity**

- Income from illegal and semi-legal activities decreased dramatically: 10% as opposed to 59% originally.
- Both the number of offenders and the number of criminal offences decreased by about 60% during the first six months of treatment (according to information obtained directly from the patients' and from police records).
- Court convictions also decreased significantly (according to the central criminal register).

## **Retention rate**

In some cases, the improvement in the participants' health and social situation referred to above occurred soon after the beginning of treatment, but in others, not until after several months of treatment. The extent to which early discontinuabon of treatment can be avoided therefore plays a major role. The retention rate in the study, 89% over a period of 6 months and 69% over a period of 18 months, proved to be above average compared with other treatment programmes for heroin dependents.

## **Drop outs**

An analysis of the drop outs shows:

- More than half of the drop outs switched to another treatment.
- By the end of 1996, a total of 83 people had decided to give up heroin and switch to abstinence therapy. The probability of this switch to abstinence therapy grows as the duration of individual treatment increases.
- The longer a patient remains in treatment, the more the rate of drop outs and exclusions from treatment decreases.
- Severe physical illness, particularly in conjunction with AIDS, is over-represented among drop outs as it leads to hospitalisation.
- Improvements in the social situation which occurred in the course of treatment persisted for at least six months, whether or not follow-up treatment was administered.
- The use of illicit drugs increased somewhat after withdrawal but remained clearly below the initial level; the same applied to contacts with the drug scene and illicit income.
- Of the 1,146 patients in the study, 36 had died by the end of 1996.
- 17 deaths are attributable to AIDS and other infectious diseases; other causes of death include overdosage of non-prescribed narcotics, suicide and accidents. In the study itself there were no fatal overdoses.
- Despite a high toll on health, the annual mortality rate of 1% in the total cohort remains at the lower limit of what is known from other studies on treated heroin dependents (0.7 to 2.6% per year). The mortality of untreated patients is markedly higher.

## **Project-related results**

As far as the Organisation and operation of the treatment centres is concerned, the following remarks may be made:

- Initially, the main problems lay in recruiting patients in some cases as well as in financing and in organisational problems in many.
- The treatment centres in the second series, having benefited from the experience of the first series, had considerably fewer difficulties.
- No disturbance of note was caused to the local neighbourhoods, or if so only temporarily.
- Security problems (storage and control of narcotics, safeguarding against forced entries, etc.) were resolved satisfactorily.
- There remained a residual risk of overdosage among patients who were heavily consuming other drugs at the same time; the precautions which were taken helped prevent the occurrence of any fatal overdoses.

## **Heroin prescription in methadone outpatient clinics**

In the eventuality of the possible continuation of heroin-assisted treatment, we examined to what extent this form of treatment could be given in the same institution providing methadone substitution treatment. The findings from three treatment centres showed that the accompanying problems could be overcome and that pre-arrest-based heroin treatment is completely feasible in the context of polyvalent outpatient clinics.

## **Heroin prescription in prison**

The pilot study of heroin prescription in a prison environment showed that this procedure required changes (in its operation and in the attitude of staff), but that the positive findings increasingly took precedence. Furthermore, it was noted that good collaboration with outpatient treatment centres could be readily established for the follow-up treatment of discharged inmates.

## **Costs and benefits**

A detailed examination of the costs arising in the outpatient treatment centres showed average total costs per patient day of Fr. 51.-, compared with revenue of on average Fr. 35.- per patient day (revenue includes contributions to costs by patients, and contributions from health insurance funds and the public purse).

- The resultant deficits as a rule were borne by the public purse and exceptionally by private sponsors.
- The study of the overall economic evaluation of the programme in terms of a cost-benefit analysis according to detailed bases for assessment shows an overall economic benefit per patient day of Fr. 96.- (the greater part relates to savings in criminal investigations and prison terms, followed by improvements in the state of health). After deduction of the costs mentioned, this yields a net economic benefit of Fr. 45.- per patient day.

## **Conclusions**

On the basis of these results, the report comes to the following conclusions and recommendations:

- Heroin-assisted treatment is useful for the designated target group and can be carried out with sufficient safety.
- As a result of above average retention rates, significant improvements can be obtained in terms of health and lifestyle and these persist even after the end of treatment; of special interest is the stoking decline of criminal activities.
- Such improvements are of great public interest too (prevention of dangerous infections diseases, struggle against drug-related delinquency etc.).
- In view of the considerably impaired state of health of patients on admission to the programme, the mortality rate of 1% per year is relatively low.
- The economic benefit of heroin-assisted treatment is considerable, particularly due to the reduction in the costs of criminal procedures and imprisonment and in terms of disease treatment.
- These improvements were achieved subject to the prescription of heroin as part of a comprehensive programme of patient education and therapy.
- The same can be said with regard to the general conditions governing the organisation and operation of the programme: the safety of participants and others can only be guaranteed by establishing appropriate supervisory measures.

The continuation of heroin-assisted treatment can be recommended for the indications described in this research and as long as the general organisational and operational conditions set out in the research protocol are established.

If the programme is continued, the unresolved questions and problems mentioned in the report should be further examined and elucidated through scientific research. The treatment itself should be appropriately monitored, documented and evaluated.

## Final recommendation

*It is apparent from these conclusions that a continuation of heroin-assisted treatment can be recommended for the group targeted by this programme, provided that it is administered in suitably equipped and supervised outpatient clinics which meet the general conditions and criteria as described above.*

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# Legalizing medicinal marijuana

By Steve Michael  
and Wayne Turner

People suffering from AIDS, cancer, glaucoma and other serious or terminal illnesses sometimes turn to marijuana on the advice of their doctors when other treatments fail. The District of Columbia's Initiative 57 would protect these patients, their doctors and immediate caregivers from criminal prosecution in the use of marijuana in medical treatment.

The tightly worded measure requires that medical marijuana be restricted to use under the supervision and care of a licensed physician. Initiative 57, proposed by the local AIDS activist group ACT UP Washington, firmly established that medical decisions are best determined within the doctor-patient relationship, not by politicians or prosecutors. Volunteers have until December to gather approximately 16,700 signatures of D.C. registered voters to place Initiative 57 on the D.C. ballot.

Under current law, the seriously ill who turn to marijuana for its possible therapeutic effects are subject to arrest, criminal prosecution and incarceration. Politicians use this issue to look tough on drugs, jailing sick and dying patients in the name of public safety.

Caregivers have no other option but to enter dangerous open-air drug markets to purchase the marijuana that might provide some comfort to loved ones in their final days. Physicians who even discuss the possible benefits of marijuana with their patients have been targeted by federal prosecutors.

Many AIDS patients have found

that marijuana eases severe nausea and vomiting and helps counter the loss of appetite and weight loss of deadly AIDS wasting syndrome. Expensive new triple-combination therapies hold little promise for those AIDS sufferers who are unable to hold their pills down.

Cancer patients enduring the side effects of radiation and chemotherapy sometimes find relief in marijuana. Some people with glaucoma, one of the leading causes of blindness among Americans, have been successfully treated with marijuana for over 20 years.

For those sick and dying patients who use marijuana to ease their suffering, marijuana is hardly a recreational drug. Initiative 57 simply provides legal protection to these patients, their physicians and caregivers from prosecution under D.C.'s Uniformed Controlled Substances Act. The D.C. initiative is much tighter than measures passed by voters in California and Arizona.

Under the provisions of Initiative 57, nonmedical use of marijuana is explicitly prohibited. Use of medical marijuana, like other prescription medicines, cannot defend against any other crime, such as driving while intoxicated. Authors have included a parent consent clause, Section 9, which prohibits the distribution of medical marijuana to any person under the age of 18 for the treatment of a minor's medical condition without the informed, written consent of a parent or legal guardian for the use of marijuana.

The marijuana sold by drug dealers on the streets is sometimes laced with drugs or other contaminants. Initiative 57 would allow legal, non-profit corporations or cooperatives to ensure a safe supply of marijuana to patients, taking drug dealers out of the equation. Patients are limited under Initiative 57 in the quantities they are permitted to possess.

The local petition effort is drawing national attention from those who

have shown little interest in the well-being of the people of D.C. The campaign for Initiative 57 is turning into the first Republican primary of the 2000 presidential election. Billionaire publisher and former presidential candidate Steve Forbes has loudly launched a big-money media campaign against Initiative 57, calling the AIDS activists sponsoring the measure "twisted drug predators." William Bennett, the failed drug czar under President Bush, is directing opposition to Initiative 57 through his group Empower America. Representatives from the Family Research Council, headed by Reagan administration domestic policy adviser Gary Bauer, tried to block Initiative 57 at the D.C. Board of Elections and Ethics, but they were unable to find a D.C. voter to oppose the initiative.

Reacting to pressure, drug czar Gen. Barry McCaffrey has weighed in, opposing the petition drive in a letter sent to D.C. officials. Gen. McCaffrey's office says they have not yet reviewed the legislative text of Initiative 57.

Meanwhile, amid the grandstanding of presidential aspirants, open-air drug markets and crack houses in Washington continue to flourish. The Drug Detox Center at D.C. General Hospital is overflowing. Waiting lists for drug treatment slots grow as funding for these lifesaving programs has been eliminated. Drug kingpins continue to import crack cocaine for sale in our city and at the Lorton prison complex. Yet these pressing problems, so apparent to Washington residents, have failed to grab the attention of political grandstanders, much like Nero fiddling while Rome burned.

By supporting D.C. Initiative 57, the people of the District can free those suffering from AIDS, cancer and other serious illnesses from the threat of prosecution and imprisonment if their doctor recommends marijuana as a medication of last resort.

— Steve Michael and Wayne Turner are founders of ACT UP, the AIDS Coalition to Unleash Power, in Washington. Mr. Michael, who is HIV-positive, is the proposer of Initiative 57.

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