

The New York Times

Agency Says Marijuana Is Not Proven Medicine

By JOSEPH B. TREASTER

3/19/92

Responding to a Federal appeals court ruling that the Government was using illogical criteria in prohibiting the use of marijuana for medical purposes, the Drug Enforcement Administration said yesterday that "far too many questions remain" for experts to "fairly and responsibly" conclude that the drug is safe.

In a 46-page clarification of Federal policy, Robert C. Bonner, chief of the agency, said, "Lay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in details they cannot be scientifically evaluated and all other forms of anecdotal proof are entirely irrelevant."

In the response, Mr. Bonner effectively rejected a petition to permit doctors to prescribe marijuana for patients suffering from cancer, glaucoma, muscular sclerosis, AIDS and other maladies with chronic pain.

The United States Court of Appeals for the District of Columbia District noted last April that the agency had based a conclusion that marijuana had no "currently accepted medical use" on factors like the drug's general availability, its use by a substantial number of doctors and recognition of its use in medical texts. Since the drug is illegal, the court said, meeting these criteria would be all but impossible.

Lack of Studies Cited

In his response yesterday, Mr. Bonner said he had concluded "that the general availability of a drug is irrelevant to whether it has a currently accepted medical use in treatment."

What was essential, he said, was that the drug's chemistry must be known and reproducible, there must be adequate safety studies as well as studies demonstrating the drug's efficacy, it must be accepted by qualified experts and the scientific evidence must be widely available.

Though advocates of the medical uses of marijuana contend otherwise, Mr. Bonner argued that the drug lacks these characteristics.

The ruling by Mr. Bonner, who deter-

mines if any addictive drug may be authorized for medical use, came less than two weeks after the Public Health Service began phasing out a small program that, in an exception to the law, provided marijuana to 13 patients.

'Coordinated Effort'

Officials of both agencies said the two actions were unrelated. But Robert Randall, the president of the Alliance for Cannabis Therapeutics in Washington, said: "This is obviously a coordinated effort by war-on-drugs bureaucrats to block marijuana for medical use. As a result of this decision tens of thousands of Americans who would benefit from the medical effects of marijuana are going to continue to suffer."

In his response to the appeals court, Mr. Bonner said: "Beyond doubt, the claims that marijuana is medicine are false, dangerous and cruel. Sick men, women and children can be fooled by these claims and experiment with the drug. Instead of being helped, they risk serious side effects."

Mr. Bonner acknowledged that he based his findings on the same testimony and documents that led a Federal Administrative Law judge, Francis L. Young, to an opposite conclusion four years ago. Judge Young contended then that the "record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people and doing so with safety under medical supervision."

"It would be unreasonable, arbitrary and capricious for D.E.A. to continue to stand between those sufferers and the benefits of this substance," he added.

Many Doctors Favor Use

The judge's finding was later overruled by John C. Lawn, then head of the drug agency.

Cocaine and morphine, both of which many experts believe to be more dangerous than marijuana, have been approved by the drug agency for medical use. But Mr. Bonner said danger is not the determining factor. What is essential, he said, is that a drug have a demonstrable medical value.

Mr. Randall, who suffers from glaucoma, said his doctors have told him that without marijuana, which he has been receiving from the Government, he would have gone blind.

In a survey of more than 2,400 cancer specialists last year, two Harvard University researchers reported that of the 1,035 who replied, nearly half said they would prescribe marijuana if it were legal. A slightly smaller percentage said they had recommended marijuana to their patients to relieve nausea from chemotherapy and radiation.

Allen St. Pierre, a spokesman for the National Organization for Reform of Marijuana Laws, said his group, which has long been trying to make marijuana available by prescription, would appeal Mr. Bonner's decision, but had begun lobbying state legislators to approve the drug's medical use.

Medicine vs. Enforcement

There has been a surge in the last year in requests for medical marijuana by AIDS patients, Government officials and advocates say, and some advocates argue that this inspired the recent Government actions. A sharp rise in the medicinal use of marijuana, the advocates contend, would undermine continued prohibition of the drug for general purposes.

"The government is not doing this to protect patients," said Kennington Wall, a spokesman for the Drug Policy Foundation in Washington, which advocates a liberal national drug policy. "They're doing this to protect their political agenda."

The American Medical Association said it supports further research "into the medicinal uses of marijuana." But, Dr. M. Roy Schwarz, a senior vice president of the group, said that "until the full effects of marijuana are known, it is preferable to utilize treatments without the harmful side effects of this drug."

3/11/92

U.S. Rescinds Approval of Marijuana as Therapy

WASHINGTON, March 10 (AP) — The Government said today that it would not provide marijuana for medical purposes to any more patients suffering from AIDS, cancer or glaucoma because it might make them sicker.

The Public Health Service said only 13 people already smoking marijuana legally for medical purposes would be allowed to continue. Those 13 get their supplies from the Federal Government.

Advocates of the medical use of marijuana say it combats the nausea, vomiting and weight loss common to cancer patients undergoing chemotherapy and to some AIDS sufferers, reduces eye pressure in the treatment of glaucoma and helps reduce muscle spasms common to neurological conditions like multiple sclerosis.

But Bill Grigg, a Public Health Service spokesman, said scientists from the National Institutes of Health had concluded that "existing evidence does not support recommending smoked marijuana as a treatment of choice for any of the medical conditions" of patients who have applied for Government-supplied marijuana.

"The decision was made by the Public Health Service primarily because of fear that the smoked marijuana would be harmful to people with compromised immune systems," he said.

No Public Statement

There was no public announcement of the decision by Dr. James O. Mason, the chief of the health service. Mr. Grigg revealed it in response to a question.

The decision was denounced by people using marijuana for medical purposes and those advocating its use.

"I think it's a decision made by some bozos that don't get their fat duffs out of the office and ask doctors who work with patients like this, talk to the patients who are using it, talk to the

No more Federal supplies of an illegal drug to some ill people.

families and friends that see the difference," said Tim Braun, 44 years old, an AIDS patient in Minneapolis.

Mr. Braun is among 28 patients whose applications for Government-supplied marijuana had been approved by the Food and Drug Administration, but who, as a result of the recent ruling, will not get the drug legally.

Waiting for a Review

Dr. Mason announced last June that until the Government finished a review of marijuana's reported health benefits and potential dangers the health service would stop processing applications and would withhold marijuana from the 28 people who had already applied for it.

That review led Dr. Mason to recommend early this year that no more patients should receive marijuana. The final decision was made last week by the Secretary of Health and Human Services, Dr. Louis W. Sullivan.

Instead of marijuana, the Government advocated use of alternative, legal medicines like Marinol, a synthetic form of marijuana's active ingredient. But some patients have said that Marinol, a prescription drug made by Roxane Laboratories Inc. of Columbus, Ohio, does not help them.

"They're giving me a death sentence," said Mr. Braun, who said a few puffs on an illegally acquired marijuana cigarette reduce his nausea and vomiting. He said that in one month when he could not get marijuana his weight dropped to 120 pounds, down 65

to 70 pounds from his normal weight.

Mr. Grigg contended that marijuana could be dangerous. "We know that marijuana contains substances which can cause lung problems," he said, "and AIDS patients are prone to pneumonia and other lung infections."

As for eye problems, Mr. Grigg said, "there simply isn't any evidence that with the new drugs that have gone into effect for glaucoma, that smoked marijuana would be any more useful or even as useful as what's already on the market."

But Bob Randall of the Alliance for Cannabis Therapeutics said the decision to withhold Government-supplied marijuana was "a devastating, immoral way to treat seriously ill people, who have legally applied through an established program for care and have been approved to receive such care."

The alliance wants the Drug Enforcement Administration to reclassify marijuana so doctors can prescribe it. That position was supported by an agency administrative law judge several years ago but the agency has resisted changing its position.

During the review of marijuana, officials of the National Institutes of Health called the doctors of the 28 people who had sought and received approval for marijuana but who had not yet gotten the drug to inform them of alternate therapies, Mr. Grigg said. Ten of the applicants later decided not to pursue the marijuana issue, he said. Doctors of the remaining 18 were told on Friday and Monday of Dr. Sullivan's decision.

Other points of view
on the Op-Ed page
seven days a week.
The New York Times



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
HEALTH LEGISLATION
WASHINGTON, D.C. 20201

PHONE: (202) 690-7450

FAX: (202) 690-8425

TO: Jose SentaFROM: Diane F. Degard

NAME: _____

NAME: _____

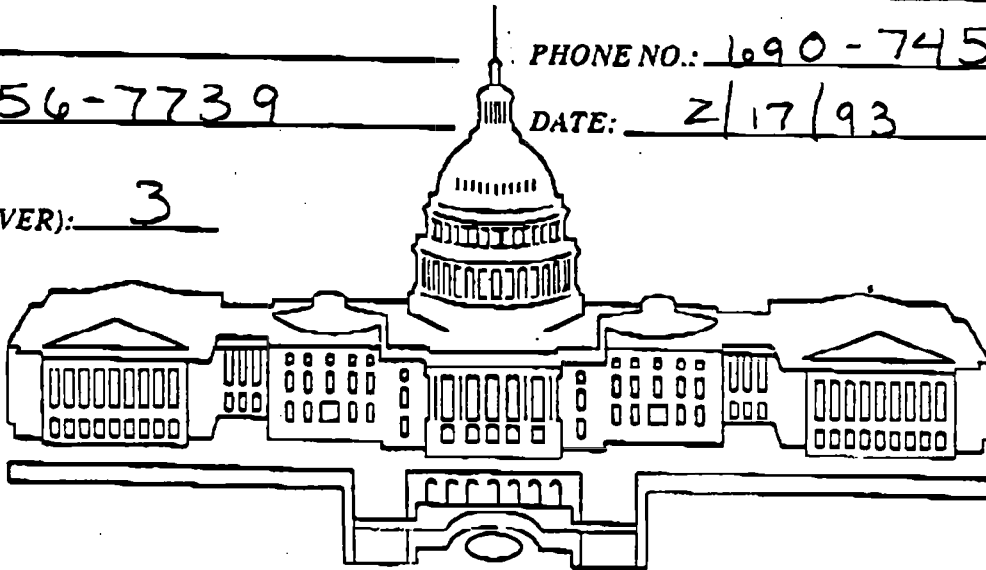
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REMARKS:

Per your request to Mr. Jerry Klepner -
Please call me if you have any questions
or need follow up information.

FACT SHEET ON PHS MARIJUANA POLICY

- o Based upon concern regarding the provision of a potentially harmful substance to patients as medicine, marijuana cigarettes are no longer being made available to additional patients through the single-IND (investigative new drug) program.
- o Last spring, all applicants were notified of the Department of Health and Human Services' decision. In addition, HHS worked with each applicant's physician to explore with them possible alternatives for management of their patient's illnesses.
- o The patients who were already getting marijuana cigarettes continue to receive them. Their physicians have also been counseled by National Institutes of Health experts about alternative therapies they might want to choose. (12 patients are receiving marijuana through the single-IND program.)

Alternative Therapies:

- o Marinol contains the active ingredient in marijuana and has been approved for treating nausea caused by cancer chemotherapy. The pharmaceutical company Unimed is completing a multi-city clinical trial of Marinol for the treatment of HIV-wasting syndrome and is expected to file a new drug application with FDA soon.

Also, a suppository formulation of Marinol has recently been developed and is now in Phase I testing.

- o Megace, or megestrol acetate, a synthetic hormone that has FDA approval for treatment of certain breast cancers has also been used for treating malnutrition associated with cancer.

Megace has also shown some efficacy for anorexia and weight loss in AIDS patients. In March, the National Institute of Allergy and Infectious Diseases (NIAID) began enrolling patients in a Phase I interactive study of Marinol and Megace for the treatment of HIV-wasting syndrome.

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Background:

The National Institute on Drug Abuse, a Public Health Service component, will continue to grow limited amounts of marijuana for research. It was from this supply that cigarettes were provided to one patient with glaucoma, in response to a lawsuit against the government. The number of patients grew when FDA granted IND applications for people with other incapacitating illnesses.

But research led to the development of a synthetic form of the active ingredient in marijuana, THC (delta-9-tetrahydrocannabinol), which was approved by the FDA in 1985 for use in the treatment of nausea and vomiting associated with cancer chemotherapy. It is currently available under the brand name Marinol.

The prescription of marijuana for AIDS patients is of particular concern to PHS because smoking marijuana could adversely affect people with compromised immune systems who are prone to pneumonia and other lung infections.

Further, scientists at NIH have concluded that existing evidence does not support recommending smoked marijuana as a treatment of choice for any medical condition.

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Marijuana contains a total of 421 chemicals, which include a variety of toxins and cancer-inducing chemicals. The primary psycho-active agent is delta-9-tetrahydrocannabinol (THC). While THC is

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DRUG WATCH

Published by Committees of Correspondence, Inc.
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July, 1992

MARIJUANA HAS NO CURRENTLY ACCEPTED MEDICAL USE

Relying on the same scientific standards used to judge all other drugs, FDA experts repeatedly rejected marijuana for medicinal use. Further hearings are unnecessary since the record is extraordinarily complete as stated in the Federal Register, Volume 57, Number 59, March 26, 1992 (copy enclosed).

Is marijuana good medicine for illnesses we all fear? The answer might seem obvious based simply on common sense. Smoking causes lung cancer and other deadly diseases. Americans take their medications in many different forms, **but never by smoking**. No medicine prescribed for us today is smoked.

- Marijuana's chemistry is neither fully known, nor reproducible.
- Adequate safety studies have not been done.
- There are no adequate, well-controlled scientific studies proving marijuana is effective for **anything**.
- Marijuana is not accepted for medical use in treatment by even a respectable minority.
- The published scientific evidence is not adequate to permit experts to fairly and responsibly conclude that marijuana is safe and effective for use in humans.

Beyond a shadow of a doubt, the claims that marijuana is medicine are false and dangerous. It is a cruel hoax to offer false hope to desperately ill people. Sick people can be fooled by false claims and waste precious time experimenting with marijuana while neglecting approved medications for their specific illness.

NOT ONE AMERICAN HEALTH ASSOCIATION ACCEPTS MARIJUANA AS A MEDICINE

American Medical Association
National Multiple Sclerosis Society
American Glaucoma Society
American Academy of Ophthalmology
American Cancer Society

The testimony of nationally recognized experts overwhelmingly rejects marijuana as medicine as compared to the scientifically empty testimony of the psychiatrists, a wellness counselor and general practitioners presented by The National Organization of the Reform of Marijuana Laws (NORML).

BY ANY MODERN STANDARD, MARIJUANA IS NO MEDICINE.

As of June 1, 1992, there are 10,500 documented scientific research papers on file at the University of Mississippi Research Institute of Pharmaceutical Sciences (RIPS) (601/232-5914). Not even one of these documents give marijuana a clean bill of health.



DRUG WATCH

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NO MEDICAL USE OF MARIJUANA FOR GLAUCOMA

A strong effort is being made by the pro-legalization forces to legalize marijuana under the guise of "therapeutic use." One of the major claims is that marijuana is much needed in the treatment of glaucoma. The statement below, by E. Michael Van Buskirk, M.D., a highly respected and well known expert in the field of glaucoma, debunks these claims.

From the glaucoma standpoint, marijuana has faded into the background for a variety of reasons:

Marijuana still has no practical use in the therapy in glaucoma. The psychotropic effect remains coupled with the hypotensive effect, requiring the sufferer to maintain the psychotropic high in order to keep the intraocular pressure reduced. Alcohol also produces a profound reduction in aqueous humor formation and intraocular pressure. The recommendation to use marijuana is exactly analogous to the recommendation to ingest alcohol and maintain a state of drunkenness to treat glaucoma.

Both marijuana and alcohol lower the intraocular pressure by reduction of aqueous humor formation. There are many agents that reduce aqueous humor formation to its minimum. New beta blockers have come on the market and there are now four marketed in the United States. In addition, there are several alpha adrenergic agonists that hold promise for reduction of aqueous humor formation. There is little motivation to develop new inhibitors of aqueous humor formation since the market is relatively saturated with such drugs. What is needed in glaucoma would be drugs that improve outflow, and marijuana has no such affect. There are drugs being developed that do improve outflow, such as the prostaglandins and these hold much greater promise for the hypotensive therapy of glaucoma. There are still some pockets of work attempting to develop cannabinoids that would diminish intraocular pressure without the psychotropic effect, but those working in that area have no difficulty obtaining these compounds through legitimate agencies.

There is increasing awareness that glaucoma is an optic neuropathy only partially related to the intraocular pressure, as well as to a variety of other factors, some of which include circulation of the optic nerve. We now have a wide variety of agents to reduce the intraocular pressure, pharmacologically, with laser, and with surgery. Only new drugs that are shown to effectively reduce intraocular pressure without concomitant side effects or that directly protect the optic nerve are likely to have a significant impact on glaucoma.

Those who advocate marijuana smoking or ingestion for glaucoma therapy commonly cite the improvement in symptoms. Actually, glaucoma patients almost never have symptoms. If they did, glaucoma blindness would be a great deal more rare than it is. Intraocular pressure for the vast, vast majority of patients does not produce any symptoms whatsoever, unless the intraocular pressure is so high as to produce swelling of the cornea. Pain, blurring vision, halos around lights, etc. are associated with acute angle closure glaucoma which is rare and is treated with laser or surgery. Open angle glaucoma, the variety treated medically, is in the vast, vast majority of cases, without symptoms and associated with mild elevation of intraocular pressure that produces chronic damage to the optic nerve.

It is unfortunate to see glaucoma used as a political tool to advocate legalization of a recreational drug.

E. Michael Van Buskirk, M.D.
Glaucoma Consultation, PC
Chairman, Dept. of Ophthalmology
DEVERS EYE INSTITUTE
1040 NW 22nd Avenue, Suite 320
Portland, OR 97210-3065
1-800-433-3122

January 16, 1992

HOW USEFUL IS MARIJUANA FOR CHEMOTHERAPY-INDUCED NAUSEA?

Some anticancer drugs cause nausea and vomiting because they affect parts of the brain that control vomiting and/or cause irritation of the stomach lining. The severity of these symptoms depends on several factors, including which chemotherapeutic agents are used and each patient's reaction to the drug(s). The management of nausea and vomiting caused by chemotherapy remains a focus of care of many cancer patients. Although patients usually receive antiemetics, drugs that help control nausea and vomiting, there is no single best approach to reducing these symptoms in all patients. Doctors must tailor antiemetic therapy to meet the individuals' needs, taking into account the type of anticancer drugs being administered, the patient's general condition, age and related factors, and, of course, the extent to which the antiemetic is helpful.

There has been much interest in the use of marijuana to treat a number of medical problems, including chemotherapy-induced nausea and vomiting in cancer patients. At present, two forms of marijuana have been used: cigarettes and compounds related to the active chemical constituents of marijuana that are taken orally. One such compound that is available by prescription for use as an antiemetic is dronabinol (trade name, Marinol), a synthetic form of the active marijuana constituent delta-9-tetrahydrocannabinol (THC). Another related synthetic drug available by prescription is called nabilone (trade name, Cesamet), which also is given by mouth to cancer patients.

At this time, National Cancer Institute scientists believe that marijuana-related compounds probably are not as effective as certain other antiemetics or combinations of antiemetics in controlling nausea and vomiting caused by the initial doses of those anticancer drugs that are known to produce these symptoms. Furthermore, the effectiveness of marijuana-related compounds varies among patients and with the circumstances in which these drugs are used. Therefore, these substances may be helpful in alleviating the nausea and vomiting caused by some but not all anticancer drugs. In addition, the absorption of oral preparations of marijuana-related compounds may vary from patient to patient. Side effects associated with these compounds may include a "high" or sensation of "unreality" or "loss of control", which is unpleasant for some patients such as the elderly and individuals who are inexperienced with use of marijuana-related compounds.

Marijuana cigarettes have been used to treat chemotherapy-induced nausea and vomiting, and research has shown that the active ingredient THC is more readily and quickly absorbed from marijuana smoke than from an oral preparation of the substance. For the most part, however, smoking marijuana is no more effective than taking synthetic THC by mouth.

Inhaling marijuana smoke is a health hazard; more than 400 potential carcinogens (cancer-causing compounds) are found in the smoke. Marijuana cigarettes obtained on the "street" can be contaminated with disease-causing agents. These agents could be particularly harmful to patients undergoing chemotherapy, which commonly affects the immune system's ability to fight infection.

Other antiemetic agents or combinations of antiemetic agents have been shown to be more useful than marijuana-related compounds as "first line therapy" for nausea and vomiting caused by anticancer drugs. Examples include a new drug called ondansetron (trade name, Zogran) used by itself or combined with dexamethasone (a steroid hormone), metoclopramide (trade name, Reglan) with diphenhydramine and dexamethasone, high doses of methylprednisolone (a steroid hormone) combined with another drug droperidol (trade name, Inapsine), and prochlorperazine (trade names, Compazine and Combid). Research with other agents and combinations of agents is under way to determine their usefulness in controlling chemotherapy-induced nausea and vomiting.

In general, National Cancer Institute scientists believe that marijuana-related compounds can be useful for certain cancer patients who have chemotherapy-induced nausea and vomiting that cannot be controlled by other antiemetic agents. The expected side effects of these compounds must be weighed against the possible benefits.

1000
Majors de Medicine

PHYSIOPATHOLOGY OF ILLICIT DRUGS (cannabis, cocaine, opiates)

**Proceedings of the First International Symposium.
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Paris, May 31, 1990**

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GABRIEL G. NAHAS and COLETTE LATOUR

Assistant Editors

NOAH HARDY and PHILIPPE DINGEON

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CHRISTIANE NAHAS

*MEDICAL
MARIJUANA*

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or marijuana were born in 1989 in the United States. It is therefore obvious that we are not confronted here with harmless substances, but with dangerous ones. The struggle against their use must be continued and intensified.

Question : What is the incidence on fertility, e.g. on frequency of conception and of abortion?

Answer : No systematic clinical studies have been performed in reference to fertility. Sassenrath reported an increased abortion rate in monkeys treated chronically with orally administered THC (Sassenrath E.N. et al. Reproduction of rhesus monkeys chronically exposed to delta THC. In Marijuana Biological Effects (pp 501-512) G. Nahas and W. Paton Editors, Pergamon Press Oxford, 1979).

CHANGES IN HUMAN SPERMATOZOA ASSOCIATED WITH HIGH DOSE MARIHUANA SMOKING.

W.C. Hembree, G.G. Nahas, P. Zeidenberg and H.F. Huang.

We have shown that four weeks of high dose marihuana use (8-20 cigarettes/day) in 16 healthy, chronic marihuana smokers was associated with a significant decline in sperm concentration and total sperm count during the fifth and sixth weeks after the first exposure. This was preceded by a decrease in sperm motility and accompanied by a reduction in the number of sperm with normal morphology. In 12 of 16 subjects, a highly significant decrease was noted which was sustained until the end of the study in 11 subjects.

No evidence was obtained suggesting an hormonal mechanism for observed effects. The most likely explanation is a direct cannabinoid effect upon the germinal epithelium during spermiogenesis. Loss of motility response to cyclic AMP and a phosphodiesterase inhibitor, theophylline, in two subjects indicates that the sperm produced following cannabinoid exposure may also have structural or biochemical defects in sperm function. The improvement in sperm motility following cessation of chronic smoking raises some optimism concerning the reversibility of the abnormalities and, if confirmed in additional subjects, gives further credence to the causal relationship between acute marihuana exposure and the abnormalities subsequently observed. No conclusion can be reached regarding the possibility of adverse effects of acute or chronic marihuana use upon human reproduction. On the other hand, it is essential that further studies be undertaken which will examine this possibility.

CANNABIS AND IMMUNITY

H. Friedman

Studies in many laboratories over the last two decades have shown that marijuana has marked immunosuppressive effects, both *in vitro* and *in vivo*. For example a number of studies have indicated that heavy smokers of marijuana show depressed immune responses of their peripheral blood cells stimulated *in vitro* with a number of mitogens which normally

stimulate lymphocytes. However, there have been a number of studies which refuted such observations. Nevertheless, it is generally believed that marijuana may have immunosuppressive activities *in vivo* and that when lymphoid cells from normal humans are exposed *in vitro* to marijuana components, especially tetrahydrocannabinol (THC), there are suppressed immune response. More definitive studies have been performed with rodents, especially mice. Injection of marijuana components, including THC, into animals suppresses a wide variety of immune functional activities of B and T cells as well as macrophages. Furthermore, treatment of normal mouse lymphoid cells *in vitro* with THC also results in marked suppression of immune responses and this is related to dose as well as the stimulator of the immune response and the time of exposure of the cells to the marijuana components. Studies in this laboratory, for example, have indicated that THC, when injected directly into mice or added to normal mouse lymphoid cells, suppresses blastogenic responses to plant mitogens as well as bacterial antigens. Furthermore, peritoneal exudate macrophages, when treated with THC *in vitro*, lose their ability to phagocytize challenge particles and to show other functional activities. This is related to the dose of THC used for treatment of the cells. Mediators produced by macrophages which can influence the immune response, such as interferons, are also inhibited by THC. In contrast, THC does not inhibit the ability of macrophage cultures to produce IL-1 and, in many cases, enhances production of this interleukin. A number of laboratories, including this one, has also shown that marijuana treatment of experimental animals makes the animals more susceptible to opportunistic infectious agents, including fungi, bacteria and viruses, including a murine retrovirus which induces an immunodeficiency. Thus studies concerning the mechanisms involved in immunomodulation induced by marijuana and its components are under way in a large number of laboratories and such studies should be applicable to the question of whether marijuana and its components do indeed have immunomodulatory effects in heavy marijuana users. Effects of marijuana on the immune response system may make individuals more susceptible to infection with organisms such as bacteria, fungi and viruses, including the AIDS virus.

MARIJUANA DECREASES MACROPHAGE ANTIVIRAL AND ANTITUMOR ACTIVITIES

G.A. Cabral and R. Vasquez

Delta-9-tetrahydrocannabinol (THC), the major psychoactive component of marijuana, was shown to decrease macrophage functional competence against tumor cells and virus-infected cells. Peritoneal macrophages of (B6C3)F1 mice receiving *Propionibacterium acnes* (*P. acnes*) as a macrophage "activator", and treated with THC (50mg/kg and 100mg/kg) exhibited a dose-related decrease in effector cell:target cell contact-dependent tumoricidal activity against rat B103 neuroblastoma cells. Macrophage-like cells of the lines J774A.1, P388D1 or RAW264.7 exposed *in vitro* to THC exhibited decreased extrinsic antiviral activity to herpes simplex virus type 2. Scanning electron microscopy demonstrated that THC administered *in vivo* or *in vitro* did not prevent *P. acnes* macrophages or the macrophage-like cells from attaching to tumor or virus-infected target cells. However, the drug inhibited protein

expression by macrophages in response to stimuli such as *P. acnes* in vivo and bacterial lipopolysaccharide in vitro. These results suggest that THC inhibits "full" activation of macrophages since tumoricidal and antiviral activities are characteristic features of macrophage "full" activation. Furthermore, since contact-dependent tumoricidal and extrinsic antiviral activities are two-step processes in which effector cell:target cell conjugation is followed by delivery of effector molecules, these results indicate that the cannabinoid acted at the level of inhibition of effector molecule expression.

MATERNAL MARIJUANA USE AND LEUKEMIA IN OFFSPRING

J.P. Neglia, J.D. Buckley and L.L. Robison

A case control study of potential in utero and post-natal exposures associated with acute non-lymphocytic leukemia (ANLL) was conducted by Childrens Cancer Study Group. Data were analyzed for 204 case control pairs. Maternal use of mind altering drugs prior to and during pregnancy was found to be associated with an eleven fold increased risk ($p=0.003$) of ANLL in offspring when compared to offspring of controls. Ten of the eleven mind-altering drug exposures were either marijuana exclusively (nine) or included marijuana (one). Mothers of ANLL cases ten times more likely to have used marijuana exposed cases of ANLL differed significantly from non-marijuana exposed cases with respect to age at diagnosis and morphologic subtype. The results of this previously reported study (Robison et al., 1989) suggest the possibility that maternal marijuana use during pregnancy may play an etiologic role in childhood ANLL. Studies to follow up these findings are currently underway.

Commentary following Professor Neglia's presentation by Pr. J.L. Binet

The paper of Professor J.P. Neglia suggests three comments :

1. The multicentric study conducted by scientists from the Universities of Minnesota, Southern California, North Carolina and Washington in Seattle, indicate that the statistical association of acute leukemia in children whose mothers consumed cannabis is 11 times higher than that of a control population of similar age. When we know the frequency of cannabis intoxication detected in prenatal clinics of Eastern and Western United States at time of delivery, one might expect an increase prevalence of acute leukemia among children in future years.
2. This leukemia is of particular cytological type, akin to that observed in Down's syndrome or after irradiation. These cytological features confirm the cause effect relationship between cannabis and acute leukemias.
3. This newly observed pathology must be considered in the light of the in vitro observations concerning the inhibitor effects of cannabis derivatives on cellular replication and anabolism discussed in this monograph and first reported in 1974 by G. Nahas and his group.

INHIBITION OF MACROMOLECULAR SYNTHESIS BY CANNABINOIDS IN REPLICATING CELLS.

B. Desoize, G.G. Nahas and C. Latour.

All cannabinoids, psychoactive like delta-9-tetrahydrocannabinol (THC) or not (cannabidiol, cannabinal) inhibit in micromolar concentration (10^{-6} to 10^{-4} M) incorporation of the precursors of DNA, RNA and proteins into mitogen stimulated lymphocytes. All of these cannabinoids have in common the ring of olivetol. Within 15 minutes of incubation, THC inhibits precursor pool formation and macromolecular incorporation of thymidine, uridine and leucine. THC inhibits also ^{14}C -aminoisobutyric acid uptake into the cell, but does not alter the cellular "leakage" of this amino acid analogue. Using isotopic dilution technique with L1210 murine lymphoma cells and human lymphocytes, it was observed that THC decreases ^3H -thymidine uptake within fifteen seconds after addition of the drug to the culture. Experiments performed at 0°C indicate that THC has no action on thymidine binding to the carrier. All of these observations suggest that THC in micromolar concentration inhibits DNA synthesis through a "non-specific" alteration of membrane configuration. This effect, due to the liposolubility of the drug, could induce conformational changes of membrane bound transport systems which would inhibit their function. Additionally treatment of HeLa cells with cannabinoids results in changes in the incorporation of ^3H -leucine into histone fractions and into non-histone chromosomal proteins. Such alterations could modify structural and functional properties of the genome.

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ACT

JOSE

Alliance for Cannabis Therapeutics

March 21, 1993

Mr. William Galston
Deputy Asst. to the President for Domestic Policy
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Dear Mr. Galston:

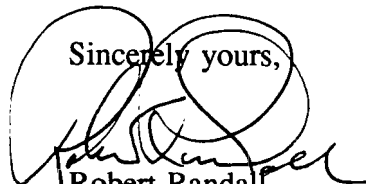
Americans are dying, going blind and being crippled by the Bush Administration's cynical, and publicly unpopular prohibition against marijuana's medical use.

Shortly after the election, Mr. Richard J. Dennis of Chicago commissioned a detailed assessment of marijuana's medical uses, and of federal policy changes which could help ease the suffering of seriously ill Americans who might medically benefit from legal, prescriptive access to marijuana.

Enclosed is a copy of the resulting publication, *Marijuana as Medicine: Initial Steps*. This document speaks to our very real desire to work closely with the Clinton Administration to define a more rational and compassionate way to meet the urgent medical needs of seriously ill Americans.

If, after reviewing the enclosed information, you or members on your staff have any questions, please feel free to contact us at the Alliance.

Looking forward to working with you and the Clinton administration to resolve this long-standing public health issue, I remain

Sincerely yours,

Robert Randall
President, ACT

RCR/bms

P.O. Box 21210 / Kalorama Station / Washington, DC 20009
Telephone: (202) 483-8595 / Fax: (202) 797-9543

MARIJUANA-AS-MEDICINE

Basic Background

Did you know:

- Thirty-four states have legislatively authorized marijuana's medical use. More than 87% of the legislators in these states voted to end legal prohibitions against marijuana's legitimate medical uses.
- Many of the nation's major legal organizations including the American Bar Association (ABA), the National Association of Attorneys General (NAAG), the National Association of Criminal Defense Lawyers (NACDL) and the American Civil Liberties Union (ACLU) have enacted Resolutions calling on Congress to end federal prohibitions against marijuana's medical use.
- More than five million Americans are afflicted with life- or sense-threatening disease which are responsive to marijuana therapy. These include patients suffering from cancer, glaucoma, multiple sclerosis, paralysis, chronic pain and HIV-infection.
- In 1988, DEA's Chief Administrative Law Judge ruled that the federal prohibition against marijuana's medical use is "*unreasonable, arbitrary and capricious*". The Judge recommended marijuana be made medically available to patients by prescription. DEA, however, refused to abide by the Judge's verdict. In 1991, the U.S. Court of Appeals ordered DEA to reconsider its opposition to marijuana's legitimate medical use.
- A Harvard survey of cancer specialists recently published in the *Journal of Clinical Oncology* reports 44% of the nation's leading oncologists have advised patients to break the law to illegally obtain the marijuana they medically need. More than 70% of the nation's cancer specialists told Harvard researchers they would prescribe marijuana if it were legally available. Until federal laws are changed, however, most patients will be forced to get the marijuana they medically need off the streets.
- The same Harvard survey reports most cancer specialists have found smoked marijuana to be a more effective nausea reducing drug than the FDA promoted synthetic substitute, marketed under the brand name, *Marinol*.
- Medical studies conducted in New Mexico, New York, Michigan, Tennessee and California consistently report the government authorized *Marinol* "pot pill" is medically inferior to marijuana and more likely to cause adverse side effects. Patients consistently report a preference for marijuana over medically inferior synthetic alternatives.
- Synthetic *Marinol* costs \$8 per pill. Marijuana costs about a penny per dose.
- The FDA's Compassionate IND program began in 1978. Under the Compassionate IND program patients with life- or sense-threatening diseases can legally obtain supplies of medicinal marijuana. FDA has authorized marijuana's compassionate medical use in the treatment of cancer, glaucoma, AIDS, multiple sclerosis, paralysis and chronic pain.
- The courts have ruled marijuana can be a drug of "medical necessity" for patients afflicted with glaucoma, multiple sclerosis and AIDS.

If you would like more information on marijuana's medical use please contact the Alliance.

The **Alliance for Cannabis Therapeutics (ACT)** is a Washington based patient-rights group founded in 1980. For more than a decade the Alliance has provided patients and policy makers with up-to-date information on marijuana's important therapeutic uses.

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MARIJUANA
AS
MEDICINE

Initial Steps

Recommendations
for the
Clinton Administration

Robert C. Randall & Alice M. O'Leary

Being aware that not one American Health Association accepts marijuana as medicine, not:

The American Medical Association
The National Sclerosis Society
The American Glaucoma Society
The American Academy of Ophthalmology
The American Cancer Society

SB 865 continues to lack merit.

Because NORML and their followers in Oregon have had opportunity at the national level since 1987 to present written documentation and public testimony at lengthy hearings, CFDFO agrees with the comments of Judge Robert E. Bonner, Administrator of the DEA, "following a review of the entire record in the marijuana matter and a comprehensive re-examination of the relevant statutory standard, I conclude that marijuana has no currently accepted medical use and must remain in Schedule I. Further hearings are unnecessary since the record is extraordinarily complete, all parties had ample opportunity and wide latitude to present evidence and to brief all relevant issues...."

Upon hearing the testimony May 6, 1993, of the proponents of SB 865, I heard no medical or scientific data to back their claims that smoking the crude marijuana plant is necessary or superior to synthetic THC or conventional medications.

NORML and their supporters consider the Robert Randall case their strongest. Robert Randall testified at the May 6th hearing; he flew in from Washington, DC to tell how smoking marijuana has saved his eyesight. Mr. Randall started smoking pot in college in 1968. He was diagnosed with glaucoma in 1972, was arrested for growing in 1975 and used "medical necessity" as his defense. Since 1975, Mr. Randall has received marijuana from the Federal Government to treat his glaucoma. He smokes 8-10 joints every day but, also, takes other glaucoma medications. Upon testimony, in the Washington, DC hearings, Randall's doctor noted "that marijuana itself is not totally effective in decreasing Mr. Randall's eye pressure" (see Federal Register, Vol 57, No. 59). Robert Randall has served on the Board of Directors of the National Organization for Reform of Marijuana Laws (NORML) since 1976 and is head of ACT (Alliance for Cannabis Therapeutics).

Citizens For A Drug Free Oregon and Sandra Bennett, Drug Watch Oregon and Vice President of Drug Watch International, have provided you and your committee with extensive medical and scientific documentation to refute the claims of the marijuana lobby regarding the crude marijuana plant for medicine.

Citizens For A Drug Free Oregon, also strongly raises the issue that smoking marijuana may actually be harmful. No medicine prescribed for us today is smoked. For the last half



CITIZENS FOR A DRUG FREE OREGON

8383 NE SANDY BLVD. • SUITE 320-I • P.O. BOX 30538 • PORTLAND • OREGON • 97230 • 503-254-9560

May 10, 1993

Jose Cerda -
FYI

Senator Bob Shoemaker, Chair
Senate Health Care and Bio-Ethics Committee
Capitol Building S-210
Salem, OR 97310

Re: SB 865 - The Marijuana Plant for Medicine (Smoking)

Dear Senator Shoemaker:

While reviewing the testimony from the May 6th hearing, it is interesting that the marijuana advocates had time to bring people in to testify from throughout the Nation. Given the fact that Citizens For A Drug Free Oregon (CFDFO) only had 2 1/2 days notice about the Thursday hearing on SB 865 and the public was given notice only one day prior to the hearing, the committee administrator has given CFDFO the opportunity to bring in expert witnesses if another hearing is scheduled. CFDFO acknowledges this is a very controversial bill and it needs thorough investigation.

After careful review of the Federal Register, Vol. 54, No. 249, December 29, 1989 and the final order of the Administrator of the Drug Enforcement Administration (DEA) concluding the plant material marijuana has no currently accepted medical use and denying the petition of the National Organization for the Reform of Marijuana Laws (NORML) to reschedule marijuana from Schedule I to Schedule II of the Controlled Substances ACT (Federal Register, Vol. 57, No. 59) Effective Date: March 26, 1992, it is our continued position that SB 865 has no merit.

After reviewing the 15 letters presented to you and the committee from nationally recognized medical specialists researching and/or specializing in the treatment of Glaucoma, AIDS, Chemotherapy, Multiple Sclerosis, Pulmonary Disease, Coronary Disease, Asthma, Allergy and Immunology, it is both their and our opinion SB 865 lacks merit.

century, drug evaluation experts at the United States Food & Drug Administration (FDA) have been responsible for protecting America from unsafe and ineffective new medicines. Relying on the same scientific standards used to judge all other drugs, FDA experts repeatedly have rejected marijuana for medical use.

However, as you know, the FDA has approved a synthetic form of THC, the only chemical found in marijuana shown thus far to have therapeutic benefits. Synthetic THC is available in pill form, eye drops, suppositories and can be injected if the physician deems it necessary and beneficial.

During the May 6th hearing, I raised the concern that smoking marijuana can be harmful to Chemotherapy and AIDS patients. As stated by Grover C. Bagby, Jr., M.D., Professor of Medicine and Molecular and Medical Genetics, Head of the Division of Hematology and Medical Oncology, Oregon Health Sciences University: "As you know, oral THC and THC taken as marijuana (smoked) are not equivalent. Patients receiving Chemotherapy for cancer are very commonly compromised immunologically by the therapy itself. These individuals are therefore extraordinarily sensitive to invasion by bacterial and fungal organisms that would otherwise be resisted. It is known that marijuana is irritating to the airway and can cause chronic bronchitis. It has also been demonstrated that infectious agents can be found on marijuana leaves (e.g. *Aspergillus* species)."

David N. Gilbert, M.D., Consultant in Infectious Diseases and Director, Infectious Diseases Research; Director, E. A. Chiles Research Institute; Providence Medical Center and Professor of Medicine, Oregon Health Sciences University: "I would like to comment on the suggestion that smoking marijuana is appropriate, and/or desirable as an anti-emetic medicine for patients with HIV infection and the acquired immunodeficiency syndrome. In general, patients with a damaged immune system are best served by not smoking anything. The chemical irritation of their airway is detrimental to defense against, and recovery from, a variety of infections of the respiratory tract. Marijuana products are known to frequently be contaminated by *Aspergillus* species. The inhalation of *Aspergillus* species into the lungs of immune-damaged patients is very undesirable."

After careful review of the extensive documentation provided to you and the committee, Citizens For A Drug Free Oregon does not believe more medical and scientific information or testimony is needed. However, after careful review of the data, if you still decide to proceed with SB 865, testimony and study by the committee is needed in the following areas:

- 1) Careful review and analysis of the language in SB 865. The District Attorney's Association and law enforcement agencies need to review the impact SB 865 would have on the state of Oregon.

- 2) SB 865 is vague as to the role the attending physician plays. It appears the patient can make the decision, grow their own pot and use at will. There is no age reference to who can grow and use, as well as, SB 865 allows others to grow for another person. Potential for entrepreneurship and selling the "medication" is a concern.
- 3) The fact that even if SB 865 passes, Oregonians would still be subject to Federal Law and Federal Prosecution needs to be addressed.
- 4) The State of Oregon can apply to the FDA for IND (Investigational New Drug) status if serious formal research is the goal of SB 865. This may be necessary for the State to do so in any case.
- 5) Liability Issues:
Would the State of Oregon be liable as pharmaceutical companies and tobacco companies currently are if harm comes to Oregonians using this state sanctioned medical remedy?
Liability questions regarding the physical and medical harm, as well as, accidental death due to marijuana intoxication.
- 6) The Federal Highway Administration rules 53FR47134 requires controlled substance testing for all heavy over-the-road truck drivers. SB 865 would be in direct contradiction and violation of these federal requirements.
- 7) Drug Free Workplace Responsibilities - safe and healthy work environment requirements (would state and employers both be legally liable)?
- 8) To assure the relief of pain and suffering, physicians must have a dependable substance of known composition and purity. Since the potency of marijuana, the plant, is constantly variable how does the committee expect these medical requirements be met for dose and strength?
- 9) Would marijuana for medical purposes be withheld from individuals serving sentences in penal institutions? If not, would the State let them grow their own or would the State have to provide marijuana to inmates?
- 10) Each of these questions raise many other questions and concerns.

Enclosed I have attached a copy of each letter we have previously presented to you and each committee member. Citizens For A Drug Free Oregon feels these letters are so compelling that they will assist you and the committee as you work to fulfill Senator Frank Robert's, chief sponsor of SB 865, request, "to evaluate the evidence dispassionately."

Sincerely,



Rosanna Creighton
Executive Director

Enclosures

CC: Senate Health Care and Bio-Ethics Committee Members:

Senator Joyce Cohen
Senator Jeannette Hamby
Senator Bill McCoy
Senator Gordon Smith

Others:

Senator Dick Springer, Majority Leader
Senator Bill Bradbury, Senate President
CFDFO Board of Directors
CFDFO Board of Trustees
CFDFO Business Supporters
CFDFO Community Supporters

Grover C. Bagby Jr., M.D.
Professor of Medicine and Molecular Medical Genetics and
Director, Oregon Cancer Center
Oregon Health Sciences University
School of Medicine
Head, Division of Hematology and Medical Oncology
May 5, 1993 - October 2, 1991

William M. Bennett, M.D.
Professor of Medicine and Pharmacology
Co-Chief, Division of Nephrology and Clinical Pharmacology
Oregon Health Sciences University
May 5, 1993

Roland W. Bennetts, M.D.
Northwest Gastroenterology Clinic
Portland, Oregon
May 5, 1993 - April 12, 1993

Stephen C. Reingold, Ph.D.
Vice President, Research and Medical Programs
National Multiple Sclerosis Society
January 7, 1993

William T. Shultz, M.D., P.C.
Neuro - Ophthalmologist
Devers Eye Institute
Portland, Oregon
March 17, 1992

Emil J. Bardana, Jr., M.D.
Professor and Vice Chairman
Department of Medicine
Head, Division of Allergy and Clinical Immunology
Oregon Health Sciences University
March, 16 1992

A. Sonia Buist, M.D.
Professor of Medicine
Head, Pulmonary and Critical Care Medicine
Oregon Health Sciences University - Lung Health Study
September 10, 1991

F. T. Fraunfelder, M.D.
Professor and Chairman
School of Medicine
Casey Eye Institute
Oregon Health Sciences University
September 16, 1991

David N. Gilbert, M.D.
Consultant in Infectious Diseases and
Director, Infectious Diseases Research
Director, E.A. Chiles Research Institute
Providence Medical Care
Professor of Medicine - Oregon Health Sciences University
October 29, 1992

E. Michael Van Buskirk, M.D.
Glaucoma Consultation, PC
Chairman, Department of Ophthalmology
Devers Eye Institute
Portland, Oregon
January 16, 1992

Medical Letters Provided to Committee

Kenneth P. Johnson, M.D.
Professor and Chairman
Department of Neurology
University of Maryland School of Medicine
December 28, 1992

John H. McAnulty, M.D.
Professor of Medicine
School of Medicine
Department of Medicine
Division of Cardiology
Oregon Health Sciences University
June 30, 1992

Keith Green, Ph.D., D. Sc.
Regents' Professor of Ophthalmology
Professor of Physiology
Director of Ophthalmic Research
School of Medicine
Department of Ophthalmology
The Medical College of Georgia
October 28, 1991

National Cancer Institute
The Cancer Information Service
"Marijuana in Cancer Treatment"
April 19, 1989

American Cancer Society
Letter dated August 28, 1992

Other Scientific and Medical Data provided to Committee:

Report "The Therapeutic Use of THC"
Office of Cancer Communication, The National Cancer
Institute, Bethesda, MD 20205

Pharmaceutical Information on Marinol

Federal Register, Vol. 57, No. 59 - Final Order of the
Administration of the Drug Enforcement Administration (DEA)
Relating to the Marijuana Plant as Medicine.

Medical quotes

Compiled by Sandra S. Bennett, DRUG WATCH OREGON

"BEST DOCTORS IN AMERICA"

written by Pulitzer Prize-winning authors Steven Naifeh and Gregor W. Smith and a team of pollsters and interviewers compiled a list of 3,850 doctors nationwide of the physicians that doctors would send their loved ones to. Included in that list were Dr. Emil J. Bardana, Dr. William M. Bennett, Dr. John McAnulty, Dr. William Thomas Shults, Dr. E. Michael Van Buskirk, who have provided me with their comments on the fallacy and dangers of using smoked marijuana to treat disease.

MULTIPLE SCLEROSIS

"In the absence of well designed, controlled clinical studies, (of marijuana and THC) no conclusion of benefits can be made for MS."

Stephen C. Reingold, Ph.D.
Vice President, research and Medical Programs
National Multiple Sclerosis Society
January 7, 1993

"While early studies indicated that THC seemed to reduce extensor spasm in MS patients, follow-up reports have not confirmed this benefit. A more recent report has indicated that smoking marijuana impairs motor performance in MS patients"

National Medical Advisory Board
National Multiple Sclerosis Society
Position Statement 1992

"I am sorry to see anyone deluded by the false promise of relief from MS or its symptoms by marijuana."

Kenneth P. Johnson, MD
Director of the Maryland Center for MS
Letter dated December 28, 1992

CANCER AND AIDS

"In general, patients with a damaged immune system are best served by not smoking anything....many other readily available FDA approved pharmaceutical products are more efficacious and lack the above mentioned detrimental effects of marijuana inhalation."

David N. Gilbert, MD,
Professor of Medicine,
Director, E.A. Chiles Research Institute,
Director, Infectious Diseases Research,
Providence Medical Center,
November 5, 1992

"Therefore, not only would I be unwilling to prescribe marijuana (smoked) in patients undergoing chemotherapy, I would attempt to dissuade such a patient from utilizing it and to persuade them to use marinol instead."

Grover C. Bagby, Jr., MD
Professor of Medicine and Molecular and Medical Genetics
Head, Divisions of Hematology & Medical Oncology, OHSU
October 2, 1991

CARDIOLOGY

"Those who promote its use have not shown a particularly reassured approach to evaluating the value of marijuana...All of us would very much like to help those

who suffer, who are sick, who are in pain, who are bothered by chronic nausea and vomiting. Any substantial clue that this approach would help them would be reason for all of us to adopt its use in a moment. I wait for the clue."

John H. McAnulty, MD, Professor of
Medicine
Division of Cardiology, OHSU
June 30, 1992

ALLERGY AND IMMUNOLOGY

"There is good scientific evidence that the consumption of a few marijuana cigarettes has the potential to cause the same degree of epithelial damage and bronchitis as a larger number of tobacco cigarettes...It has also been demonstrated that the combined use of marijuana and tobacco may be more harmful than the use of either substance alone."

Emil J. Bardana, Jr., MD
Professor of Medicine
Head, Division of Allergy and Clinical
Immunology
Vice Chairman, Department of
Medicine, OHSU
March 16, 1992

GLAUCOMA

"If any of the standard methods of treating elevations of intraocular pressure had side effects similar to those induced by therapeutic levels of marijuana they would never be allowed to see the light of day by the FDA...In short, I can see no compelling reason whatsoever for the use of marijuana by patients with glaucoma and believe that

to propose such a use works a cruel hoax on the public and especially those with a chronic ocular disease for which many other better treatments are currently available."

William T. Shults, MD
Neuro Ophthalmologist
Devers Eye Institute
March 17, 1992

"The recommendation to use marijuana is exactly analogous to the recommendation to ingest alcohol and maintain a state of drunkenness to treat glaucoma...there are still some pockets of work attempting to develop cannabinoids that would diminish intraocular pressure without the psychotropic effect, but those working in that area have NO difficulty obtaining these compounds through legitimate agencies."

E. Michael Van Buskirk, MD
Director of Glaucoma Service
Chairman, Dept. of Ophthalmology
Devers Eye Institute
January 16, 1992

"All the 'old' arguments apply to marijuana, i.e., lack of standardization, the multiplicity of ingredients that vary with habitat, non-uniformity of response, unacceptable side effects (even in young, healthy volunteers, that would not necessarily be as mild in an older, glaucomatous population), requirements for continuous smoking on a daily basis for life that is counter to the smoking cessation efforts of many (and certainly

against the maintenance of overall general health), and the absence of evidence of longer term (or even short-term) beneficial effects of marijuana on visual field."

(Even the oft quoted Judge Francis Young agrees that evidence for using marijuana for treatment of glaucoma "falls far, far short.")

Kenneth Green, Ph.D., D.Sc.
Regent's Professor of Ophthalmology
Professor of Physiology
Director of Ophthalmic Research
Department of Ophthalmology
October 28, 1991

"The problem is that the side effects of it (smoked marijuana) are such that patients on an effective dosage to control their intraocular pressure would not be able to work around machinery, would have difficulty in any fine hand-eye coordination, and a significant number would be dysfunctional in the work place."

F. T. Fraunfelder, MD
Professor and Chairman
School of Medicine, Casey Eye Institute,
OHSU
September 16, 1991

PULMONARY

"Furthermore, I would maintain that its use (smoked marijuana) is contraindicated because marijuana smoke is extremely irritating to the airways and may add additional pulmonary problems in these very susceptible individuals. (She is speaking of AIDS patients).

Marijuana smoke is even more irritating to the airways than tobacco smoke and leads to severe inflammation, mucus secretion and bronchitis."

A. Sonia Buist, MD
Professor of Medicine
Head, Pulmonary and Critical Care
medicine, OHSU
September 10, 1991

AS A DANGEROUS AND ADDICTIVE SUBSTANCE

The argument that marijuana is not dangerous because "no one has ever died of an overdose" readily dismissed when correlated to tobacco use. No one has died of an "overdose" of tobacco, yet it claims nearly 500,000 victims each year. Marijuana is also involved in a substantial number of vehicular accidents including more trucking fatalities than even alcohol.

"...The fact that there are over 77,000 admissions a year to treatment programs for marijuana use and that annually almost 8,000 persons require emergency hospital care for marijuana use is sufficient evidence of the drug's dangerousness. The danger of a drug should not simply be defined in terms of its ability to induce addiction."

Dr. Charles R. Schuster
Director, National Institute on Drug
Abuse, 1988 letter to Thomas J.
Gleaton, President of PRIDE

Jose - see p. 4 + p. 8

SUBSTANCE ABUSE REPORT

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PITFALLS FOR SUBSTANCE ABUSE TREATMENT IN HEALTH CARE REFORM

There are several key issues for substance abuse treatment providers to remember as the nation considers different proposals to revamp health care, according to Constance Horgan of the Institute for Health Policy at Brandeis University. Speaking at a recent conference, Horgan outlined these issues as follows.

1. The goal of most proposals is universal coverage. But the substance abuse treatment population is disproportionately low-income and unemployed. Many are hard to reach, and perhaps even homeless. Just because the government guarantees coverage doesn't necessarily mean these substance abusers will take advantage of it. "Enrollment and access are not guaranteed by coverage alone," said Horgan.

2. Will substance abuse treatment be included in the benefits package? Treatment advocates have concentrated their efforts on this. In some health care reform proposals, a substance abuse benefit is in, and clearly defined. In others, the benefit is included, but not defined. Sometimes it is left up to an independent board, part of the mental health component, or not mentioned at all. And sometimes it is explicitly left out. There are bound to be cost tradeoff issues involved in resolving this controversy, said Horgan. For example, treatment may include non-medical services like educational or vocational help. Where do these fit in with health care reform?

3. How the treatment delivery system is organized is crucial. With provider networks or HMOs, as envisioned under managed competition, there would be less fragmentation of the treatment system. The private tier is already using HMOs, and even Medicaid is trying HMOs in experimental settings in some states. But ultimately, the public system -- Medicaid -- has existed as a safety net for the private system. What role will the public system play under health care reform? Will Medicaid disappear entirely?

4. Cost sharing, or putting the financial burden on the patient, has been shown to work in one respect: it decreases utilization. This technique is used extensively in mental health care. But whether it contributes to good outcomes is not known.

In viewing responses to these issues, policy-makers will need to take the following areas into consideration in terms of substance abuse treatment, said Horgan.

- Special needs of substance abuse population... There is a lack of appreciation of the nature of this disease: that it is chronic, relapsing, and has non-medical as well as medical needs.

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- Effectiveness of treatment...Most people simply don't believe treatment works. Outcome studies have never been more important.
- State reform initiatives...States are serving as research labs for national health care reform, which will take years. Many initiatives are being tried at the state level.
- Integration of public system...Most care is provided in the public tier now. How this will be integrated into national health care reform is key.

Many different proposals

It is important to remember that the Clinton Administration's plan won't be the only one under consideration, said Horgan. "There's a whole gamut of proposals out there." And she said that she has a sense of "deja vu" because the same problems which are driving health care reform now existed 20 years ago: the costs are rising, and there are too many people without any health coverage at all.

The current substance abuse treatment system has an unfair way of dividing dollars between the private and public tiers, perhaps because the public system uses the money more efficiently. Two thirds of substance abuse treatment facilities, and three quarters of the substance abuse patients, are in the public tier, according to Horgan. Privately funded treatment centers, which have only one quarter of the patients, have almost half of the treatment dollars. A big question, said Horgan, is how the public tier will fare under health care reform.

SUBSTANCE ABUSE TREATMENT NECESSARY TO HEALTH CARE SAVINGS: CASA

Not only is substance abuse treatment important for the health of Americans, but the nation cannot save money on health care reform unless such treatment is made available to all who need it, according to Jeffrey Merrill, vice president of the Center on Addiction and Substance Abuse at Columbia University. Without a comprehensive, integrated substance abuse benefit, there will be no cost savings in health care reform, said Merrill, speaking at a recent conference.

"We need a substance abuse benefit," said Merrill. "Would we bankrupt the system? No. Would we make it unaffordable? No. It would probably add only \$60 to the average premium." So what's the problem? There is still skepticism about whether treatment works, said Merrill. No surgical procedure or pharmaceutical cure is involved. It is what the health economists call "squishy," said Merrill. "People think of it as an endless pit."

Not just another interest group

Substance abuse, including alcohol and tobacco, costs the United States \$70 to \$140 billion a year, said Merrill. That is out of a total of \$900 billion for all health care. Substance abuse pervades every aspect of the health care system, and either causes or complicates every other diseases, from cancer to heart disease to trauma, said Merrill. "This is not simply rhetoric," he told the treatment providers gathered at the conference. "This is not another interest group trying to feed at the trough."



Comments, problems,
suggestions?
Call Allison Knopf at
1-800-622-7237, or fax
1-212-475-1790.

According to Merrill, substance abuse affects health care costs in the following ways:

- Direct costs of treatment substance abuse,
- Costs of treatment where substance abuse is the only cause of a disease (for example, cirrhosis and fetal alcohol syndrome),
- Costs associated with a disease in which substance abuse is a major risk factor (such as the links between alcohol and trauma, and between smoking and lung cancer), and
- Costs of treatment of a disease which is complicated by, although unrelated to, substance abuse (for

example, a person who is an alcoholic and in the hospital for an unrelated disease tends to stay in the hospital three-and-a-half days longer than someone who is not an alcoholic).

It is important that tobacco be considered as part of the substance abuse problem, especially in terms of its health effects: 87 percent of all lung cancer is caused by smoking, as is 21 percent of all coronary disease.

The combined effects of alcohol and tobacco produce dramatically elevated risks of head and neck cancers. Someone who smokes and doesn't drink is two times as likely as someone who doesn't smoke to develop this kind of cancer. Someone who drinks and doesn't smoke is also twice as likely. Someone who drinks and smokes is 15 times as likely to get cancer of the head or neck than someone who does neither.

WHITE HOUSE PLANS FOR SUBSTANCE ABUSE TREATMENT STILL FUZZY

President Clinton says he will present his health care reform proposal to Congress around the middle of May, according to Eric Goplerud, who is the representative of the federal Substance Abuse and Mental Health Services Administration on the working group on mental health, part of the health care reform task force. But what the proposal will say about substance abuse treatment was still unclear, judging from Goplerud's comments.

Yes, there will be a substance abuse treatment benefit in the White House proposal, Goplerud assured treatment providers at a conference last month. But what it will be was still undecided -- as was much about the plan, even three weeks before its scheduled introduction to Congress. What is decided, at least by those on the task force, said Goplerud, is that the current treatment system is "broken." The overall principles for the Clinton proposal have been mapped out, however. These principles are as follows, according to Goplerud.

1. Security...Americans will know that they have health coverage even if they switch jobs or have a pre-existing condition. The coverage will include screening, early identification and rehabilitation for substance abuse.

2. Choice...The Clinton proposal will allow choice of doctors and health plans. The employer won't pick the health plan; the individual will.

3. Quality...The family doctor will be the link to appropriately trained and credentialed addiction treatment providers.

4. Affordability...Managed care has made access to treatment difficult. Under managed competition, treatment would be the least restrictive, least expensive, with the best outcome.

5. Comprehensiveness...Exactly what is meant by this in terms of substance abuse treatment has not been decided, but the package will be comprehensive.

6. Simplicity...Health care reform will allow for elimination of fraud and abuse, and reduced administrative paperwork. The new system will be cheaper to manage, with competition based on costs and outcomes. It should move insurance companies toward community rating, in which all premiums will be the same in a given geographical area.

Paying for ancillary activities

Some activities which are necessary to substance abuse treatment don't fit well into the insurance-type system envisioned under managed competition, Goplerud admitted. These include:

- outreach, transportation, child care, paying staff for interagency linkages (social services, housing);
- capacity development/human resources development -- if fully integrated, a lot of staff training will be needed; and
- prevention -- reducing alcohol and other drug abuse by prevention (the only way demand for treatment can be reduced).

Payment for individual services would be accomplished by a health benefit card, which would be issued to every American. But how services like drug prevention and fluoridation of the water would be covered would be different. There would need to be some funding mechanism for non-individual needs, said Goplerud.

Asked who would pay for ancillary services, Goplerud responded: "Any time we talk about financing, we immediately get fuzzy." He did say, however, that some roles would still fall to the federal and state governments, leaving some people queasy about the role which will fall to states -- without any money.

A representative of the federal Center for Substance Abuse Prevention asked Goplerud who would pay for delivery of prevention services, currently funded by the block grant. "As much as we preventionists want to advocate for prevention, it's not really part of their agenda," said Goplerud. "You'll have to fight for it."

Feedback from field

The mental health working group is the only diagnosis-specific working group in the health care reform task force. The following substance abuse treatment groups have met with the mental health working group over the past few months, according to Goplerud.

- National Coalition on Alcohol and other Drug Issues
- National Association of State Alcohol and Drug Abuse Directors
- National Council on Alcohol and Drug Dependency
- National Association of Addiction Treatment Providers
- American Society of Addiction Medicine
- Center on Addiction and Substance Abuse, Columbia University
- Brown University
- National Association of Alcohol and Drug Abuse Counselors
- Therapeutic Communities of America
- Legal Action Center
- Hazelden
- Pitch

In addition, Betty Ford and Joseph Califano (of CASA) have both spoken with Hillary Rodham Clinton, who chairs the task force.

But Goplerud chided treatment providers for not having their patients play a role in health care reform. The White House apparently expected consumers -- recovering substance abusers -- to descend in droves to champion a substance abuse benefit. "There is no movement of consumers saying we must have a substance abuse benefit," Goplerud said. "Where are the alumni? Where are the people we treat?"

LEE BROWN'S APPOINTMENT AS DRUG CZAR RAISES QUESTIONS

Just as the substance abuse field was beginning to lose its temper about President's Clinton's slowness in appointing a director for the Office of National Drug Control Policy, the White House finally settled on someone who agreed to take the job: Lee Brown, former police commissioner of New York City. Brown had reportedly been holding out for the directorship of the Federal Bureau of Investigation, but, late last month, apparently decided to accept the drug czar post.

When rumors of Brown's appointment began circulating in Washington, there was some concern among treatment advocates that his expertise in law enforcement would make it even more difficult to redirect the drug war away from the criminal arena and towards health policy. However, for a law enforcement executive (Brown has run police departments in Atlanta, Houston, and Portland, Oregon as well as New York City), he is more focused on the importance of treatment than might be expected. But the treatment that interests him is likely to be for offenders.

The budget which the White House presented to Congress last month contains basically the same spending components on drugs as that of former President Bush. This includes a heavy law enforcement approach to drugs. The only real difference is that the staff of ONDCP has been cut drastically -- one of President Clinton's first moves in office -- so that there will be fewer people to coordinate national drug policy. It is possible that Brown, as drug czar, will be able to refocus the budget and the way the drug problem is handled.

EIGHTH-GRADE SUBSTANCE ABUSE ON THE RISE: SURVEY

While drug use has been on the decline among high school seniors, eighth graders do not seem to be getting the same anti-drug message, judging from results of the federal Monitoring the Future Survey.

The annual survey, also known as the National High School Senior Survey on Drug Abuse, was expanded in 1991 to include eighth and 10th graders. The 1992 results, released last month, show that rates of illicit drug use rose between 1991 and 1992 for eighth graders, but not for 10th graders or seniors. Included in the increases: cocaine, marijuana, inhalants, and LSD.

"We see continued improvement among high school seniors, but we need to be sure that younger students are still learning the facts about drug and alcohol abuse," said Donna Shalala, Secretary of Health and Human Services. "As each new generation of students is about to enter high school, they need to understand that alcohol and other drug abuse can put their futures and their very lives at stake."

A reversal in the downward trend?

There is concern at the National Institute on Drug Abuse, which funds the survey, over these findings, called "troubling" by acting director Richard Millstein. The fact that eighth grade drug use is up may herald a reversal of the downward trend that was fought for so hard in the 1980s, he said.

"These findings underscore the need to continue our research efforts to learn more about the negative health consequences associated with drug abuse and to transmit research-based information about the dangers of drugs as the cornerstone of effective education and prevention programs."

What is the reason for the increase in drug use among younger students? The researchers who conducted the survey say: Attention to the drug issue has waned, and we're paying the price. "The drug abuse issue has pretty much fallen off the screen in this country," said Lloyd Johnston, the University of Michigan social psychologist who leads the survey research each year.

According to Johnston, the decline of interest in the drug issue is largely due to the Gulf war of the late 1980s, in which President Bush sent American troops to help rescue Kuwait from Iran's Saddam Hussein. "Ever since the buildup to the Gulf war, political leaders and the press talk about [drugs] less, television networks have backed off on their prime-time placement of anti-drug ads, and in general, national attention has moved away from the issue."

Attitudes, perceived risk, and 'generational forgetting'

One of the most important factors in preventing substance abuse among young people is "attitude," contends Johnston. Therefore, any let-up in the effort to change the attitudes of youth about drugs results in increased drug use. And in fact, the 1992 survey showed that in addition to using drugs more, eighth graders are losing the perception that drugs are dangerous.

Perceived risk is another key factor in drug abuse prevention, according to Johnston. The researchers have found no evidence linking reduced availability of drugs to declines in use.

Generations can forget about the dangers of drugs if not reminded, the researchers said. "LSD may be a prime example of generational forgetting, since it was perhaps the first drug in the epidemic of the past 25 years to decline as a result of concerns about its consequences," said Johnston. "Today's youngsters don't hear what an earlier generation heard -- that LSD causes bad trips, flashbacks, schizophrenia, brain damage, chromosomal damage, and so on. While some of those early assertions never were substantiated, some were, and young people today are not as likely to know about the dangers of the drug."

One class of drug, anabolic steroids, has had a large increase in the proportion of students who perceive it as dangerous. Johnston and his colleagues attribute this change to the highly publicized illness and death of Lyle Alzado, a former football player who claimed he developed brain cancer as a result of taking anabolic steroids.

Smoking and drinking

As for legal drugs, the prevalence of both smoking and drinking is still high among eighth and 10th graders as well as seniors. Thirty-day prevalence rates of smoking for eighth graders were 16 percent; for 10th graders, 22 percent; and for seniors, 28 percent. This did not represent any change from 1991, in spite of smoking prevention efforts under way in schools across the country. Johnston blames cigarette advertising, much of it aimed at young people.

Thirty-day prevalence rates for drinking were 26 percent for eighth graders, 40 percent for 10th graders, and 51 percent for seniors. Over 3 percent of seniors drank on a daily basis.

Annual prevalence

Below are some statistics on annual prevalence, connoting use at least once a year, from the survey, which consisted of over 16,000 seniors, 14,000 10th graders, and 19,000 eighth graders.

1992 Annual Prevalence of Drug Use (%)

	Eighth Graders	10th Graders	Seniors
Marijuana	7.2	15.2	21.9
Inhalants	9.5	7.5	6.2
LSD	2.1	4.0	5.6
Cocaine	1.5	1.9	3.1
Crack	0.9	0.9	1.5
Heroin	0.7	0.6	0.6
Stimulants	6.5	8.2	7.1
Tranquilizers	2.0	3.5	2.8
Alcohol	53.7	70.2	76.8
Been Drunk	18.3	37.0	50.3
Steroids	1.1	1.1	1.1

Source: National Institute on Drug Abuse

These figures generally are lower than they were in 1985, before the big anti-drug push began. However, the rise in eighth-grade drug use is reason to worry about the next generation of teens, according to the researchers, who are concerned about current and future eighth graders.

Losing 'hard-won ground'

"No one can deny that over the last 13 years, we have made a lot of progress in reducing the numbers of young Americans using illicit drugs -- in particular, marijuana, cocaine, and crack," said Johnston. "But we may now be in danger of losing some of that hard-won ground as a new, more naive generation of youngsters enters adolescence, and as society eases up on its many communications to young people of all ages about drugs."

Think of society's drug problem as an individual's, said Johnston. It is chronic and relapsing, and instead of being able to do away with it and forget about it, the struggle must be ongoing.

"For the foreseeable future, American youngsters are going to be aware of a smorgasbord of abusable drugs," said Johnston. "In the face of that, each new cohort of youngsters must be given the knowledge, skills, and motivation to resist using these drugs, which means that adult society needs to become more effective and more committed for the long term."

NRC PROPOSES CUTTING RANDOM TESTING RATE TO 50 PERCENT

Citing cost factors, the Nuclear Regulatory Commission has proposed cutting the minimum random testing rate for utility employees to 50 percent from 100 percent. This means that a company with 100 employees would, under the proposed rule, have to conduct only 50 random tests a year instead of 100 -- a substantial savings in drug-testing fees.

Under the proposed rule, published in the Federal Register March 24, NRC licensees would be the only nuclear workplaces which could reduce the random testing rate to 50 percent. Vendors and contractors with the NRC would still have to random test at a 100-percent rate. This is because the rate of positive tests is higher for vendors and contractors than for licensees: .25 percent for licensees, and .56 percent for vendors.

There are two main purposes for random testing, according to the NRC: deterring drug use by those employees who are afraid of getting caught, and detecting drug use by those employees who are undeterred. Lowering the random testing rate will probably not have an effect on the first group, the NRC says, because this group may overestimate the likelihood of being tested and just remember the risk. However, lowering the random testing rate would result in fewer of the second group being caught.

Comments on the proposed rule go to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attn: Docketing and Service Branch. The comment period expires June 22.

40 BIG COMPANIES REPORT DRUG DEALING IN THE WORKPLACE

Forty of the 100 corporate members of the Institute for a Drug-Free Workplace have had a worker convicted of selling drugs. And the drugs were not sold on the street -- they were sold in the workplace. "Thousands of convictions are going on," says Mark de Bernardo, executive director of the Washington, D.C.-based group. How do employers find out about employee drug trafficking? "A lot of employers are using undercover agents, but you don't have to," said de Bernardo. "You can find drugs in a desk -- it depends on your company policy."

Smart businesses have policies which allow them to search desks, lockers, and cars in the company lot, said de Bernardo. "The employers say that it's the company's right," he said. If this right is clearly articulated in the company policy, the employer has more protection against a lawsuit, he added. The important point is that drug dealing does occur in the workplace. In fact, many workers who might not buy drugs on the street find it convenient to get drugs in the workplace, de Bernardo acknowledged. How did the Institute for Drug-Free Workplace get the 40-percent statistic? "We sent a survey to our members," said de Bernardo. The nine-page, 71-question survey is "meant for internal use," he said. "It's useful in terms of membership networking." However, de Bernardo did meet with The Wall Street Journal, which published the item as a brief on the first page. The item did not mention that the companies surveyed by the Institute for a Drug-Free Workplace were all members of the Institute -- mostly very large companies, according to de Bernardo.

ETHIX ADDS NATIONAL PROVIDER NETWORK FOR SUBSTANCE ABUSE TREATMENT

The Ethix Corporation has added a national provider network to its mental health and substance abuse cost management program. The Beaverton, Oregon-based health care management company has tied in the network with its existing utilization review and case management program. There are over 22,000 providers and facilities in the network, which exists in all 50 states. "The addition of this network reaffirms Ethix's commitment to developing comprehensive, integrated solutions for behavioral health cost management problems," said Spencer Ward, executive director of Ethix Behavioral Services. According to Ethix, 10 to 30 percent of today's health-care dollar is spent on mental health and substance abuse treatment.

In addition to preferred provider programs, Ethix offers: utilization management, negotiation services, lifestyle management, and health care information services.

Date: 03/21/95 Time: 14:05

Marijuana Club Offers Pot to Cancer and AIDS Patients

SAN FRANCISCO (AP) Behind the nondescript door is no ordinary smoky dive. If your nose doesn't detect the sweet smell of marijuana, the sign behind the bar says it all: ``Thank you for pot smoking.''

At the San Francisco Cannabis Buyer's Club, AIDS, cancer and glaucoma patients come to buy and smoke the illegal weed they say is one of the few things that give them relief.

``This is about love,''' said Dennis Peron, who founded the club after his partner died of AIDS in 1990. ``People in the autumn, in the sunset of their lives, have a right to any medicine that helps them feel better.''

Although Peron knows he is risking arrest, the 3,200-member club has yet to be busted.

In 1992, the city Board of Supervisors, in a unanimous resolution signed by Mayor Frank Jordan, ordered police and the district attorney to make enforcing laws against marijuana as medicine their lowest priority.

``The mayor supports medicinal use of marijuana as long as it's under the supervision of a doctor,''' said Jordan spokeswoman Meredith Halpern.

To join the club, you have to produce a photo ID and a doctor's letter certifying a condition that could be alleviated by pot. Members are issued a prosaic-looking membership card (and if you lose it twice, you're out.)

The club, on the second story of a drab building near the Castro, San Francisco's mostly gay district, buys in bulk and sells at a small markup.

Since the drug is purchased underground, it's more expensive than growing your own, and members are charged \$5 to \$25 a gram. But Peron said that's about 50 percent cheaper than street prices.

Similar clubs have been formed in major U.S. cities in recent years, said Bob Randall of the Washington-based Alliance for Cannabis Therapeutics. But he wouldn't say where or how many, because the clubs are illegal.

On a recent morning, the clientele at the nonprofit San Francisco Cannabis Buyer's Club reflected the democratizing power of disease.

Old, young, black, brown, white, well-dressed and grungy were all represented in the 50 to 100 people sitting at small tables or lounging on couches as candles glowed dimly through the haze and a stereo pounded out '70s hits.

Hazel, a 75-year-old retired office manager, said she takes a couple of tokes a day, just enough to relieve the pressure in her eyes from glaucoma but not so much that she gets that ``very uncomfortable'' feeling of being high.

Michael, who has Hodgkin's disease, stops by every two weeks for the only cure he's found for the waves of nausea that follow his chemotherapy.

Bob, a 36-year-old AIDS patient whose face is covered with the dark lesions of Kaposi's sarcoma, said he comes to the club for the marijuana that keeps his appetite up and the support that boosts his spirit.

``I love the interaction. I draw from it. I've met some of my best friends now from this club,''' he said.

``A lot of times, you can't turn things off. It's like I have all these problems and I have to deal with them all the time. With marijuana, I just kind of drift away. It's my only way to turn it

Administration Keeps Ban on Medicinal Marijuana

WASHINGTON (AP) Dying patients can't get individual prescriptions for marijuana under a Clinton administration decision to uphold the ban on the medicinal use of the illegal drug.

But the Public Health Service's decision Monday left open the possibility of privately funded studies to finally prove whether marijuana has health benefits.

``Sound scientific studies supporting these claims are lacking despite anecdotal claims that smoked marijuana is beneficial,''
Assistant Health Secretary Philip Lee wrote members of Congress who support medicinal marijuana.

``This is a bureaucracy that is too dumb to figure out whether a weed could help AIDS patients survive,''
responded Robert Randall, the first person to legally receive medicinal marijuana under a government program.

Starting in 1976, certain patients who didn't find relief in traditional medications could apply to the Food and Drug Administration for permission to use marijuana.

The FDA allowed medicinal marijuana to ease nausea and loss of appetite caused by cancer and AIDS treatments, ease muscle spasms for people with spinal cord injuries or multiple sclerosis and alleviate the eye pressure that blinds glaucoma sufferers like Randall.

Some studies showed marijuana helped those diseases, but others disagreed. President Bush in 1992 banned the medical testing or use of marijuana, saying it could harm patients who had safer alternatives. The 15 people then receiving the drug, including Randall, were allowed to continue; eight are still alive.

Advocates pushed President Clinton to allow medicinal marijuana, citing the pleas of dying patients who believe it could help and noting that various groups, including the legislatures of California and Missouri, support lifting the ban. Lee announced in January that he was reviewing the policy.

In Monday's letter, he concluded that there are legal drugs to help all the diseases marijuana advocates fear but that marijuana studies aren't scientifically sound.

But, Lee wrote, private groups who want to test marijuana can apply to do so. They will be subject to the same regulations governing safety and effectiveness that FDA requires of any other medicines, he said.

The Drug Policy Foundation of Washington already is discussing such trials, said president Arnold Trebach. ``But while that is being settled and it could take a while there is no reason in the world to say to a patient who is suffering from AIDS or cancer that you cannot try this drug.''

APNP-07-19-94 0849EDT

Date: 07/18/94 Time: 17:18

Administration Keeps Ban on Medicinal Marijuana

WASHINGTON (AP) The Clinton administration decided Monday not to lift a ban on medicinal marijuana, but said it may allow privately funded experiments to try to conclude whether the illegal drug has any real health benefits.

The Public Health Service made the announcement in letters to members of Congress who had urged the administration to overturn former President Bush's ban on medicinal marijuana.

``Sound scientific studies supporting these claims are lacking despite anecdotal claims that smoked marijuana is beneficial,''

wrote Assistant Health Secretary Philip Lee.

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Starting in 1976, certain patients who didn't find relief in traditional medications could apply to the Food and Drug Administration for permission to use marijuana.

The FDA allowed medicinal marijuana to: ease nausea and loss of appetite caused by cancer and AIDS treatments; ease muscle spasms for people with spinal cord injuries or multiple sclerosis; and alleviate the eye pressure that blinds glaucoma sufferers such as Randall.

Some studies showed marijuana helped those diseases, but others disagreed. Bush in 1992 banned the medical testing or use of marijuana, saying it could harm patients who had safer alternatives. The 15 people then receiving the drug were allowed to continue; eight are still alive.

After patients' outcry, Clinton officials in January began reviewing the ban. In Monday's letter to Rep. Dan Hamburg, D-Calif., the administration concluded there are legal drugs to help all the diseases marijuana advocates fear, and that marijuana studies aren't scientifically sound.

But, Lee wrote, the government may allow private groups to fund special clinical trials aimed at finally proving whether marijuana has any medical benefit. These would be designed under FDA guidance.

The Drug Policy Foundation of Washington already is discussing such trials, said president Arnold Trebach. ``But while that is being settled and it could take a while there is no reason in the world to say to a patient who is suffering from AIDS or cancer that you cannot try this drug.''

``Our people tell us these other medicines make them very sick,''

said Meg Ryan O'Donnell, spokeswoman for Hamburg who, along with seven other lawmakers, had pushed to restart the marijuana program. ``But this is it for us, there's nothing else we can do.''

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