FOIA Number: 2018-0764-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member:

Subseries:

OA/ID Number: 21069

FolderID:

Folder Title:
Medical Marijuana [4]

Stack:	Row:	Section:	Shelf:	Position:
S	67	1	2	1

Appendixes

A

Workshop Agendas

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
Division of Neuroscience and Behavioral Health

Medical Used of Marijuana: Assessment of the Science Base
Workshop on
Perspective on the Medical Use of Marijuana: Basic and Clinical Science

December 14-16, 1997
Beckman Center, Irvine, California

WORKSHOP AGENDA

Sunday, December 14, 1997

2:00 Introduction
Constance Pechura, *IOM Division Director*,
Neuroscience and Behavioral Health

2:30 Public input session, *5 minutes per person*
Moderator, Stanley Watson, Jr., *IOM Study Investigator*
University of Michigan

5:30 ADJOURN

Monday, December 15, 1997

Cannabinoid Neuroscience

8:30 *Moderator*
Stanley Watson, *IOM Study Investigator*
University of Michigan

8:45 Neuropharmacology of Cannabinoids and Their Receptors
Steven R. Childers, Wake Forest University School of Medicine

9:15	Precipitated Cannabinoid Withdrawal and Sensory Processing of Painful Stimuli J. Michael Walker, Brown University
9:45	Role of Cannabinoids in Movement Clara Sanudo, Brown University
10:15	Tolerance and Cannabinoid-Opioid Interactions Sandra P. Welch, Medical College of Virginia
10:45	BREAK

Medical Uses of Marijuana: Clinical Data and Basic Biology

11:10	*Moderator* John A. Benson, Jr., *IOM Study Investigator* Oregon Health Sciences University
11:15	Profile of Medical Marijuana Users John Mendelson, University of California at San Francisco
11:45	Immune Modulation by Cannabinoids Norbert Kaminskl, Michigan State University
12:15	Psychological Effects of Marijuana Use Charles R. Schuster, Wayne State University
12:45	LUNCH
1:45	Marijuana and Glaucoma Paul Kaufman, University of Wisconsin
2:15	Effects of Marijuana and Cannabinoids in Neurological Disorders Paul Consroe, University of Arizona Health Sciences Center
2:45	Neural Mechanisms of Cannabinoid Analgesia Howard Fields, University of California at San Francisco
3:15	Pain Management Michael Rowbotham, University of California at San Francisco
3:45	Wasting Syndrome Pathogenesis and Clinical Markers Donald Kotler, St. Lukes'-Roosevelt Hospital
4:15	Clinical Experience with Marijuana Stephen O'Brien, East Bay AIDS Center
4:45	ADJOURN

Tuesday, December 16, 1997

Medical Uses of Marijuana: Clinical Data and Basic Biology

8:30 *Moderator*
John A. Benson, Jr., *IOM Study Investigator*
Oregon Health Sciences University

8:45 Marijuana in AIDS Wasting: Tribulations and Trials
Donald I. Abrams, University of California at San Francisco

9:15 Nausea and Vomiting: Underlying Mechanisms and Upcoming Treatments
Alan D. Miller, The Rockefeller University

9:45 Post-chemotherapy Nausea and Anti-emetics
Richard J. Gralla, Ochsner Cancer Center

10:15 BREAK

Summary Views

10:30 Marijuana is Different from THC: A Review of Basic Research and State Studies of Anti-emesis
Richard E. Musty, University of Vermont

11:00 Medical Uses of Crude Marijuana: Medical and Social Issues
Eric A. Voth, The International Drug Strategy Institute

11:30 General Questions
Moderator, John A. Benson, Jr., *IOM Study Investigator*

12:00 ADJOURN

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
Division of Neuroscience and Behavioral Health

Medical Use of Marijuana: Assessment of the Science Base
Workshop on
Acute and Chronic Effects of Marijuana Use

January 22-23, 1998
New Orleans Marriott Hotel
New Orleans, LA

WORKSHOP AGENDA

Thursday, January 22, 1998

2:00 Introduction
Constance Pechura, *IOM Division Director*
Neuroscience and Behavioral Health

2:30 Public Input Session, *5 minutes per person*
Moderator, Stanley Watson, Jr, *IOM Study Investigator*
University of Michigan

4:30 ADJOURN

Friday, January 23, 1998

8:30 *Moderator*
John A. Benson, Jr., *IOM Study Investigator*
Oregon Health Sciences University

Health Consequences of Marijuana Use

9:00 Health Consequences of Marijuana Use: Epidemiological Studies
Stephen Sidney, Kaiser Permanente, Oakland, CA

9:30 Immunity, Infections, and Cannabinoids
Thomas Klein, University of South Florida

10:00 Pulmonary Effects of Smoked Marijuana
Donald Tashkin, Unversity of California at Los Angeles

10:30 BREAK

10:45 Is Marijuana Carcinogenic?
Epidemiological evidence for and against biological evidence for and against
Panel Discussion
Stephen Sidney
Donald Tashkin

12:00 LUNCH

Effects of Marijuana on Behavior

1:30 Marijuana: Addictive and Amotivational States, the Scientific Evidence
John Morgan, City University of New York Medical School

2:00 Marijuana's Acute Behavioral Effects in Humans
Richard Foltin, Columbia University

2:30 Tolerance and Dependence Following Chronic
Administration of oral THC or smoked marijuana to humans
Margaret Haney, Columbia University

3:00 Patterns of Continuity and Discontinuity of Marijuana Use in Relationship to Other Drugs
Robert Pandina, Rutgers University

3:30 ADJOURN

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
Division of Neuroscience and Behavioral Health

Medical Use of Marijuana: Assessment of the Science Base

Workshop on

Prospects for Cannabinoid Drug Development

February 23-24, 1998
National Academy of Sciences Building
Washington, D.C.

WORKSHOP AGENDA

MONDAY, FEBRUARY 23, 1998

1:30 Introduction
CONSTANCE PECHURA, *IOM Division Director*
Neuroscience and Behavioral Health

2:00 Public Input Session, *5 minutes per person*
Moderator: JOHN A. BENSON, JR., *IOM Study Investigator*
Oregon Health Sciences University

5:30 ADJOURN

TUESDAY, FEBRUARY 24, 1998

8:30 Introduction
CONSTANCE PECHURA, *IOM Division Director*
Neuroscience and Behavioral Health

Moderator: STANLEY J. WATSON, Jr., IOM Study Investigator
University of Michigan

Overviews of Preceding Workshops

8:45 Acute and Chronic Effects of Marijuana
BILLY R. MARTIN, Medical College of Virginia

9:25 Perspectives on the Medical Use of Marijuana
ERIC B. LARSON, University of Washington Medical School

9:55 The Neurobiology of Cannabinoid Dependence
GEORGE F. KOOB, Scripps Research Institute

10:25 BREAK

TUESDAY, FEBRUARY 24, 1998

Drug Development

10:45 Regulatory Requirements Affecting Marijuana
J. RICHARD CROUT, Crout Consulting

11:15 Marinol and the Market
ROBERT E. DUDLEY, Unimed Pharmaceuticals, Inc.

11:45 Development of Cannabis-based Therapeutics
DAVE PATE, HortaPharm, B.V.

12:15 LUNCH

Drug Delivery

1:30 Alternative Drug Delivery Technologies for the Therapeutic Use of Marijuana
PHYLLIS I. GARDNER, ALZA Corporation, Stanford University

2:00 Delivery of Analgesics via the Respiratory Track
REID M. RUBSAMEN, Aradigm Corporation

2:30 Current Concepts for Delivery of THC
MAHENDRA G. DEDHIYA, Roxanne Laboratories, Inc.

3:00 D9-THC-Hemisuccinate in Suppository Formulation: An Alternative to Oral and Smoked THC
MAHMOUD A. ELSOHLY, University of Mississippi,
ElSohly Laboratories, Inc.

3:30 Concluding Remarks
JOHN A. BENSON, JR., *IOM Study Investigator*
Oregon Health Sciences University

3:45 ADJOURN

AA

Individuals and Organizations that Spoke or Wrote to the Institute of Medicine

A complete list will appear in the published report

B

Scheduling Definitions

Scheduling Definitions Established by the Controlled Substances Act of 1970

Schedule I (includes heroin, LSD, and marijuana)

(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has no currently accepted medical use in treatment in the United States.
(C) There is a lack of accepted safety for the use of the drug or other substance under medical supervision.

Schedule II (includes Marinol®, methadone, morphine, methamphetamine, and cocaine)

(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

Schedule III (includes anabolic steroids)

(A) The drug or other substance has a potential of abuse less than the drugs or other substances in schedules I and II.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States.
(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV (includes Valium® and other tranquilizers)

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States.
(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Schedule V (includes codeine-containing analgesics)

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
(B) The drug or other substance has a currently accepted medical use in treatment in the United States.
(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

Sources: LeCraw (1996) and 21 U.S.C. 812.

C

Statement of Task

The study will assess what is currently known, and not known about the medical use of marijuana. It will include a review of the science base regarding the mechanism of action of marijuana, an examination of the peer-reviewed scientific literature on the efficacy of therapeutic uses of marijuana, and the costs of using various forms of marijuana versus approved drugs for specific medical conditions (e.g., glaucoma, multiple sclerosis, wasting diseases, nausea, and pain).

The study will also include an evaluation of the acute and chronic effects of marijuana on health and behavior; a consideration of the adverse effects of marijuana use compared with approved drugs; an evaluation of the efficacy of different delivery systems for marijuana (e.g., inhalation vs. oral); and an analysis of the data concerning marijuana as a gateway drug; and an examination of the possible differences in the effects of marijuana due to age and type of medical condition.

Specific Issues

Specific issues to be addressed fall under three broad categories: the science base, therapeutic use, and economics.

Science Base

- Review of neuroscience related to marijuana, particularly relevance of new studies on addiction and craving
- Review of behavioral and social science base of marijuana use, particularly assessment of the relative risk of progression to other drugs following marijuana use
- Review of the literature determining which chemical components of crude marijuana are responsible of possible therapeutic effects and for side effects

Therapeutic Use

- Evaluation of any conclusions on the medical use of marijuana drawn by other groups
- Efficacy and side-effects of various delivery systems for marijuana compared to existing medications for glaucoma, wasting syndrome, pain, nausea, or other symptoms
- Differential effects of various forms of marijuana that relate to age or type of disease.

Economics

- Costs of various forms of marijuana compared with costs of existing medications for glaucoma, wasting syndrome, pain, nausea, or other symptoms
- Assessment of differences between marijuana and existing medications in terms of access and availability

These specific areas, along with the assessments described above will be integrated into a broad description and assessment of the available literature relevant to the medical use of marijuana.

D

Recommendations made in Recent Reports on the Medical Use of Marijuana

---

Recommendations from five recent key reports pertaining to the medical use of marijuana are listed by subject. Recommendations made on issues outside the scope of this report, such as drug law and scheduling decisions, are not included here. The following reports were reviewed:

- Health Council of the Netherlands, Standing Committee on Medicine. 1996. Marihuana as medicine. Rijswikj, the Netherlands: Health Council of the Netherlands.
- Report of the Council on Scientific Affairs. 1997. Report to the AMA House of Delegates. Subject: Medical Marijuana.
- British Medical Association. 1997. Therapeutic uses of cannabis. Harwood Academic Publishers, United Kingdom.
- National Institutes of Health. 1997. Workshop on the medical utility of marijuana. Bethesda, MD: National Institutes of Health.
- World Health Organization. 1997. Cannabis: a health perspective and research agenda.

In November 1998, the British House of Lords Science and Technology Committee published, *Medical Use of Cannabis*, in which they reported their conviction that "cannabis almost certainly does have genuine medical applications." The House of Lords report was released too late in the preparation of the IOM report to permit careful analysis, and is not summarized here. It is available on the internet at: *www.parliament.uk*.

General recommendations

Health Council of the Netherlands

In order to assess the efficacy of marihuana and cannabinoids, the committee studied literature published during the past 25 years. Based on their findings, the committee concluded that there was insufficient evidence to justify the medical use of marijuana.

AMA House of Delegates

Adequate and well-controlled studies of smoked marijuana be conducted in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy including AIDS wasting syndrome, severe acute or delayed emesis induced by chemotherapy, multiple sclerosis, spinal cord injury, dystonia, and neuropathic pain.

British Medical Association

Further research is required to establish suitable methods of administration, optimal dosage regimens and routes of administration for the above indications.

National Institutes of Health

For at least some potential indications, marijuana looks promising enough to recommend that there be new controlled studies done for the following indications: appetite stimulation and wasting, chemotherapy-induced nausea and vomiting, neurological and movement disorders, analgesia, glaucoma (but see note below). Until studies are done using scientifically acceptable clinical trial design and subjected to appropriate statistical analysis, the question concerning the therapeutic utility of marijuana will likely remain largely unanswered.

World Health Organization

Therapeutic uses of cannabinoids warrant further basic pharmacological and experimental investigation and clinical research into their effectiveness. More research is needed on the basic neuropharmacology of THC and other cannabinoids so that better therapeutic agents can be found.

Analgesia

Health Council of the Netherlands

No recommendations

AMA House of Delegates

Controlled evidence does not support the view that THC or smoked marijuana offer clinically effective analgesia without causing significant adverse events when used alone. Preclinical evidence suggests that cannabinoids can potentiate opioid analgesia and that cannabinoids may be effective in animal models of neuropathic pain. Further research into the use of cannabinoids in neuropathic pain is warranted.

British Medical Association

The prescription of nabilone, THC and other cannabinoids should be permitted for patients with intractable pain. Further research is needed into the potential of cannabidiol as an analgesic in chronic, terminal and post-operative pain.

National Institutes of Health

Evaluation of cannabinoids in the management of neuropathic pain, including HIV-associated neuropathy, should be undertaken.

World Health Organization

No recommendations, although the report notes that some newly synthesized cannabinoids are extremely potent analgesics; however, separation of the analgesia and side effects remains to be demonstrated.

Nausea and vomiting

Health Council of the Netherlands

No recommendations

AMA House of Delegates

Research involving THC and smoked marijuana should focus on their possible use in treating delayed nausea and vomiting, and their adjunctive use in patients who respond inadequately to 5-HT_3 antagonists. The use of an inhaled substance has the potential for benefit in ambulatory patients who are experiencing the onset of nausea, and are thus unable to take oral medications.

British Medical Association

Further research is needed on the use of Δ^8-THC as an anti-emetic, the use of cannabidiol in combination of THC, and the relative effectiveness of cannabinoids compared with 5-HT_3 antagonists. Further research is needed in other cases, such as post-operative nausea and vomiting.

National Institutes of Health

Inhaled marijuana merits testing in controlled, double-blind, randomized trials for nausea and vomiting.

World Health Organization

More basic research on the central and peripheral mechanisms of the effects of cannabinoids on gastrointestinal function may improve the ability to alleviate nausea and emesis.

Wasting syndrome and appetite stimulation

Health Council of the Netherlands

No recommendations

AMA House of Delegates

THC is moderately effective in the treatment of AIDS wasting, but its long duration of action and intensity of side effects preclude routine use. The ability of patients who smoke marijuana to titrate their dosage according to need and the lack of highly effective, inexpensive options to treat this debilitating disease create the conditions warrants formal clinical trial of smoked marijuana as an appetite stimulant in patients with AIDS wasting syndrome.

National Institutes of Health

There is a need for further research where long term administration of marijuana might be considered for therapeutic purposes. individuals who are HIV-positive or who have tumors or diseases where immune system function may be important in the genesis of the disease.

Areas of study for the potential appetite-stimulating properties of marijuana include the cachexia of cancer, HIV/AIDS symptomatology, and other wasting syndromes. Investigations should be designed to assess long-term effects on immunology status, the rate of viral replication, and clinical outcomes in participants as well as weight gain . In therapeutic trials of cachexia, research should attempt to separate out the effect of marijuana on mood versus appetite. Some questions need to be answered in the studies: (1) Does smoking marijuana increase total energy intake in patients with catabolic illness. (2) Does marijuana use alter energy expenditure? (3) Does marijuana use alter body weight, and to what extent? (4) Does marijuana use alter body composition and to what extent?

World Health Organization

No specific recommendation, although the report notes that dronabinol is an effective appetite stimulant for patients with AIDS wasting syndrome.

Muscle spasticity

Health Council of the Netherlands

No recommendations

AMA House of Delegates

Considerably more research is required to identify patients who may benefit from THC or smoked marijuana, and to establish whether responses are primarily subjective in nature. A therapeutic trial of smoked marijuana or THC may be warranted in patients with spasticity who do not derive adequate benefit from available oral medications, prior to their considering intrathecal baclofen therapy or neuroablative procedures.

British Medical Association

A high priority should be given to carefully controlled trials of cannabinoids in patients with chronic spastic disorders which have not responded to other drugs are indicated. In the mean time, there is a case for the extension of the indications for nabilone and THC for use in chronic spastic disorders unresponsive to standard drugs.

National Institutes of Health

Few available therapies provide even partial relief for the neuropathic pain that complicates many diseases affecting the central nervous system. Cannabinoid drugs are potentially valuable in these areas, especially if deivered by other than the smoked route. More research is needed.

Movement disorders

Health Council of the Netherlands

No recommendations

AMA House of Delegates

Considerably more research is required to identify dystonic patients who may benefit from THC or smoked marijuana, and to establish whether responses are primarily subjective in nature.

British Medical Association

The potential of (+)-HU-210 for neruodegenerative disorders should be explored through further research

National Institutes of Health

More studies are needed in movement disorders

World Health Organization

No recommendations, although the report notes that cannabinoids have not yet been proven useful in the treatment of convulsant or movement disorder or in treating multiple sclerosis.

Epilepsy

Health Council of the Netherlands

No recommendations

AMA House of Delegates

No recommendations

British Medical Association

Trials with cannabidiol (which is non-psychoactive) used to enhance the activity of other drugs in cases not well controlled by other anticonvulants are needed.

National Institutes of Health

No recommendations

World Health Organization

No recommendations

Glaucoma

Health Council of the Netherlands

No recommendations

AMA House of Delegates

Neither smoked marijuana nor THC are viable approaches in the treatment of glaucoma, but research on their mechanism of action may be important in developing new agents that act in an additive or synergistic manner with currently available therapies.

British Medical Association

Cannabinoids do not at present look promising for these indications, but much further basic and clinical research is needed to develop and investigate cannabinoids which lower intraocular pressure, preferably by topical application (eg. eye drops, inhalant aerosols), without producing unacceptable systemic and central nervous system effects.

National Institutes of Health

Further studies to define the mechanism of action and to determine the efficacy of delta-9-tetrahydrocannabinol and marijuana in the treatment of glaucoma are justified.

World Health Organization
No recommendations

Physiological harms

Health Council of the Netherlands
No recommendations
AMA House of Delegates
No recommendations
British Medical Association
Further research is needed to establish the suitability of cannabinoids for immunocompromised patients, such as those undergoing cancer chemotherapy or with HIV/AIDS.
National Institutes of Health
Additional studies of long term marijuana use are needed to determine if there are or are not important adverse pulmonary, central nervous system (CNS), or immune system problems. The suggested design for clinical studies is to add marijuana, oral THC, or placebo to standard therapy under double-blind conditions: (1) Establish dose-response and dose-duration relationships for IOP and CNS effects. (2) Relate IOP and blood pressure measurements longitudinally to evaluate potential tolerance development to cardiovascular effects. (3) Evaluate CNS effects longitudinally for tolerance development.
World Health Organization
Further studies are required of marijuana use on fertility effects, respiratory function and disease, immunological function, and cardiovascular effects.

Psychological harms

Health Council of the Netherlands
No recommendations
AMA House of Delegates
No recommendations
British Medical Association
No recommendations
National Institutes of Health
No recommendations
World Health Organization
There is a need for controlled studies investigating the relationships between cannabis use, schizophrenia and other serious mental disorders.
Insufficient research has been undertaken on the 'amotivational' syndrome which may or may not result from heavy cannabis use. It is not clear that the syndrome exists, even though heavy cannabis use is sometimes associated with reduced motivation to succeed in school and work. New research is needed to show whether the reduced motivation seen in some cannabis users is due to other psychoactive substance use and whether it precedes cannabis use. Further

development of cognitive and psychomotor tests for controlled studies that are sensitive to the performance effects of cannabis use and that reflect the complexity of specific daily functions (e.g., driving, learning, reasoning) also need additional research. More research in examining the relationship between THC concentrations in blood and other fluids and the degree of behavioral impairment produced.

Physiological harms

Health Council of the Netherlands

No recommendations

AMA House of Delegates

No recommendations

British Medical Association

No recommendations

National Institutes of Health

There significant health risks associated with smoked marijuana that must be considered not only in terms of immediate adverse effects, but also long-term effects in patients with chronic diseases. The possibility that frequent and prolonged marijuana use might lead to clinically significant impairments of immune system function is great enough that relevant studies should be part of any marijuana medication development research.

World Health Organization

Research on chronic and residual cannabis effects is also needed. The lack of knowledge restricts the ability of researchers to relate drug concentrations in blood or other fluids and observed effects.

More studies are needed on the fertility effects in cannabis users, in view of the high rate of use during the early reproductive years.

More research is required on the effects of cannabis on respiratory function and respiratory diseases. More studies on whether cannabis affects the risk of lung malignancies and what level of use that may occur. More studies are needed to clarify the rather different results of pulmonary histopathological studies in animals and man.

More clinical and experimental research is needed on the effects of cannabis on the immunological function. More clarity should be sought concerning the molecular mechanisms responsible for immune effects, including both cannabinoid receptor and non-receptor events.

The possibility that chronic cannabis use has adverse effects on the cardiovascular system.

Smoked marijuana and use of plants as medicine

Health Council of the Netherlands

Not recommended. The committee believes that physicians cannot accept responsibility for a product of unknown composition that has not been subjected to quality control.

AMA House of Delegates

NIH should use its resources to support the development of a smoke-free inhaled delivery system for marijuana or THC to reduce the health hazards associated with the combustion and inhalation of marijuana.

British Medical Association

Prescription formulations of cannabinoids or substances acting on the cannabinoid receptors should not include either cigarettes or herbal preparations with unknown concentrations of cannabinoids or other chemicals.

National Institutes of Health

NIH should use its resources and influence to rapidly develop a smoke-free inhaled delivery system for marijuana or THC. This will also bring this research effort in line with other Government initiatives to curtail cigarette smoking. "Taking the smoke" out of an inhaled dosage form of marijuana or THC would remove an important obstacle to the accurate determination of inhaled marijuana's beneficial and deleterious effects.

World Health

Not discussed in the context of medical use, although many health hazards associated with chronic marijuana smoking are noted.

Drug development

Health Council of the Netherlands

Not discussed.

AMA House of Delegates

NIH should use its resources to support the development of a smoke-free inhaled delivery system for marijuana or THC to reduce the health hazards associated with the combustion and inhalation of marijuana.

British Medical Association

Pharmaceutical companies should undertake basic laboratory investigations and develop novel cannabinoid analogues which may lead to new clinical uses.

National Institutes of Health

NIH should use its resources and influence to rapidly develop a smoke-free inhaled delivery system for marijuana or THC. This will also bring this research effort in line with other Government initiatives to curtail cigarette smoking. "Taking the smoke" out of an inhaled dosage form of marijuana or THC would remove an important obstacle to the accurate determination of inhaled marijuana's beneficial and deleterious effects.

World Health Organization

Not discussed.

E

Rescheduling Criteria

DEA's Five Factor Test for Rescheduling
(Formulated in 1992 in Response to Court Challenge to Scheduling)

(1) The Drug's Chemistry Must Be Known and Reproducible

The substance's chemistry must be scientifically established to permit it to be reproduced in dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 USC 321(f), is sufficient generally to meet this requirement.

(2) There Must be Adequate Safety Studies

There must be adequate pharmacological and toxicological studies done by all methods reasonably applicable on the basis of which it could be fairly and responsibly concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder.

(3) There Must Be Adequate and Well-Controlled Studies Proving Efficacy

There must be adequate, well-controlled, well-designed, well-conducted, and well documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of which it could fairly and responsibly be concluded by such experts, that the substance will have its intended effect in treating a specific, recognized disorder.

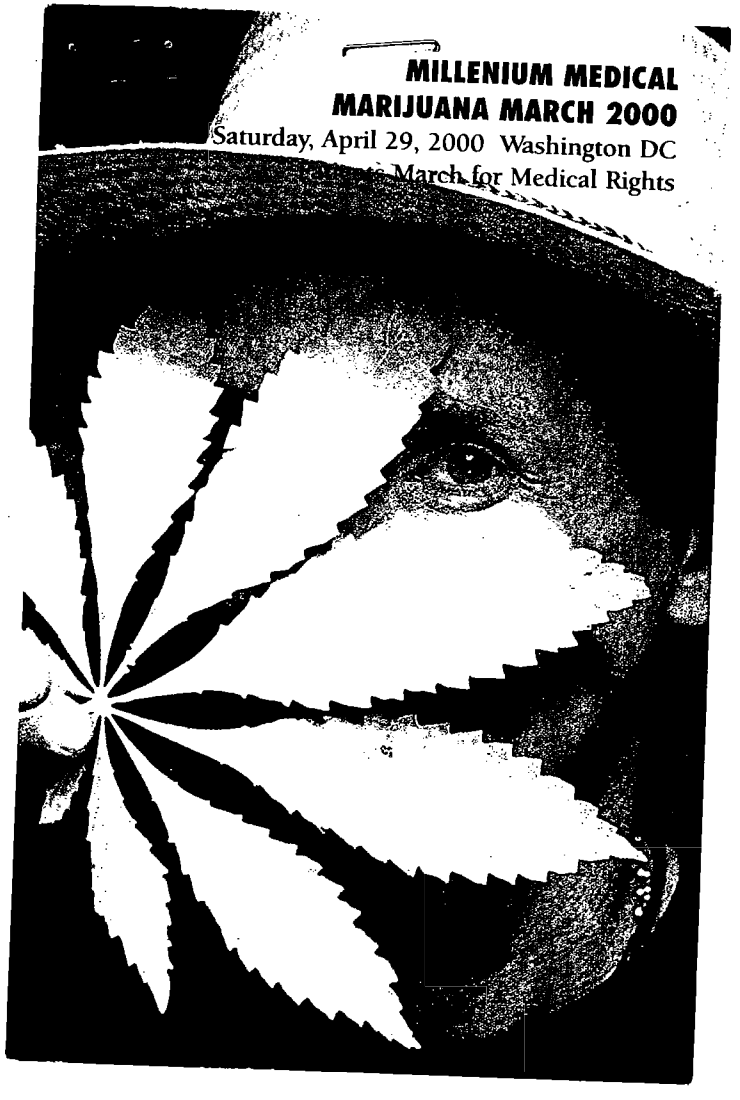
(4) The Drug Must Be Accepted by Qualified Experts

The drug must have a New Drug Application (NDA) approved by the Food and Drug Administration...Or, a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, accepts the safety and effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among experts precludes a finding of consensus.

(5) The Scientific Evidence Must Be Widely Available

In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance must be reported, published, or otherwise widely available in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder.

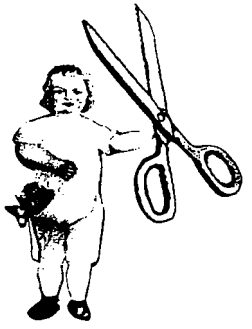
Sources: LeCraw (1996) and 57 Fed. Reg. 10499– (1992).



MILLENIUM MEDICAL
MARIJUANA MARCH 2000
1331 Berkely St. Suite #3
Santa Monica, CA 90404
ph: 310-453-2700
fax: 310-586-1566

M.M.M.M. 2000
Saturday, April 29, 2000 Washington DC

PHOTO: BLAKE LITTLE



CARA SCISSORIA

O Little Town of Hollywood

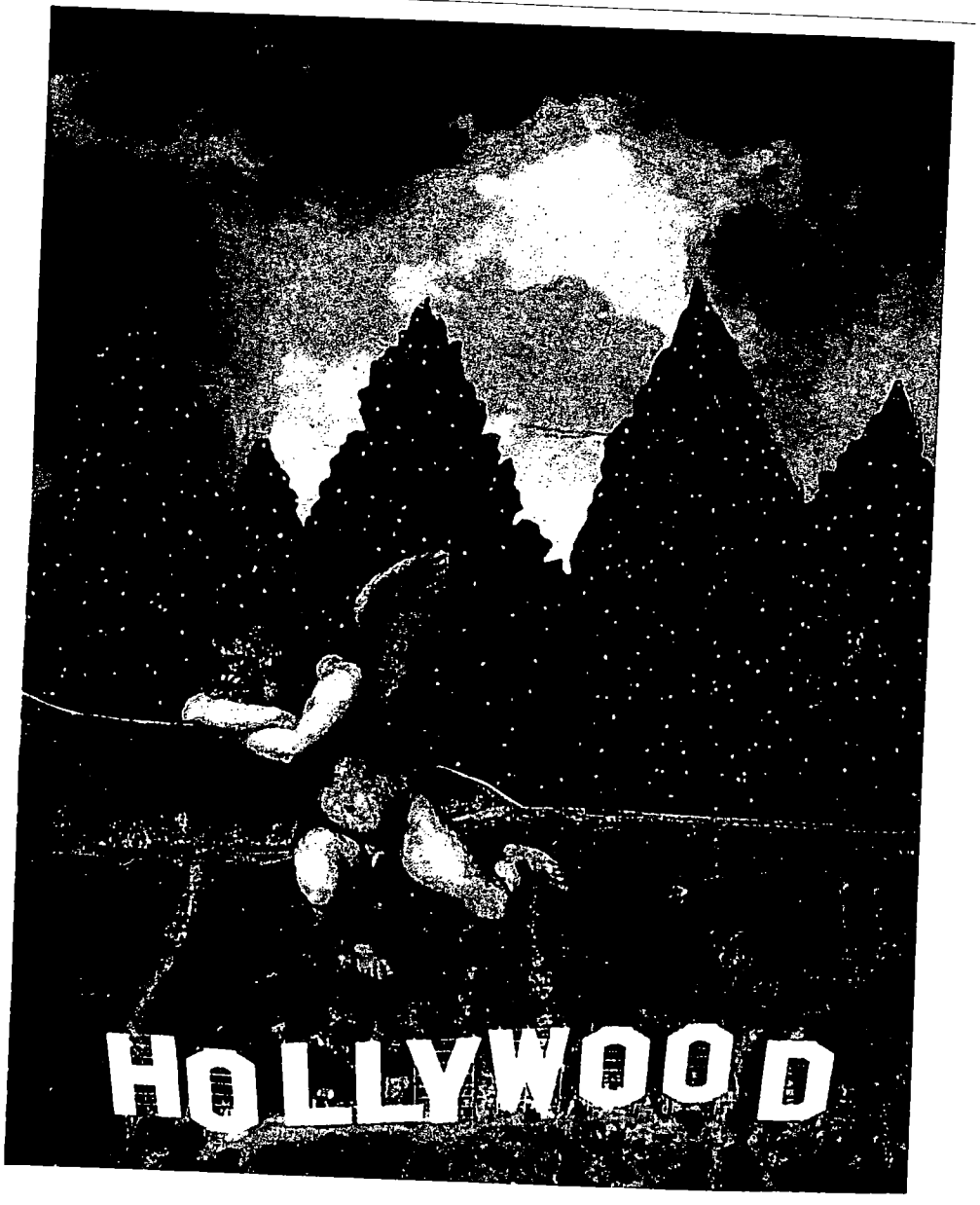
4109 $2.00

6 13181 64109 4

ISBN 0-9653715-0-6

9 780965 371506

P.O. BOX 1076
VENICE, CA 90294
FAX (714) 722-7909



12/3/99

DEAR SANDY THURMAN!

JUST GOT TO "MEET"
JANET RENO, I GAVE HER
THE INSTITUTE OF MEDICINE
BOOK ON MEDICAL MARIJUANA!
HOPE SHE READS IT!

Season's Greetings

ALSO MET PRES. BILL CLINTON
I TOLD HIM I KNOW YOU!

YOUR FRIEND
IN CALIFORNIA!

Ronald W. Easthman

HAPPY HOLIDAYS!!!

Media Availability/Advisory

CONTACTS:
Richard Eastman (323) 547-9000 S.M. Corchado (310) 264-0269
Also: (323) 661-1720

Millennium Medical Marijuana March 2000 Washington, DC

U.S. National Park Services
Grant Permit for
Millennium Medical Marijuana March 2000

Saturday, April 29, 2000
Washington, DC

What: MMMM 2000 "Patient Rallies & March"

NOTE: **Organizers of International Event are Available for Media Interview in L.A.**
(Contact Above Media Contacts in L.A.)

Where: Event is in **Washington, DC, USA;** pre-event interviews available in **Los Angeles, CA**

When: **Saturday April 29, 2000**

12:00noon **Rally at Lafayette Park**
3:00pm **MMMM 2000 March (Patients & Activists)**
4pm – 8pm **Medical Rights Rally & Concert at Henry Bacon Ball Field**
(Speakers & Entertainment TBA)

1 October 1999, LOS ANGELES, CA--The United States Park Services took the unprecedented step of issuing the first-ever rally and march permit (#00-0075) to a group of organized patients for a national Millennium Medical Marijuana March 2000. Organized patients and participants from throughout the United States of America will attend the rallies to be followed by the march which is expected to be attended by thousands of Medical Marijuana patients and individuals who support safe access and legal availability now! Participants will hear patients and doctors and others speak on Medical Marijuana. *Concert info and speakers to be announced at a later date.*

What: **MMMM 2000** happens the day before the Millennium March on Washington for Equality Sunday April 30, 2000, Washington DC

Help Support Safe Access for Medical Marijuana Patients in all 50 States and our Nation's Capital, Washington, DC. Thank you.

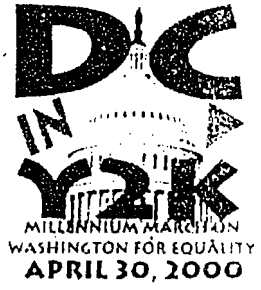
Richard Eastman & Steve M. Corchado, *Event Producers*

Millennium Medical Marijuana March 2000
1331 Berkeley Street, Suite 3 Santa Monica CA 90404
Tel: (310) 453-2700 Fax: (310) 586-1566

THE MILLENNIUM MARCH ON WASHINGTON FOR EQUALITY: THE FOOTSTEPS OF HISTORY

By Joseph S. Amster

Were you there in 1979, 1987 or 1993? For those that have been, participation in a March on Washington is remembered as one of the highlights of their lives. For those that haven't been, April 30, 2000 will be a chance to deepen their commitment to ensuring equality for the gay, lesbian, bisexual and transgender community by participating in the Millennium March on Washington for Equality.



A CALL FOR ACTION

Few of the estimated 100,000 who took part in the 1979 march could d
event.
which
Califo
Milk. I
Washi
place t
nation,
very s
nation
and es
their d

The March on Washington of 1987 was a bigger affair. Held at the height of the Reagan administration and the with the AIDS pandemic as a backdrop, this march was attended by an estimated 600,000 participants. The march took place on October 10 - 13, 1987, and included the unveiling of the Names Project AIDS Memorial Quilt, with over 2,000 panels displayed on the Mall in front of the Capitol. Two thousand gay

nerican Civil Liberties Union the Wisconsin State Journal. lina refers to himself as a ibed bigot and homophobe – ent of a gay son. He is an who now says his greatest gift racism helped him battle this new enemy of homophobia. Although in May of 1998 the Board of Education voted to uphold a disciplinary action against Karl, he has not stopped fighting. He clearly understands the links of different types of prejudice and need for coalition building.

Steven Cozza – 14 year-old straight Boy Scout who has led a national campaign on behalf of gays who wish to participate in the Boys Scouts. He took on the Boy Scouts discrimination against gay youth and adults. He has received numerous awards, including awards from the ACLU, and is a prolific speaker.

SO MUCH TO DO

There will no doubt be cultural programs on par with the 1993 March on Washington, which included many events during the week of the march. With five months remaining before the march, expect to see announcements of entertainment, exhibits and functions geared to coincide with the march. Some of the confirmed events include Equality Rocks, sponsored by the Human Rights Campaign, on Sunday, April 30 at Robert F. Kennedy Stadium. With Melissa Etheridge, Ellen DeGeneres, Ann Heche and Kristen Johnston on the bill, this event promises to be one of the highlights of the March weekend. HRC is planning comedy concerts on Thursday, April 27 and Friday, April 28, with locations to be announced. Also taking place is the National Conference of Parents and Friends of Lesbians and Gays, to be held from April 28-30 at the Crystal Gateway Marriott in Arlington Virginia, the Vice Versa Awards for Excellence in the Gay and Lesbian Press (where this publication will be honored with four awards) on April 27 and the Millennium Medical Marijuana March 2000 on April 29. Club Montage has a MMOW Dinner scheduled for Friday, April 28 and dances at the Ronald Reagan

WHAT TO EXPECT

11/30/99 BEVERLY HILLS CALIF.

12/3/99 OAKLAND CALIF.

City of West Hollywood
California 1984

CITY OF WEST HOLLYWOOD

CITY HALL
8300 SANTA MONICA BLVD.
WEST HOLLYWOOD, CA
90069-4314
TEL: (323) 848-6460
FAX: (323) 848-6562

April 13, 1999

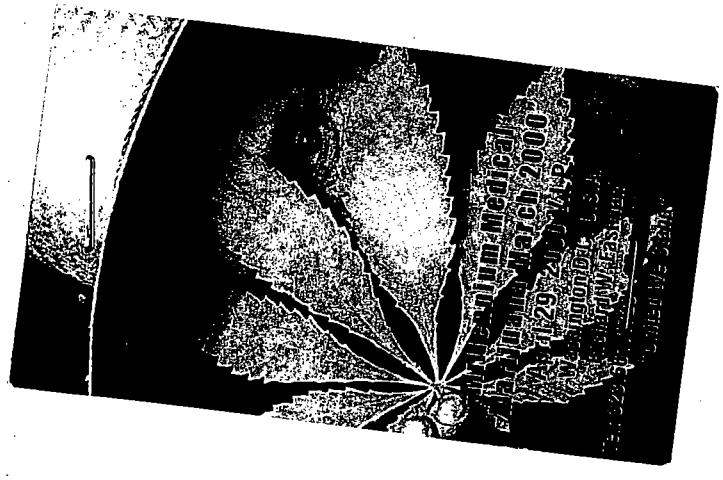
SANTA MONICA PATIENTS MEDICAL MARIJUANA SOCIETY 215
STEVE CORCHADO
PHONE: 310-453-2700
FAX: 310-586-1566
E-MAIL: steve215@gte.net
Serving Santa Monica and The Bay Area

To Whom It May Concern:

This letter will introduce you to Richard W. Eastman. He and his friend Steve M. Corchado are planning and co-producing a national patient's march to be held Saturday, April 29, 2000 in Washington, D.C. The event is to be called the "Millennium Medical Marijuana March 2000."

Both Mr. Eastman and Mr. Corchado are well known medical marijuana activists, having lobbied nationally and locally in both California and Washington D.C. for legislation that provides safe access to those who have a real and legitimate need for medical marijuana.

Richard Eastman is one of the original co-founders of the Los Angeles Cannabis Resource Center, which opened in 1995 and has been located in West Hollywood since 1996, operating with the co-operation of local law enforcement and city officials. Any assistance you could provide to help secure permits for the march would be greatly appreciated by them and all those patients in need of safe access to medical marijuana.



Very truly yours,

John Heilman

John Heilman
Mayor

MILLENNIUM MEDICAL
MARIJUANA MARCH 2000

215 SANTA MONICA PATIENTS
MEDICAL MARIJUANA SOCIETY

April 22, 1999

To Whom This May Concern:

This letter will introduce to you Richard W. Eastman and Steve M. Corchado. Mr. Eastman and Mr. Corchado are co-producers of the upcoming *MILLENNIUM MEDICAL MARIJUANA MARCH 2000*, in Washington, D.C., and are co-founders of the 215 SANTA MONICA PATIENTS MEDICAL MARIJUANA SOCIETY.

Mr. Eastman, a long-term AIDS survivor, and Mr. Corchado, a long-term asbestos lung cancer survivor who also suffers from epilepsy and PTSD, are well-known medical marijuana activists. Each has lobbied in California and Washington, D.C., for legislation which would provide safe access to individuals who have a legitimate need for medical marijuana.

MILLENNIUM MEDICAL MARIJUANA MARCH 2000 is the up-coming event planned for April 29th, 2000 in Washington, D.C. The goals of this event are to work with, and bring awareness and knowledge to, the legal community and public-at-large, as well as bring real help and relief to deserving patients.

Sincerely,

215 SANTA MONICA PATIENTS MEDICAL MARIJUANA SOCIETY

Serving Santa Monica and the Bay Cities

February 23, 1999

Dear Friends,

The purpose of this letter is to inform you of the intent of the ***215 Santa Monica Patients Medical Marijuana Society*** to open, and operate, a club for the purpose of providing safe and affordable distribution of medical marijuana and medicinal baked goods to all qualifying patients. Hours of operation will be Monday to Friday, 10 a.m. until 7:00 p.m. All items will be dispensed but not consumed on the premises.

Medical necessity includes relief of the symptoms from chronic and disabling conditions such as cancer, AIDS/HIV, multiple sclerosis, glaucoma and other applicable conditions.

The ***215 Santa Monica Patients Medical Marijuana Society*** was started on January 13, 1999, by Steve M. Corchado and Richard W. Eastman, both known activists in Los Angeles County, Sacramento and Washington, D.C.

The following conditions will apply:

- Membership is free. All patients/care-givers must carry a membership card and their recommendation form.
- Recommendation forms will be on file at the club, and available for inspection.
- All patients will be verified with the physician's office and all physicians will be verified with the AMA.
- A program will be implemented to distribute low-cost or no-cost medicine to Social Security recipients and others identified as needing assistance.
- Counseling resources and information will be made available to all staff members, patients and care-givers.
- Our target patient is the more seriously ill, but all recommendations will be carefully reviewed.

- An attorney will be on retainer and available to all staff, patients and care-givers.

- The product will be black-market free and will be inspected for mold or other problems

- Inappropriate behavior by staff, patients or care-givers will be immediately reported.

Our goal is to be in "partnership" with the local medical marijuana community, law-enforcement officials, public health officers and community-based physicians. We hope to also be working with the California State Attorney General's new Task Force to help federal and state governments develop a plan for the safe and legal implementation of Proposition 215.

Sincerely,

Steve M. Corchado and Richard W. Eastman
215 Santa Monica Patients Medical Marijuana Society

Phone: 310-453-2700 Fax: 310-586-1566 E-Mail: steve215@gte.net

cjs/wp/215/loi2rev/2-99

PHYSICIAN'S STATEMENT

This is to certify that _____has requested/I have recommended, the use of medical marijuana to gain relief from the chronic and debilitating symptoms of _____. ICDM-9_____.

My patient has been advised of all other treatment options for this illness, as well as the use of medical marijuana in conjunction with other treatments.

I have informed my patient that the use of medical marijuana is restricted by federal laws. If the patient chooses to use medical marijuana, his/her condition will be monitored at regular intervals.

Physician, Clinic or
Agency's name_____State Lic. #_____

Address_____City_____State____Zip_____

Phone#( )_____Fax#( )_____

_____DEA#_____Date_____
Physician's signature

cjs/wp/medmar3/3-99

215 SANTA MONICA PATIENTS MEDICAL MARIJUANA SOCIETY

Serving Santa Monica and the Bay Cities

Rules and Regulations of the **215 Santa Monica Patients Medical Marijuana Society** shall be as follows:

- Club hours will be Monday through Friday from 10 a.m. to 7 p.m.
- This is a "membership only" club. All members/care-givers must carry their membership card at all times.
- Membership in other clubs is prohibited.
- Medicine is dispensed only, and is not to be consumed within the club.
- Medicine is solely for the use of the patient and is not for resale, or for the use of any other person.
- All members must submit a Physician's Statement, to be kept on file in the Club, which states the need for medical marijuana and other pertinent information.
- All Physician's Statements will be verified. All physicians will be verified.
- All records are confidential will be on file in the Club.
- No inappropriate behavior inside the Club will be accepted, and will be reported.

I have read the above and agree to abide by the rules of the **215 Santa Monica Patients Medical Marijuana Society:**

Signature _____ Date _____

Name of intake counselor _____

cjs/wperr2/399

215 Santa Monica Patients
Medical Marijuana Society

Club Intake Form

Patient
Name:_____
First *Last* *MI*

Address:_____
Street # *Street Name* *Apt.#*

City:_____State_____Zip:_____Phone:( )_____

I have requested/been approved for medical marijuana use because of the following condition:

☐AIDS/HIV ☐Multiple Sclerosis

☐Cancer _____ ☐Epilepsy
Type

☐Crohns Disease ☐Glaucoma

☐Acute, chronic pain due to _____

☐Other_____

_____

Physician/Clinic Name_____

Address_____

City_____State____Zip_____Phone( )_____

_____
Name of Intake Counselor *Date*

cjs/wpcif4/399