

The Commonwealth of Massachusetts

Executive Office of Human Services

Department of Public Health

Division of Food and Drugs

305 South Street

Jamaica Plain, Mass. 02130

Bailus Walker, Jr., Ph.D., M.P.H.

COMMISSIONER

Telephone  
(617) 727-2670

August 12, 1983

Paul E. Healy  
City Clerk  
City of Cambridge  
City Hall  
Cambridge, Ma. 02139

Dear Mr. Healy:

Enclosed is a package of material we have collected concerning the use of marihuana in therapeutic research.

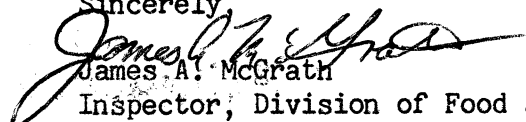
Senate bill No. 570, under consideration by the current session of the legislature, is designed to establish a patient qualification review board within the Department of Public Health. This Board will review patients who were certified by a physician to be threatened by loss of life or sight, and who may receive benefecial therapeutic effects from the administration of marihuana. The Board will review applicants for the program, and approve participation on an individual basis but would not circumvent the legal process by giving blanket approvals for any physician or patient.

S. 570 passed the Senate before recessing and is currently in House Ways and Means. The Department of Public Health supported S. 570 in February as did the American Cancer Society, National Cancer Institute, Senator Louis Bertonazzi (sponser of the bill), WCVB-TV, and a variety of states which have already enacted similar legislation. Opponents to this legislation include the National Federation of Parents for Drug Free Youth, and the World Psychiatric Association.

The Department believes that this bill will make marihuana more readily available as a therapeutic modality in alleviating the nausea and ill effects of cancer chemotherapy, and in decreasing intraocular pressure in glaucoma patients. Marihuana will be approved only for those patients who are resistant to standard therapy.

We have enclosed some material from our files for the City Council to review, and will be happy to answer any further questions you may have concerning the Department's role, should this legislation be finalized. We would strongly recommend that you also contact Senator Bertonazzi's office should further information be necessary and it's current status.

Sincerely,

  
James A. McGrath

Inspector, Division of Food and Drugs

Enclosures  
JM/dd



*The Commonwealth of Massachusetts*

*Department of Public Health*

OFFICE OF CITY CLERK

600 Washington Street, Boston 02116 PH '83

Alfred L. Frechette, M.D., M.P.H.

COMMISSIONER

CAMBRIDGE, MASS.

February 16, 1983

Honorable Edward L. Burke  
Honorable Richard A. Voke  
Chairmen, Joint Committee on Health Care  
State House  
Boston, MA 02133

RE: Senate 570 - An Act Providing for the Use  
of Marihuana in Therapeutic Research  
  
House 1988 - An Act Establishing the  
Controlled Substances Therapeutic Research  
Board

Dear Senator Burke and Representative Voke:

The Department of Public Health wishes to support the enactment of legislation which would permit the use of marihuana in therapeutic research. The legislation would also establish a Board, within the Department, to oversee all therapeutic research involving marihuana.

Support for this legislation stems from our need to see the process of approved therapeutic research simplified and made more available to individual investigators and clinicians who are treating patients afflicted with life- or sense-threatening diseases. The process will also allow for a centralized program which monitors the short and long-term effects of such treatments, and may hopefully lead to the accumulation of significant information which will be useful in making decisions as to the adoption of therapeutic regimens which someday may benefit and be available to the public in general.

In reviewing the two bills, the Department feels the S.570 would be preferable to H.1988 in terms of meeting the above referenced program goals. One provision of House 1988 which the Department finds unacceptable is the inclusion of epileptics as one of the identified patient conditions in which marihuana may be used. Information from the Investigational Drug Branch of the National Cancer Institute indicates that the use of delta-9-tetrahydrocannabinol can enhance seizure activity in patients with epilepsy and other seizure disorders. Additional disease entities can still be evaluated by the Board under S.570, s.3 on an individual basis should medical data and scientific information so allow.

H.1988 does contain some necessary provisions not currently included in S.570, and the Department recommends the following additions and amendments be made to S.570:

Section 1

- (1) Amend definition of marihuana to include products derived by chemical synthesis.

Section 2

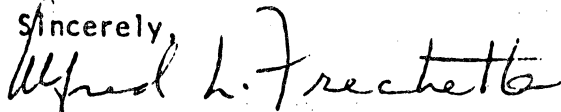
- (1) Amend by allowing the Department to also contract with the National Cancer Institute and any other manufacturer, distributor or analytical laboratory approved under provisions of federal law as a source of marihuana which can be used for human administration purposes.

Section 3

- (1) Add the following sentences related to confidentiality of information: Except for its annual and interm reports, if any, the records of the board should not be deemed to be public records within the meaning of section seven of chapter four of the General Laws. The board, upon the request of one or more of its members, shall close any of its proceedings or meetings and the provisions of section eleven A  $\frac{1}{2}$  of chapter thirty A of the General Laws shall not be applicable thereto.
- (2) Add a provision for the initial appointments to be staggered for one, two and three year terms.
- (3) Amend the process of physician referral/certification to the Board by requiring the physician to certify to all of the requirements for participation identified in Section 2, lines 22 - 32.

Representatives of the Department would be pleased to work with Committee staff and sponsors to develop the revised language referenced above, and to discuss possible mechanisms necessary to implement such a program.

Sincerely,



ALFRED L. FRECHETTE, M.D., M.P.H.  
COMMISSIONER  
DEPARTMENT OF PUBLIC HEALTH

F/Fnc



25 severe side-effects from the administration of conventional  
26 controlled substances; and who have given in writing their  
27 informed consent based upon information about the nature,  
28 duration and purpose of the research, the method and means  
29 by which it is to be conducted, the inconveniences and haz-  
30 ards reasonably to be expected, and the effects upon the pa-  
31 tients' health or person which may reasonably be expected to  
32 come from his participation.

33 The department shall contract with the national institute  
34 on drug abuse for the receipt of analyzed marihuana for dis-  
35 tribution to an approved patient upon the written prescription  
36 of a physician.

37 For the purpose of implementing this act, the commissioner  
38 shall make such rules and regulations as may be necessary.

39 *Section 3.* There shall be in the department a patient quali-  
40 fication review board, hereinafter called the board, consisting  
41 of the commissioner of public health, the commissioner for  
42 the blind, and the commissioner of mental health, or their  
43 designees, who shall serve ex officio, four physicians licensed  
44 in accordance with the provisions of section two of chapter  
45 one hundred and twelve, one of whom shall be eligible for  
46 certification by the American Board of Ophthalmology; one  
47 of whom shall be eligible for certification by the American  
48 Board of Internal Medicine in the subspecialty of medical  
49 oncology; one of whom shall be eligible for certification by  
50 the American Board of Internal Medicine in the subspecialty  
51 of pulmonary medicine; and one of whom shall be eligible for  
52 certification by the American Board of Psychiatry, and a clin-  
53 ical pharmacologist. Members of the board shall be appointed  
54 by the commissioner to serve for terms of three years. Upon  
55 the expiration of the term of any appointive member, his suc-  
56 cessor shall be appointed in like manner for a term of three  
57 years. No person shall be appointed to serve more than two  
58 consecutive three-year terms. Members of the board shall  
59 serve without compensation but shall be reimbursed for actual  
60 and necessary expenses incurred in the discharge of their  
61 duties.

62 The board shall review all applicants for the program and  
63 approve participation in the program by patients who meet  
64 the requirements of section 2 of this act, and whose physi-

65 cians certify that the administration of marihuana may have  
66 beneficial therapeutic effects. Upon presentation of sufficient  
67 medical data by a physician to the board, the board may ap-  
68 prove the experimental use of marihuana in the treatment of  
69 additional disease entities.

70 The board shall review the plans, studies, and proposed  
71 annual budget of the program and file an annual report of its  
72 activities with the governor and the general court.

MAY 4 1983

COMMONWEALTH OF MASSACHUSETTS  
MASSACHUSETTS SENATE  
STATE HOUSE, BOSTON 02133

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P R E S S   R E L E A S E

From the Office of: SENATOR LOUIS P. BERTONAZZI (D-MILFORD)

April 27, 1983

BOSTON-- If the House follows the action taken in the Senate this week, people suffering from glaucoma, cancer and asthma may soon find new relief from their pain, according to Senator Louis P. Bertonazzi (D-Milford).

A bill sponsored by the Milford Legislator authorizing the use of marijuana for treatment of the side effects of chemotherapy, glaucoma and asthma, has won the approval of the Senate and has been sent to the House.

During debate on the Senate floor, Bertonazzi pointed out that 33 states have already legalized the use of THC, the active ingredient in marijuana, for medicinal purposes. "Massachusetts is the only state in New England that has not yet enacted such legislation," he said.

The effectiveness of marijuana as a therapeutic drug has been scientifically demonstrated, Bertonazzi explained, with uses including easing the pressure in the eyes of glaucoma patients, decreasing airway resistance in asthmatics, and relief from the feelings of nausea in cancer patients receiving chemotherapy. Another benefit of permitting THC treatment for cancer sufferers is the drug's ability to serve as an appetite enhancer so patients can maintain a stable body weight and better withstand the effects of the disease and its treatment.

Senate Bill 570 would direct the Department of Public Health (DPH) to make marijuana available under supervised conditions for victims of glaucoma and asthma and to people undergoing chemotherapy.

"This piece of legislation is long overdue," Senator Bertonazzi said. "With our knowledge of the therapeutic benefits of marijuana, it is senseless to deny treatment when we know how to help relieve the suffering of cancer patients."

To qualify a patient for participation in the treatment program, a physician would have to submit evidence that the patient would benefit from the use of marijuana to a DPH Review Board. The Board created by this Bill would be comprised of the Commissioners of Public Health, Mental Health, an ophthalmologist, a psychiatrist, specialist in lung diseases and a clinical pharmacologist. The Bill requires the Review Board to report its activities annually to the Governor and the General Court.

The legislation has been held up in the Legislature for five years because of "the misguided notion that allowing the supervised medical use of marijuana for patients handicapped by glaucoma or devastated by the side effects of chemotherapy would be the first step toward legalization," Bertonazzi said. "This legislation has absolutely nothing whatsoever to do with legalization, decriminalization or the use of marijuana for any other purpose than medicinal," he said.

"How much longer can we let a small, vocal group of close-minded people with little medical knowledge create a roadblock which prevents people from receiving closely supervised treatment with marijuana which can bring relief from pain, freedom from the terror of gasping for breath, and deliverance from the frustration of encroaching blindness?" Senator Bertonazzi asked.

*for debate time*  
3/17/83

# Editorial

CVBTV BOSTON, CHANNEL 5  
Editorial Department  
5 TV Place, Needham Br. Boston, MA 02192  
(617) 449-0400

Title: Marijuana for Medical Use

Presented By: S. James Coppersmith, Vice President & General Manager

Reference No.  
27

Broadcast: February 23: 6:57 AM; 12:28 PM; 6:55 PM; 3:40 AM  
February 26: 6:58 PM; 3:50 AM

1983

For the sixth year, Massachusetts lawmakers are considering a bill to legalize marijuana for medical use. This time around, they must pass the legislation.

Some people view marijuana as a harmless diversion, while others view it as society's downfall. But for many cancer patients, marijuana is the only cure for the nausea and vomiting caused by chemotherapy. Marijuana can also be used to treat glaucoma and asthma. Yet Massachusetts still bans marijuana for such patients. Some of them, desperate for relief, are driven to buy it on the streets. Its quality is unknown, and patients caught buying it could face fines or even jail.

The proposed law would set up a controlled substance therapeutic research board in the Public Health Department. By participating in a research program, severely afflicted patients could be treated with marijuana.

The law should be passed. But that's not enough. The legal and bureaucratic barriers that keep doctors from prescribing marijuana should come down. After all, doctors may now prescribe morphine, a far stronger drug related to heroin.

Half the states in the country now allow marijuana for medical use. Tell your legislator that you favor legalizing marijuana for humane and effective medical treatment.

Dept. of Pub. Health  
**RECEIVED**

MAY 4 1983

**DIVISION OF  
FOOD & DRUGS**

CVB-TV Channel 5 presents editorials in the public interest on issues of concern to our community. Responsible opposing views are regularly broadcast. All comments from our viewing audience, and all requests for time to reply to editorials, should be directed to the Editorial Department, WCVB-TV, 5 TV Place, Needham, Massachusetts 02192. Telephone (617) 449-0400.

Channel 5 wishes to make clear that all requests for time to reply to editorials are considered equally from individual viewers as well as from spokesmen for government, business, and organized groups.

# Editorial Reply

WCVB-TV BOSTON, CHANNEL 5

Editorial Department  
5 TV Place, Needham Br. Boston, MA 02192  
7-449-0400

Re: Marijuana for Medical Use

Reference No.

Presented By:

Connie Moulton, Massachusetts Parents for Drug-Free Youth 24

Broadcast:

April 12: 6:57 AM; 12:28 PM; 6:55 PM; 3:40 AM 1983

A recent Channel 5 editorial supported a bill before the Massachusetts legislature to legalize marijuana for medical use. We disagree. To begin with this was already done in 1971 at the federal level with specific restrictions.

Marijuana is now a Schedule I drug; it may not be marketed. It is for approved research programs only.

The legislators want to down-schedule it to a Schedule II drug; which means it may be sold by prescription. Do you have to be reminded of the rampant fraudulent use of prescription drugs? Marijuana should not have easy public accessibility. Too many health hazards are associated with its use - especially the slowing down of transmitted messages within the brain due to accumulation of chemical substances. Marijuana contains over 421 chemicals which multiply into 4,000 different chemicals when smoked. These chemicals are absorbed by every cell in the body.

Cancer patients are very sick; their resistance is low. It is a known A.M.A. fact that marijuana use lowers the immune-response system.

Marijuana's potential for harm FAR outweighs its potential benefit as a medication. State legislators do not have the time, staff or inclination to properly investigate this question.

Write or call Chairman Senator Atkins and Rep. Creedon and your own legislator to vote NO on S-570.

AMERICAN CANCER SOCIETY  
MASSACHUSETTS DIVISION, INC.

CARHART MEMORIAL BUILDING • 247 COMMONWEALTH AVENUE  
BOSTON, MASSACHUSETTS 02116 • PHONE 617-267-2650 • 800-952-7664

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February 18, 1981

Senator Louis P. Bertonazzi  
Massachusetts Great and General Court  
State House  
Boston, MA 02109

Dear Senator Bertonazzi:

This is in response to your request for our opinion of Senate Bill #598 which authorizes the experimental distribution of marijuana as a controlled drug for cancer patients and others undergoing treatments causing serious side effects.

As you may remember, this Division, along with most of the medical and scientific community in Massachusetts supported the previous bill which would have the effect of providing cancer patients with marijuana to ameliorate the side effects of chemotherapy and radiation therapy.

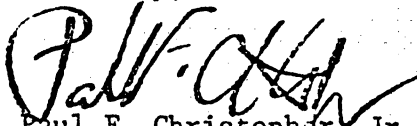
Our parent organization, the American Cancer Society, Inc., headquartered in New York, also approves the experimental use of marijuana to overcome damaging side effects of treatments received by cancer patients.

There is substantial evidence to indicate marijuana does help patients in great distress. Distress which if untreated exacerbates the worry, emotional tension, pain and discomfort cancer patients experience. The relief of this distress would be beneficial to the health, morale and emotional stability of affected cancer patients.

We are hopeful that this year the legislature will pass a bill such as #598 which would be both a medically effective and humane act.

With all good wishes.

Sincerely,

  
Paul F. Christopher, Jr.  
Executive Director

PFC:AS

# HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P80-27

FOR IMMEDIATE RELEASE

Thursday, June 26, 1980

(Food and Drug Administration)

NIDA (301) 443-3285

(Home) -- (301) 365-4574

FDA's Oncologic Drugs Advisory Committee today recommended that THC, a derivative of marijuana, be allowed widened use in the treatment of nausea and vomiting in cancer patients undergoing chemotherapy. The recommendation of the non-governmental advisers will be promptly reviewed by the agency, FDA officials said.

If the recommendation is approved, THC would be available through cancer investigators for an estimated 50,000 patients who might benefit from it. Distribution would be through hospital pharmacies and would be monitored by the Justice Department's Drug Enforcement Administration.

However, the drug would remain investigational, or "experimental." Although earlier this year, several drug companies discussed with FDA the possibility of submitting a New Drug Application for THC or for a synthetic version of it, no firm has yet submitted one. Under the law, THC must remain "experimental" until such a New Drug Application has been approved.

THC, or Delta 9 Tetrahydrocannabinol, a chemical found in marijuana, has been used experimentally for nearly ten years to treat nausea and vomiting in cancer patients undergoing drug therapy. (Some other patients have obtained marijuana cigarettes to help them combat vomiting and continue to tolerate their chemotherapy.)

The research, with THC distributed by the National Institute on Drug Abuse, has been sanctioned by FDA. The Cancer Institute now wishes to make the drug available to a greater number of patients. This requires FDA approval.

-MORE-

FDA's Oncologic Drugs Advisory Committee met today to hear a presentation by the Cancer Institute to support widening distribution of THC to affiliated cancer specialists working at other institutions or in private practice.

The Cancer Institute presented the results of seven studies including a total of 356 patients. Given as a capsule, THC appeared to be effective for nausea and vomiting connected with cancer-drug treatment. In 5 of 6 controlled, double-blind studies, THC had superior antiemetic (anti-vomiting) effect compared to a placebo or phenothiazine drugs. In the sixth study, with patients whose median age was 61, only 8 of whom were under 40, THC was only about as effective as another antiemetic, prochlorperazine.

According to the Cancer Institute, THC is an effective antiemetic for some patients receiving cancer chemotherapy. The drugs should be used in patients who cannot be managed with other antiemetics.

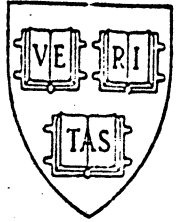
After hearing the Cancer Institute's presentation of the study findings, FDA's Oncologic Drugs Advisory Committee voted 5 to 4 to recommend to FDA approval of wider distribution of the drug. The first vote was tied. It was broken by the committee chairman, Dr. Philip S. Schein, professor of medicine and pharmacology at the Georgetown University Medical School, Washington, D.C. NCI estimated that of 100,000 persons undergoing chemotherapy, 50,000 have nausea and vomiting problems that are not helped by conventional drugs.

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# The Cambridge Hospital

Affiliated with  
Harvard Medical School



February 14, 1983

The Honorable Louis Bertonazzi  
Chairman, Joint Committee on Health Care  
Room 314, State House  
Boston, MA 02133

Re: House 1988

Dear Senator Bertonazzi:

Beginning in October 1973, Emil Frei III, M.D., Director of the Dana Farber Cancer Institute, Stephen E. Sallan, M.D., Chief of Pediatric Oncology, Ms. Carol Cronin, Pharmacologist, and I initiated an experiment giving delta-9-tetrahydrocannabinol (THC-- the most active ingredient of marihuana) to patients under controlled conditions, and this program has continued to the present. Some of the results of this work have been published in the New England Journal of Medicine (293:795-797, 1975, and 302:135-138, 1980). Suffice it to say here that these experiments provided evidence that marihuana and the THC component were effective against the extremely painful vomiting and nausea caused by cancer chemotherapy.

In our experiments about one-third of the patients involved who were helped by marihuana or its derivative had not been helped by any other anti-emetics. Our experiments were the first, but they have since been repeated many times by other investigators. All have found this drug to be effective, although not all have agreed on the one-third figure who have been relieved by nothing else. We believe that this lack of exact agreement is based on different research protocols which do not take into account the nature of the mechanisms of action.

Perhaps the most important finding to emerge from these experiments is the fact that this drug has a humane and important therapeutic use. Of additional importance is the fact that the drug can be worked with effectively and safely. It is always difficult for scientists to begin to work with a drug that not only is used illicitly to a large extent but also has a reputation as being dangerous. With the exception of minor anxieties--mainly in older

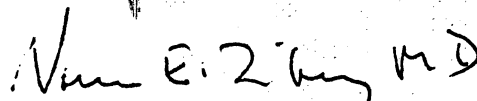
February 14, 1983

people who are unfamiliar with the potentially subjective effects of marihuana--there are no major hazards associated with the experiments and no major sequelae with any patients at all. Whatever their views of the efficacy of marihuana, other investigators report the same finding. That is a remarkable result from any experimental drug.

Worthy of note is the difference in atmosphere when an illicit drug is used therapeutically in a licit setting. When these experiments were begun, fears were expressed that in effect we would be condoning "pot parties." From the beginning, however, it was apparent that in a therapeutic setting like the Dana Farber Cancer Institute with serious medical purpose, there is no hint of this work as a deviant activity. There is no problem whatsoever with the diversion of the drug for other purposes, although this fear had been expressed. In fact, it is my subjective opinion that this therapeutic use of marihuana has had the effect of demystifying marihuana with certain groups. Far from condoning or glamorizing its use, the therapeutic function has acted to put marihuana into the category of one more practical substance that is neither magical nor exerts fascination for further use.

As a physician and scientist, I believe that it is important to have this drug available within the medical armamentarium in a way that makes it accessible.

Sincerely yours,



Norman E. Zinberg, M.D.  
Acting Director of Training  
Department of Psychiatry

Clinical Professor of Psychiatry  
Harvard Medical School

6-5-80

B1

York, New Jersey, Connecticut

# New Bill Backs Using Marijuana As Medical Aid

## 2 Albany Panels to Press for Passage This Session

By ROBIN HERMAN  
Special to The New York Times

ALBANY, June 4 — The Senate and Assembly Health Committees have agreed to press for the legalization of marijuana for therapeutic medical use, particularly for cancer and glaucoma patients.

The legislation is described by leaders in both houses as having an excellent chance of passage this session, principally because of the support of the State Health Commissioner, Dr. David Axelrod. Governor Carey is expected to sign such a bill.

Dr. Axelrod said the chemical agent in marijuana, tetrahydrocannabinol, "has been shown to be an effective anti-emetic, that is an inhibitor of vomiting, for patients who are receiving cancer chemotherapy."

"It also has been shown to have some effect in the treatment of glaucoma," he said. "It prevents the buildup of pressure in the eye. Both of these we feel provide a rationale for permitting marijuana to be used under carefully controlled circumstances."

...that Dr. Axelrod's statement "reflects the Governor's sentiments."

According to an official at the National Organization for the Reform of Marijuana Laws, 23 states have legalized the use of marijuana for medical use — all in the last 30 months.

One of the lobbyists for the New York bill was Antonio G. Olivieri, a New York City Councilman, who on May 19 underwent his third cancer operation. Yesterday, from his hospital bed at New York University Medical Center, Mr. Olivieri telephoned Senator Tarky J. Lombardi, chairman of the Senate Health Committee, who until this week had not committed himself on the marijuana issue.

"I told him in my personal experience it was really the only thing during one course of chemotherapy that allowed me to combat nausea and keep eating," Mr. Olivieri said.

### Mention of Heroin Deleted

Senator Lombardi, a Republican-Conservative of Syracuse, said he felt able to introduce the bill in the Senate after Assemblyman Alan G. Hevesi, the bill's framer, amended it to refer only to marijuana. An earlier version of the bill had stipulated use of heroin as well as marijuana.

"It was on the political theory 'a foot in the door,'" said Mr. Hevesi, a Democrat from Forest Hills. "I still think there is an appropriate use of heroin for pain killing in certain situations for a limited time under a doctor's supervision. But we didn't want to jeopardize the use of marijuana, so we left out the heroin because it is a red flag for a lot of people."

Morphine has been used for many years to reduce cancer pain but, Dr. Axelrod said: "Marijuana is not designed to deal with pain, it is to alleviate nausea and vomiting as a side effect of chemotherapy. In fact, morphine produces nausea in some people."

He said morphine was usually administered intramuscularly or intravenously. Marijuana or its chemical derivative can

Continued on Page B13

be administered in capsules, in cigarettes or intramuscularly.

Senator Lombardi said that he had not spoken with Dr. Axelrod but that the commissioner's endorsement would lend some weight to the bill's chances for passage. "I think we have a good chance in the Senate," he said.

The bill would allow the use of marijuana and tetrahydrocannabinol, a chemical derivative, by patients approved by a hospital review committee. Under the bill the state is authorized to obtain the marijuana from the New York State Police bureau of criminal investigation and local law enforcement officials. - 30 -

1980

# THE MEDICAL LETTER<sup>®</sup>

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on Drugs and Therapeutics

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Vol. 22, No. 10 (Issue 557)

May 16, 1980

## MARIHUANA FOR NAUSEA AND VOMITING DUE TO CANCER CHEMOTHERAPY

Cancer chemotherapy often causes severe nausea and vomiting that sometimes continues for days without relief. Delta-9-tetrahydrocannabinol (THC), the main active ingredient of marihuana, can relieve these symptoms in some patients who do not respond to other antiemetic drugs.

**EFFECTIVENESS** - THC is an effective antiemetic for many patients. One randomized double-blind crossover trial compared 15- or 20-mg oral doses of THC with placebo in 22 patients; 20 of these patients had symptoms refractory to other antiemetics. Complete or partial relief was obtained in 14 of 20 with THC and in none of 22 with placebo. In this study, a "high" often accompanied the antiemetic effect of THC, and maintaining the "high" with additional THC maintained the antiemetic effect (SE Sallan et al, N Engl J Med, 293:795, 1975). In another controlled trial, 14 of 15 patients with osteogenic sarcoma receiving high-dose methotrexate had less nausea and vomiting with THC than with placebo; the antiemetic effect was correlated with plasma concentrations of THC. Other patients with soft-tissue sarcomas being treated with both cyclophosphamide (Cytosan) and doxorubicin (Adriamycin) did not respond as well to the antiemetic effect of THC (AE Chang et al, Ann Intern Med, 91:819, Dec 1979). Another study also reported good results with THC in 38 of 53 cancer patients with nausea and vomiting refractory to other antiemetics; patients being treated with cisplatin (Platinol), however, generally did not respond to THC (VS Lucas, Jr, and J Laszlo, JAMA, 243:1241, March 28, 1980).

**COMPARED WITH PROCHLORPERAZINE** In a randomized, crossover trial comparing THC with prochlorperazine (Compazine; and others) in patients with symptoms refractory to standard antiemetic therapy, 20 of 25 patients preferred THC; patients also had improved appetite with THC (SE Sallan et al, N Engl J Med, 302:135, Jan 17, 1980). In another study, THC was more effective than prochlorperazine against nausea in children and also enhanced appetite during chemotherapy (H Ekert et al, Med J Austr, 2:657, Dec 15, 1979).

In a much larger controlled trial, however, in 116 patients receiving combined fluorouracil and semustine (methyl-CCNU) for gastrointestinal carcinoma, THC was no more effective than prochlorperazine, and patients considered THC more unpleasant than either prochlorperazine or placebo (S Frytak et al, Ann Intern Med, 91:825, Dec 1979). Patients in this large study were older than those in the other trials, with a median age

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of 61 years, but frequent intolerance to THC was also reported in a European study of 11 patients from 21 to 53 years old, with a median age of 32 years; THC was effective as an antiemetic, but its adverse effects were unacceptable for most patients (JC Kluin-Neleman et al, Vet Hum Toxicol, 21:338, 1979).

ADVERSE EFFECTS - The adverse effects of THC vary with the age of the patient and the dose. The most prominent effect is drowsiness, which can be disabling. Some patients complain of dry mouth, dizziness, inability to concentrate or disorientation. Anxiety, tachycardia, depression, paranoia, visual hallucinations and manic psychosis can also occur. These effects are most troublesome in older patients, especially those who have never used marihuana before.

DOSAGE AND ADMINISTRATION - THC is available from the U.S. National Institute on Drug Abuse as a Schedule I research substance in 2.5-, 5- and 10-mg THC capsules and in cannabis cigarettes. In published studies doses usually have ranged from 5 mg/m<sup>2</sup> to 15 mg/m<sup>2</sup>. Five mg/m<sup>2</sup> is probably the safest starting dose, particularly in older patients. As with other antiemetics, preadministration of THC may increase its effectiveness; some clinicians begin treatment with THC as much as eight to 12 hours before chemotherapy (J Laszlo, Ann Intern Med, 91:916, Dec 1979).

HOW TO OBTAIN THC FOR PATIENTS - Patients should be warned that illegal marihuana varies greatly in potency and may be adulterated with various toxic substances, such as "Agent Orange" or phencyclidine (PCP - Medical Letter, 19:70, 1977).

Under current U.S. regulations, physicians who wish to obtain THC for their patients must register with the Drug Enforcement Administration (DEA) as researchers and apply to the Food and Drug Administration (FDA) for an investigational new drug application. Approval may require a visit from an agent of the Drug Enforcement Administration to inspect security arrangements (Fed Reg, Code of Federal Regulations, Title 21, April 1, 1979, p 24) and, according to Medical Letter consultants, can take months or longer. Additional information can be obtained from the Drug Abuse Staff, Food and Drug Administration, Bureau of Drugs, HFD-123, 5600 Fishers Lane, Rockville, Maryland 20857.

In the six states listed below investigational new drug applications have been issued for the entire state; in these states, the approval of the DEA may be easier to obtain and no application to the FDA is necessary. Some state requirements may also be time-consuming, however, and local health authorities can obstruct the prescribing of THC even after the state has given its approval. More information is available from the following sources:

Florida:

Mr. Douglas Palin  
Department of Health and Rehabilitative Services  
1317 Winewood Boulevard  
Tallahassee, Florida 32301

Illinois:

Mr. Robert Stachura  
Illinois Dangerous Drugs Commission  
300 North State Street, Suite 1500  
Chicago, Illinois 60610

Louisiana: Dr. Philip Jobe  
Department of Pharmacology  
LSU School of Medicine, Box 33932  
Shreveport, Louisiana 71130

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Michigan Department of Public Health  
3500 North Logan Street, P.O. Box 30035  
Lansing, Michigan 48909

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Lynn Pierson Therapeutic Research Program  
Box 968, Crown Building  
Santa Fe, New Mexico 87503

Washington: Dr. Jan Penna or Dr. David Dunner  
Marihuana Research Program  
Harborview Medical Center  
325 Ninth Avenue  
Seattle, Washington 98104

CONCLUSION - Delta-9-tetrahydrocannabinol (THC), the main active ingredient of marihuana, can relieve nausea and vomiting in some cancer chemotherapy patients who have not responded to other antiemetic drugs. Although specific indications, dosage and safety have not been established, THC may be worth trying in some cancer patients when other antiemetics are ineffective. The adverse effects of THC may be intolerable, however, especially for older patients.

### PLASTIC CONTAINERS FOR INTRAVENOUS SOLUTIONS

Since the last Medical Letter evaluation (17:43, 1975), the use of plastic containers for intravenous solutions has steadily increased over glass bottles. Now two types of plastic containers are available: a flexible polyvinyl chloride bag (Life Care - Abbott; Viaflex - Travenol) and a semi-rigid polyolefin container (Accumed - McGaw).

LEACHING OF CHEMICALS - The leaching of chemicals from plastic IV fluid containers may result in the delivery of harmful substances to patients. Studies of leaching have focused mainly on the plasticizer di-2-ethylhexyl phthalate (DEHP), which is extremely insoluble in water but is soluble in blood and other fluids that contain lipoproteins. DEHP is delivered to patients in appreciable quantities with blood products from plastic bags (RJ Jaeger and RJ Rubin, N Engl J Med, 287:1114, 1972; RJ Rubin and CA Schiffer, Transfusion, 16:330, 1976). The amount of plasticizer leached from PVC bags containing IV fluids other than blood products is much less (JH Corley et al, Am J Hosp Pharm, 34:259, 1977). DEHP causes hypolipidemia and hepatomegaly in rats and mice (DE Moody and JK Reddy, Toxicol Appl Pharmacol, 45:497, 1978) and severe seminiferous tubular atrophy and cessation of spermatogenesis in rats (TJB Gray et al, Food Cosmet Toxicol, 15:389, 1977). The acute and chronic toxic effects of DEHP on people are unknown. Polyolefin containers do not contain DEHP; the manufacturer says that no plasticizers or other mobile additives are present and total extractables from the plastic after four years of storage are less than three parts per million.

ADSORPTION OF IV DRUGS - Some therapeutic agents, such as diazepam or nitroglycerin, lose much more activity in PVC containers than in glass bottles (JC Cloyd et al, Am J Hosp Pharm, 37:492, April 1980; WA Parker and ME MacCara, Am J Hosp Pharm, 37:496, April 1980; DM Baaske et al, Am J Hosp Pharm, 37:201, Feb 1980). Polyolefin containers probably cause fewer problems with adsorption than PVC bags, but no published data are available. The FDA now requires manufacturers of IV solutions in plastic containers to conduct compatibility studies for commonly used additives (Fed Reg, 43:58557, Dec 15, 1978), but so far this information has not been added to the labeling for these containers.

INJECTION OF ADDITIVES - Several years ago incomplete mixing of additives in IV solutions was reported when drugs were added to PVC bags already hung in the infusion position. With some additives, such as potassium chloride, pooling at the bottom of the container could be dangerous for the patient (Medical Letter, 17:43, 1975). Since that time, some changes have been made in the design of PVC bags, particularly in the length of the injection ports, in an effort to minimize this problem. According to one report, addition of medication to IV solutions may be easier and quicker with semi-rigid polyolefin containers than with soft PVC bags (RR Allinson et al, Am J Hosp Pharm, 36:513, 1979).

MICROBIAL CONTAMINATION - The incidence of in-use airborne microbial contamination is lower with plastic containers than with glass containers that are packaged with a partial vacuum and require air venting (open system). Glass containers that use a closed system, with a filter in the air inlet of the administration set, are comparable to plastic containers in the incidence of in-use contamination. IV solutions in any container are subject to contamination when drugs are added and when the solution is connected to an administration set and hung at the bedside.

STORAGE AND HANDLING - Plastic IV containers have some advantages over conventional glass containers for storage and handling; they are lighter, easier to ship and to store, and more resistant to breakage. Semi-rigid polyolefin containers take up about twice as much space as flexible PVC bags (HG Levine and ZI Hanan, Hosp Pharm, 15:124, March 1980). PVC containers are easily compressed and can be used in clinical conditions requiring rapid administration of large amounts of fluid, but they are susceptible to small punctures, and each bag should be squeezed before being hung in order to detect minute leaks; semi-rigid polyolefin containers are much more difficult to puncture. PVC bags require an outer plastic wrap to minimize water vapor loss; semi-rigid polyolefin containers are impermeable to moisture. Flexible plastic containers can expand with addition of large volumes of fluids, which may cause volume calibrations to become inaccurate; with the semi-rigid polyolefin containers, volume calibrations are reported to be as accurate as they are with glass bottles.

CONCLUSION - Both soft polyvinyl chloride and semi-rigid polyolefin containers for IV solutions are more convenient than conventional glass containers. The polyolefin containers require more room for storage than the polyvinyl chloride bags, but they are less likely to leak and do not introduce DEHP into IV solutions. With any plastic container, adsorption of added medications may be greater than with glass bottles.

# Pot use bill clears 1st hurdle

By JOAN FALLON

News Statehouse Bureau

BOSTON — The Senate Monday gave initial approval to a bill which would legalize the therapeutic use of marijuana for cancer, glaucoma and asthma patients.

Sen. Louis Bertonazzi, D-Milford, sponsor of the legislation, said he was very encouraged by the Senate's 24-10 vote and called it "an act of compassion and common sense."

"There are people in Massachusetts who are suffering the sad and tragic pains that are connected with cancer, glaucoma and asthma. In each case, studies have shown therapeutic use of marijuana can eliminate some of that pain. In the case of cancer, some people have actually refused chemotherapy which might save their lives because of the extreme nausea, vomiting and side effects connected with it.

"Research at the Sidney Farber Cancer Institute has found that therapeutic use of marijuana in many instances eliminates these dreaded side effects," Bertonazzi said.

The bill would allow physicians to prescribe marijuana as an experimental drug. Recipients would be screened by a new panel of state health officials and private doctors.

Following the vote, Senate Minority Leader John Parker of Taunton moved reconsideration. Bertonazzi said he is

hopeful the wide margin of support the bill received Monday, however, will be maintained.

The local lawmaker sponsored the same measure last year. It passed the Senate but did not make it to the floor of the House before the Legislature adjourned for the 1979 session.

All area senators voted in favor of the measure Monday, except Sen. David Locke, R-Wellesley, who was not present.

There was no debate.

The measure is opposed by Concerned Citizens for Drug Prevention, who claim marijuana causes brain damage. The group also feels legalization of marijuana for therapeutic purposes will lead to its general legalization for social use.

Proponents say marijuana is therapeutic in alleviating the nausea which can occur after cancer chemotherapy for up to 24 hours, in decreasing intraocular pressure in glaucoma patients, and in decreasing airway resistance in asthmatics.

Bertonazzi, who has voted against the general legalization of marijuana, said Monday the bill applies to use of marijuana for therapeutic use only and has nothing to do with its social use.

"Some people have attempted to intertwine the two issues. They are totally separate and in no way connected," Bertonazzi said.

He claimed it is "unconscionable to

have a rule which would place people in the position of breaking the law or suffering this kind of pain.

"Some people," he said, "have obeyed the law all their lives and can't bring themselves to break it. They don't want to traffic in the illegal sale of marijuana," he said.

Last year when the bill came up for a hearing before the Legislature's Joint Committee on Health Care, a 31-year-old speech therapist and glaucoma patient from Washington, D.C., was taken into custody by state drug agents for displaying marijuana cigarettes to lawmakers at a public hearing.

He was intercepted by the agents at the Statehouse just after he had finished telling the committee that he smokes 10 marijuana joints a day under doctors prescription to keep him from going blind.

He was detained for three hours before the federal drug enforcement administration confirmed the marijuana was prescribed for him as part of a federal experiment.

The man made national headlines earlier that year when he won federal permission to smoke marijuana for his glaucoma condition.

Marijuana for therapeutic purposes has since been legalized in eight states.

Bertonazzi's bill needs one more approval in the Senate before it goes to the House.

For Therapeutic Use

10/6/82

## 'Pot' Bill Roadblock Termed 'Heartless'

BOSTON (AP) — The Senate sponsor of a plan to allow therapeutic use of marijuana for cancer and other patients says any further roadblocks to the bill in the Massachusetts House would border on the heartless.

The bill passed the Senate 20-11 without debate Tuesday, but was put on the next session's agenda for reconsideration at the request Sen. David H. Locke, R-Wellesley.

"I think its the fourth year in a row that I've filed that legislation," Sen. Louis P. Bertonazzi, D-Milford, said after the vote.

Each year the bill passes the Senate, he said, and then dies in the House.

"This is for the alleviation of suffering by an awful lot of people in the commonwealth," Bertonazzi said. "I'm just outraged that it's taking this long ... To hold this bill up any longer is bordering on the heartless."

Bertonazzi was confident the bill would survive Senate reconsideration and go to the House.

"They keep trying to somehow mix the therapeutic use with talking about the social use of marijuana," Bertonazzi said. "It has nothing whatsoever to do with the legalization of marijuana. This is purely therapeutic use."

He said the bill would allow a panel of medical experts to review requests for therapeutic use of marijuana by cancer patients experiencing side effects from chemotherapy and radiation treatments. The side effects can be serious enough to hamper or completely prevent therapy, he added.

Glaucoma and asthma patients could also ask to use marijuana, which has been effective in easing those problems, the sponsor said.

"We have taken every precaution in the legislation to make absolutely certain that it can't be misused or abused," he added.

The bill has the support of the American Cancer Society, Bertonazzi said.

### REMINDER

Millville residents may deposit news releases for *The Call* at the convenient drop-box inside Millville Market & Package Store, Main Street.





THE COMMONWEALTH OF MASSACHUSETTS

DRUG ABUSE REHABILITATION ADVISORY BOARD

P.O. BOX 2078

HANOVER, MASSACHUSETTS 02339

(617) 826-8205

March 3, 1983

Lucy Forti

Chairman

To: The Health Care Committee, State House, Boston, Mass.  
To: The Joint Chairmen, Senator Burke, and Rep. Voke, and  
the Committee Members

Re: S570

More Taxes? 1971 Federal Law Adequate

This bill foolishly duplicates what we already have. The U. S. Taxpayer is already paying for a multi-million dollar program which does everything and more that this bill calls for. It even gives free THC pills for cancer chemotherapy patients. \*See attached "DRUG ABUSE ISSUE OF THE MONTH" or call the Sydney Farber Cancer Institute in Boston.

1. S570, a bill providing for the use of marijuana for therapeutic research is a PRO-POT PROPAGANDA PITCH.
2. This bill is absolutely unnecessary. Marijuana has been legal for research by federal statute since 1971. Anyone who wants THC for medical reasons can now obtain it if their doctor deems it wise. Free THC pills are available. (See Dr. DuPont Letter). This bill is being promoted by NORML to make marijuana acceptable. NORML is the national organization which is heavily funded by pro-drug culture which includes donations of millions of dollars from Playboy magazine, the drug paraphernalia industry and those who profit from use of marijuana. They have lobbied for years to legalize marijuana and seek to legalize all the illegal drugs. Dr. Grinspoon is on their Board of Directors.
3. Some would never vote to legalize marijuana but are taken in by the emotional pitch that dying people should be able to have marijuana if it helps them. Our most eminent scientists and doctors agree that marijuana is a DANGEROUS DRUG which LOWERS THE IMMUNE SYSTEM, has 430 CHEMICALS WHICH ADVERSELY AFFECT EVERY CELL IN THE BODY. Not one of them say that marijuana should be given as medicine. THC has been extracted (one chemical) and sometimes is given in pill form to cancer patients to relieve nausea. Most doctors prefer to give compazine or a wonderful new drug metoclopramide which are more effective without the high and without dangerous side effects.
4. Most importantly passage of this bill would result in schoolchildren saying that marijuana cures cancer, is good for your

eyes so it must be healthy to use it and the largest growing group of marijuana users are ages 8 to 14. AS ADULTS WE MUST BE CONSCIOUS OF THE MESSAGES WE ARE GIVING TO CHILDREN.

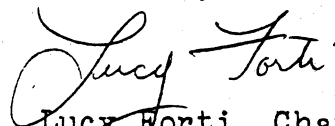
5. It would be a scandal for the Massachusetts Legislature to give approval to spend large sums of money for this unnecessary and absurd program when the same legislature has voted down money for drug prevention education. Kids are falling victims to drug abuse because they are not receiving up-to-date factual drug education on marijuana. That's where the money should be spent.

This bill should be scrapped and never introduced as legislation again because it is such bills as this one and those which speak of legalizing marijuana which have been responsible for millions of children under the age of 18 becoming regular drug users. The truth will conquer the drug problem but those responsible for passing laws must educate themselves to know the truth.

NORML (National Organization for the Reform of Marijuana Laws) are using this issue as a red herring to give marijuana a good name (See Families in Action). There is no truth to what they say about marijuana as medicine. No reputable doctor, scientist, or researcher supports this absurd claim that marijuana is good medicine. No person who has informed himself on marijuana by reading what those scientists who have thoroughly researched marijuana have to say would waste their time giving any support to this bill. Marijuana is a dangerous drug with 430 chemicals which insidiously damages every cell in the body and lowers the immune system. (Read Pot Safari, by Peggy Mann.)

As responsible, conscientious legislators who are for the public good, please support monies for drug education, not for this bill.

Sincerely,



Lucy Forti, Chairperson.  
Governor's Drug Advisory Board  
Executive Director,  
Concerned Citizens for Drug  
Prevention/National Federation  
of Parents for Drug-Free Youth

Enclosures :

Families in Action

Dr. DuPont Letter

Drug Abuse Issue of Month on Marijuana for Therapeutic Research

Dr. Hardin Jones - No Usefulness on Marijuana as Medicine

Pot Safari

P.S. Pot use for glaucoma is another red herring. An individual would have to smoke 10 joints a day to get the desired effect that can be had by proper medication already available to them.

# Drug Abuse Issue of the Month

Vol. 1 No. 6



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## The National Federation of Parents For Drug Free Youth Invites Your Participation

The drug epidemic can best be arrested by working together. The drug/alcohol problem is, in truth, everyone's problem.

Many of you are working at the local level in parent groups, through your PTA, service organization or church or synagogue. You have begun to see how working as a team or in large groups can make a significant difference.

There is also an imperative need to work together at the national level.

Your membership is needed in a growing national organization that has begun to make a real difference at the Federal level.

The National Federation of Parents for Drug Free Youth (NFP) is located in the Washington suburbs. It is comprised,

principally, of parents who are determined to stop the use of mind altering drugs by children and youth.

It is a non-profit, tax exempt organization formed to promote the growth and effectiveness of parent groups and all others who wish to halt drug use. NFP is currently in communication with over 1000 parent groups throughout the nation.

Member (individuals and groups) receive: "NFP Starter Kit", NFP Newsletter, NFP tax free status and other benefits.

You can join by sending the membership application to:  
 National Federation of Parents for Drug Free Youth  
 Box 722  
 Silver Spring, MD 20901 Phone: (301) 593-9256

PLEASE FILL OUT AND RETURN TODAY.....

YES, I wish to be a part of the National Federation of Parents for Drug Free Youth.  
 I would like to participate as:

\_\_\_\_\_ Parent Group Member (one vote per group) \$25 dues/yr.

\_\_\_\_\_ Individual Member (non-voting) ..... \$10 dues/yr.

PLEASE ATTACH YOUR CHECK TO THIS FORM

Individual or Group Name: \_\_\_\_\_

Contact Person (if group): \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number: Home: \_\_\_\_\_ Office: \_\_\_\_\_

PARENT GROUPS:  
 So that we may learn a little more about each of you, please complete the following. Thank You!

- When was your group started? \_\_\_\_\_
- Does your group center around:
 

_____ Church	_____ Social _____
_____ or	
_____ Neighborhood _____ Synagogue _____	
_____ School _____ Community _____	_____ Other _____
- How many members do you have? \_\_\_\_\_
- How frequently does your group meet?
 

_____ Once a week _____	_____ Once a month _____
_____ Twice a month _____	_____ Other (specify) _____
- Would you be willing to have your name given as a contact for inquiries from your area? YES \_\_\_\_\_ NO \_\_\_\_\_

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- Marijuana as Medicine? . . . No!
- THC As An Experimental Anti-Nausea Drug? . . . Yes. But --- With Limitations.
- Might There Be A New And Better Answer? . . . Yes!

This is one of the most confusing subjects in the entire "drug scene". But it is important that we understand the why's and wherefore's because pro-pot groups are using the "marijuana as medicine" ploy to further their ends of legalizing marijuana.

In June 1980 a strategic meeting was held in the offices of the Food and Drug Administration building in Bethesda, Maryland. Members of the FDA's Oncologic Drug Advisory Committee had gathered to discuss and vote upon this question: should THC capsules be made available, through the Federal Government's National Cancer Institute, to oncologists (cancer specialists) throughout the country?

One member of the Committee could not attend the meeting: Dr. Charles Moertel, Director of Mayo Clinic's Comprehensive Cancer Center. However, Dr. Moertel had sent a letter in his stead. This letter expressed the strongest objections to making THC available to oncologists. His objections were based on studies done at the Mayo Clinic in New Zealand, and elsewhere, which showed that THC, the chief psychoactive (mind-altering) chemical in marijuana was effective as an anti-emetic (anti-vomit agent) for young cancer patients who'd had prior experience with marijuana. However, older patients with no prior pot smoking experience had, said Dr. Moertel, "all sorts of central nervous system side effects." And most cancer patients are older patients. He pointed out a chemotherapy study conducted in the Netherlands which showed a 33% incidence of THC-induced hallucinations, some of them requiring psychiatric care.

The Committee, however, did not count Dr. Moertel's letter as a "vote". When the vote was taken, it was a tie. Therefore, the Chairman was asked to cast his vote. It was pro. And the FDA Commissioner adopted the Advisory Board's recommendation that THC capsules be made available through the Federal Government's National Cancer Institute, to oncologists throughout the country for cancer patients experiencing nausea and vomiting after cancer chemotherapy treatments.

This has developed into a multi-million dollar program, paid for by the U.S. taxpayer.

According to an article in the *Journal of the American Medical Association* (April 17, 1981) about 200,000 Americans may be taking drugs to combat cancer. Of these, about 50,000 experience nausea and, "while estimates vary, it is suggested that THC might help about one half this group".

Help how?  
 "Partying" young people learned long ago that pot "turns off the vomit center" in the brain. Smoking a joint while drinking enables them to imbibe quantities of alcohol without throwing up. This practice, not surprisingly, has resulted in a new phenomenon: youngsters OD-ing on alcohol.

However, the same "anti-emetic" (anti-vomiting) phenomenon caused by THC has proved to be beneficial for some cancer patients suffering from severe nausea and vomiting after undergoing some types of wracking chemotherapy treatments. Any U.S. oncologist may now obtain, free of charge, through the Federal Government's National Cancer Institute, synthetic THC pills for cancer chemotherapy patients. The pills are available through hospital pharmacies in cancer-treatment centers throughout the U.S. (The THC pills, it is reported, must be kept under lock and key -- for the disappearance rate is "high".) The free pills are thus available for any cancer chemotherapy patient in the U.S. So far, so good. Then:

## CONFUSION ENTERS THE PICTURE

Research has clearly shown that it is THC which has the anti-emetic effect. And THC is only one of over 400 chemicals in marijuana. (Some of the other chemicals in marijuana are carcinogenic; and some of these are found in 50 to 100 times greater amounts in marijuana smoke than in tobacco smoke.)

Media is often enthusiastic about publishing stories showing the "good side" of marijuana. Their tendency is to headline the THC capsule story in "Marijuana as Medicine" terms. By the time this "news" gets down to the schoolyard, there are so many mixed messages surrounding it, that sometimes youngsters report: "Pot must be good for you. They even use it to cure cancer".

Nor are youngsters the only ones who are confused. Many well-meaning adults refute facts about the health hazards of marijuana with mis-statements about pot "being good for cancer and glaucoma".

## What About Glaucoma?

Glaucoma is an eye disease characterized by increased pressure within the eye (intraocular pressure) and progressive damage to the optic nerve with accompanying impaired visual function. Treatment for glaucoma, either with drugs or surgery, is primarily aimed at lowering the pressure in an attempt to preserve vision.

Although it has been shown that THC drops and smoked marijuana can lower interocular pressure, it is not known whether visual function can be preserved. Indeed, some recent studies are proving to be disappointing. According to an article prepared by the National Eye Institute for the **Journal of the American Medical Association**:

"Widespread publicity about marijuana as a possible treatment for glaucoma has generated interest in this subject among glaucoma patients and their physicians. . . Reports of marijuana's effectiveness in reducing intraocular pressure in a few such patients under carefully controlled experimental conditions may have led to serious consideration of this drug as a possible alternative to conventional therapy, particularly in patients who do not respond well to existing medications. **These reports have also encouraged some glaucoma patients to assume that smoking marijuana may be beneficial for treating this eye disorder. Since no definitive clinical studies have been completed, this assumption is misleading and could result in serious ocular damage and systemic side effects. . .**" (Emphasis added)

Dr. Coy Waller, a noted marijuana researcher, is currently studying the subject of THC eyedrops to validate use by glaucoma patients. He points out that "Pilocarpine is one of the most effective drugs now used in the eye for the treatment of glaucoma. It comes from the leaves of the pilocarpus plant. It would be just as sensible to smoke pilocarpus leaves and take medical history back a hundred years, as it would be to smoke marijuana to get THC, instead of using synthetic eyedrops".

Yet pro-pot groups such as NORML (the National Organization for the Reform of Marijuana Laws) are pushing for the "rights" of glaucoma and cancer chemotherapy patients to smoke "legal" pot.

In the forefront of this movement is Robert Randall, who is on the Advisory Board of NORML. Randall sued the National Institute on Drug Abuse (NIDA) and won. The court directed NIDA to supply Randall with seventy free government-issued marijuana cigarettes a week. It is

interesting to note that despite all his professed faith in "the weed" as a glaucoma cure, Randall, in addition to smoking ten joints a day, continues to take all the traditionally prescribed medication for his glaucoma. Recently Randall founded the Alliance for Cannabis Therapeutics (ACT) which concentrates on promoting laws aimed at legalizing marijuana for medical uses.

## The Red Herring

There is far more to "the THC story" than its effects on cancer or glaucoma patients. And this part of the story involves all of us.

As far back as February, 1979, Keith Stroup, then-outgoing director of the National Organization for the Reform of Marijuana Laws (NORML), told Emory University students that NORML was trying to get marijuana reclassified medically. "If we do that, and we'll do it in at least 20 states this year for chemotherapy patients," he said, "we'll be using the issue as a red herring to give marijuana a good name". (Emory Wheel, Feb. 1979.)

The following year, in April, 1980, Dr. Robert DuPont, former director of the National Institute on Drug Abuse and Chairman of the World Psychiatric Association's Drug-Dependency Section, issued the following warning:

"For years 'decriminalization' was the stalking horse for the marijuana lobby. Today 'medical uses' has become the symbol behind which the pro-pot activists are marching. Their target is state legislatures.

"The fact is that no state legislation is needed in this area. Medical research on possible medical uses is well-formed and on-going. Federal laws are adequate. When and if . . . medical uses are identified, the mechanism is available for making this product (or more likely, purified components of marijuana) available.

"The sad fact is that state legislatures have been targeted by the pro-pot lobby precisely because they generally lack the time and staff resources to sort through this type of issue which is subject to emotional exploitation.

"I urge state legislators to oppose bills to make marijuana available as a 'medicine'. Such laws are not needed and passage of such laws are widely interpreted by the public, especially by youth as a signal that pot is 'okay' or, even worse, that it is 'healthy'".

One year later, (as reported in the April 1981 issue of *High Times*), "The National Organization for the Reform of Marijuana Laws emerged in December from its tenth-anniversary conference in Washington, D.C.; with renewed energy and a belief among most conferees that the time of financial desperation and organizational disarray was over. Among the issue widely discussed at the conference, and which NORML activists expect to pursue in the coming year are: widespread antiparaphernalia legislation, recruitment of active members and support of efforts to make pot available for therapeutic use". (Emphasis added).

By now this "red herring" has been used successfully in twenty-four states. Passage is often accompanied by intense emotional appeals which succeed in clouding the scientific and realistic side of the subject. For example, in one state a legislator stood up, announced for the first time to his colleagues that he had cancer of the colon, and followed this by asking them to please pass his "marijuana bill". (Which they did).

In such states headlines about newly-legislated "legal pot" further confuse the public.

If this is happening, or has happened in your state, it is important that you understand the issue so that you can help set your legislators straight. Setting them straight does not mean that THC pills will become any less available for

## What You Can Do

There Are Four Important Areas In Which Your Input Can Have Beneficial Results

1) NORML, ACT, and other pro-pot organizations, as well as drug-promoting publications such as *High Times*, are putting on an intensive campaign promoting legal marijuana through the "marijuana as medicine" route. They have succeeded in 24 states in getting laws passed which are unnecessary.

Some of the unnecessary laws simply echo and reinforce the existing Federal law which makes free THC capsules available in bulk to Federally-approved hospital pharmacies for dispensing by oncologists (cancer specialists) to patients who need them

Free government-issued marijuana cigarettes are also available for chemotherapy patients wishing to participate in approved clinical studies. The publicity surrounding these totally unnecessary state laws comes coated with the confusing "message" about "legal pot".

Several other proposed state laws suggest that confiscated "street pot" be used; and/or that "your local pharmacy" will have THC and/or marijuana. Such state laws would, in fact, violate Federal law.

If you live in a state which is considering passing one of these two types of laws, write the Governor and meet with a state legislator to discuss the information in this Drug Abuse Issue. Virtually all such laws are passed because State legislators and Governors do not have accurate information.

For further information and clarification write Committees of Correspondence President, Otto Moulton, for a copy of the Question and Answer Section on this subject included in hearings conducted by the Select Committee on Narcotics Abuse and Control.

2. Media wittingly--or unwittingly--continues to confuse the issue by headlining a "THC as medicine" story in "Marijuana as Medicine" terms, and by referring to THC capsules as "pot pills". If you see this occurring in your local media write in to "set them straight". (For example, "It's okay to call them 'pot pills' as long as you're willing to call penicillin capsules 'mold pills.'")

3. The third area concerns THC and the anti-emetic alternatives. Your letters can speed up the slowly turning wheels so that the many thousands of cancer chemotherapy patients who obtain no relief from THC pills or smoked marijuana, may be able to find relief from nausea and vomiting through other anti-emetic drugs now commonly used for this purpose in Europe, Canada and other countries. (Note: This can be a matter of life-saving concern for many cancer patients whose nausea is so intense and long-lasting that they refuse to continue with the chemotherapy treatments which are necessary to contain or cure the malignancy.

4. If you know a cancer chemotherapy patient suffering from nausea and vomiting and not responding to THC or other anti-emetics, we suggest you send this Drug Abuse Issue to the physician. You might ask whether the "compassionate" clause can be applied in the case of metoclopramide, for example. This clause allows a doctor to use anti-cancer drugs, which have been shown in controlled research trials to be helpful. Ask whether this clause can be used to include the use of anti-emetics for cancer chemotherapy.

## Sample Letters

Here are sample letters, but it is essential that you write your letters in your own words.

Dr. Vincent de Vita  
Director  
National Cancer Institute  
N.I.H.  
Bethesda, MD 20205

Dear Dr. de Vita:

Thanks to the leadership of the National Cancer Institute and your own pioneering studies, new chemicals are now increasing the incidence of cancer cure. However, as you know, the much-publicized THC pill or NIDA marijuana does nothing to stop nausea and vomiting in patients receiving the widely-used chemotherapy drug cisplatinum, for example. I understand that the "benzamide" compounds such as metoclopramide, and its parent compound alizapride, have been shown by their use in Europe and Canada, to be effective as anti-emetics for cancer chemotherapy patients, including those on cisplatinum.

I am therefore writing to ask whether you plan to initiate a comprehensive series of studies on metoclopramide and alizapride.

I would also like to know whether you plan to do more comparative research on THC to see whether its present free distribution is, in fact, warranted.

Dr. Arthur Hayes, Jr.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Hayes:

Congratulations on your new appointment as FDA Administrator.

I heard you on "Good Morning America" and was interested in your comment, "I hope to speed up our drug approval process and make it more effective."

In line with this, I have a question:

I understand that THC pills and smoked marijuana does help many cancer chemotherapy patients suffering from nausea and vomiting. On the other hand, there are many thousands of patients who get no relief; for example, those undergoing cisplatinum treatments.

Since there are effective and non-psychoactive anti-emetic drugs in the 'benzamide family' which have proved their efficiency with cisplatinum and other forms of chemotherapy drugs in Europe, Canada and elsewhere, I wonder whether the FDA cannot set a higher priority on the evaluation of drugs such as metoclopramide, and alizapride and/or other anti-emetic agents for clinical studies in the U.S.?

I would also like to know whether such drugs and THC are being compared in studies as to their relative anti-emetic effectiveness?

cancer patients who may want or need them.

Dr. Coy Waller, consultant to NIDA and the FDA on drugs of abuse, puts it this way: "Legal marijuana' for research is being promoted in the U.S. and state legislatures are passing laws for this effect. The truth is: **Marijuana is legal for research.** THC has been legal and available for human research projects under Investigative New Drug applications (IND's) approved by the Food and Drug Administration, since 1971, or earlier in certain cases."

Despite this, pro-potters pursue their goal of using the "marijuana as medicine" red herrings towards their final end: legalization of all marijuana for the U.S.A. They continually distort information when presenting it to legislators and to the news media.

Once the states had passed legislation making it legal to smoke marijuana cigarettes as well as using THC capsules in the experimental research, pressure was brought to bear on the government to distribute NIDA-grown marijuana cigarettes to cancer treatment centers in those states which had authorized it. This further "enhanced" the image of "legal marijuana". (Little was said about the fact that in all of these state laws only those cancer patients who do not respond to other anti-emetics or to THC capsules are eligible to risk smoking marijuana with its 421 known chemicals, many of which are injurious.)

The most dangerous aspect of the legislation was that some of the state laws authorized the use of seized street marijuana in the event that the National Cancer Institute is unable to provide an adequate supply of NIDA-grown marijuana cigarettes. Using seized marijuana in experimental medical research violates several Federal statutes designed to protect unwitting sick people from the administration of unapproved drugs.

The final blow is that new studies have found the presence of aspergillus spores (fungus) in random samples of street pot.

In February, 1981, Dr. Steven Kagen, writing in the *New England Journal of Medicine*, reported on fungi of the aspergillus family contained in marijuana. "We have yet to find a sample of marijuana that does not have fungal organisms in it," Dr. Kagen said. "Blood samples of marijuana smokers and those who had never smoked pot were examined. Fifty-two percent of the smokers showed evidence in their blood of exposure to this fungus, compared to one percent of the nonsmokers." (These fungi are not found in tobacco cigarettes.)

Kagen noted that cancer patients often smoke marijuana to lessen the nausea associated with their drug therapy. "While relieving the nausea, patients also expose themselves to fungal spores. This use of marijuana as an anti-emetic ought to be vigorously discouraged. In the lungs of a healthy person, the fungus is battled by the body's immune system. The result may be coughing, wheezing, congestion or a fever (which, in some cases, does not appear until three to 12 hours after smoking).

"But in persons with weak immune defenses, such as cancer patients being treated with chemotherapy, the same infection could cause death."

## The "Synthetic" Story

One common cry of those seeking to use the "marijuana as medicine" route towards legalization of this drug is: "Synthetic" THC pills are less effective than "Real" THC. This is not true. Most of our most effective medications are, in fact, "synthetic", which merely means that researchers

have been able to copy the exact molecular structure of a substance so that it can be reproduced more efficiently, and at far less expense.

Furthermore, natural THC, whether it's still in marijuana, or has been extracted from it, is extremely unstable and loses potency over time. Synthetic THC, according to the National Cancer Institute, "can be manufactured as a pure substance in large quantities and precisely standardized to ensure constant potency." Needless to say, the synthetic THC capsules are free of fungus and of all the other harmful chemical ingredients in marijuana.

But, THC itself--as has been proven by countless studies--has harmful **physical and psychological side effects.** This is so disturbing to some patients, that many have chosen to give up the THC capsules and return to standard anti-emetics such as compazine.

Oncologists' reports as to the numbers of patients helped by THC vary from 30 to 50 percent; chiefly younger patients. In one study comparing THC, a placebo, and compazine, researchers found that the patients on THC pills did as well but no better than those on compazine, but the THC patients had many more side effects. The major THC toxicities noted by oncologists are incoordination, dizziness, ataxia (unstable gait) and paranoia.

Many cancer victims who do get help from THC feel, understandably, that any THC side-effects must play a subsidiary role to the prime job of making the chemotherapy treatment more tolerable.

There are, however, certain types of cancer chemotherapy drugs on which THC does not "work" at all. One such is higher doses of cisplatin, a standard and very effective drug used against ovarian and testicular cancers, as well as lung, bladder, prostate and other cancers.

Fortunately, there are promising alternatives to the THC capsules. And it is here that you, as a Committee of Correspondence member, can play an additionally important role.

## The Alternatives

A group of anti-emetic compounds called **benzamides** were developed in France in 1964. Thus far, the most commonly used of the benzamides is called metoclopramide, which is now used as an anti-emetic in over 100 countries, including Canada. But it is not yet available as an anti-emetic in the U.S. A still newer and even more promising compound is called alizapride, now in use as an anti-emetic in Europe.

Metoclopramide is now being tested in twelve cancer centers around the U.S. Tests have shown that large intravenous doses of this drug, as well as oral doses, block vomiting produced by cisplatin--one of the most "vomit-producing" anti-cancer drugs (on which THC has no effect).

Not only did metoclopramide stop vomiting in 75 percent of the cases, but the physical side effects were minimal and there were no psychological side effects. Because the drug is also effective against nausea and emetic effects of other cancer chemotherapy drugs, it may turn out to be a far more useful anti-emetic than THC.

Dr. George Hyman, a noted oncologist at Columbia College of Physicians and Surgeons, pointed out: "Because THC is fat soluble, it cannot be injected. Consequently, whether taken in pill form or in smoked marijuana, it is only 6 to 20 percent bioavailable (the amount of active ingredients which enter the bloodstream). Metoclopramide, on the other hand, is 100 percent bioavailable, because it can be given intravenously. **Instead of 'pushing' THC any**

further, a better answer would seem to be using a drug like metoclopramide, or its parent compound, alizapride which have a proven margin of safety, a lower toxicity than THC, and far fewer side effects.

"Furthermore," Dr. Hyman said, "in my experience, the benefits of THC, when they do occur, are primarily in the under-30 population, (many of whom are users). Most cancer patients are over thirty. They often get no benefits from THC. All they get is the side effects.

"Pressure should be brought on the FDA to approve metoclopramide for further study in hospitals and medical centers throughout this country."

Dr. Richard Gralla of Memorial Sloan Kettering Cancer Center, has conducted one of the most comprehensive studies using metoclopramide for cancer chemotherapy patients. He concluded that: 1) "metoclopramide is safe to administer at high doses; 2) side effects are mild (slight diarrhea in 50% of patients and mild sedation in 20%) 3) metoclopramide provides a high degree of protection against cisplatin-induced nausea."

In a second study comparing oral doses of metoclopramide to the commonly used anti-emetic compazine, the Mayo Clinic Comprehensive Cancer Center also found that metoclopramide was superior to compazine.

Dr. Don Poster, of the Federal Government's National Cancer Institute has a long title. He is head of the Investigational New Drug Section of the Biologics Evaluation Branch of the Cancer Therapy Evaluation Program. He says: "In preliminary studies using the intravenous high-dose form of metoclopramide, there have been positive effects."

## Fortunately . . .

Metoclopramide, under the trade name Reglan Injectable, has already been approved by the Food and Drug Administration for other purposes (diagnostic use in intubation and radiologic diagnosis). In January, 1981, the pharmaceutical company, A.H. Robins, amended their FDA-approved New Drug Application for Reglan Injectable to make the drug available for patients receiving vomit-producing cancer chemotherapy.

It is important that you write to the FDA urging that they immediately start a comprehensive series of clinical studies on metoclopramide for use by cancer chemotherapy patients. Some of the studies might compare its effectiveness with the THC capsules and/or smoked marijuana. Other studies might compare the effects of metoclopramide and its "parent" alizapride, with the synthetic THC pill and its derivatives, developed by the pharmaceutical companies Lilly and Pfizer. These drugs are called Nabilone and Levonatradol. They are currently under clinical trials. They may be given intramuscularly or orally. They are psychoactive, but do not have as many side effects as the THC pill.

## A "Puzzling" Question

Why is it that, thus far, no commercial ethical drug company has wanted to make THC available as medicine. They could have applied for a license to develop this drug for medicine. But none did so--perhaps for good reason. THC's chemical instability, its variable absorption from one subject to another when given by mouth, its inconsistent production of therapeutic effects, and its wide-ranging effects on the heart, the lungs, the brain, reproductive functions,

etc. has led the pharmaceutical industry to abandon THC and to look for synthetic derivatives. Such derivatives (Nabilone and Levonatradol) have been synthesized and they are readily absorbed (far more soluble than THC). Furthermore, they appear to have more specific effects on nausea and vomiting than THC and they are devoid of many of the side effects of THC.

If the pharmaceutical companies have thus far not been willing to invest in THC capsules for cancer chemotherapy patients, why should U.S. taxpayers be footing the bill to give out this drug? This is an unprecedented step. Never before has the U.S. Government had a multi-million dollar program to disperse free medicine which the private sector (pharmaceutical companies) felt to be not worth developing.

One of the answers to this puzzling question might lie in a Families in Action Newsletter which notes:

"Very few of us would do anything to deny relief to cancer patients suffering from the hideous side effects of chemotherapy, which is one reason NORML has been so successful in its cruel and exploitive campaign. To get what it wants, NORML has played on public empathy for the terminally ill, on our not understanding the scientific method, and on our lack of information about the difference between THC and marijuana.

"The extent to which NORML has been willing to exploit terminally ill cancer patients for its own political ends is appalling."

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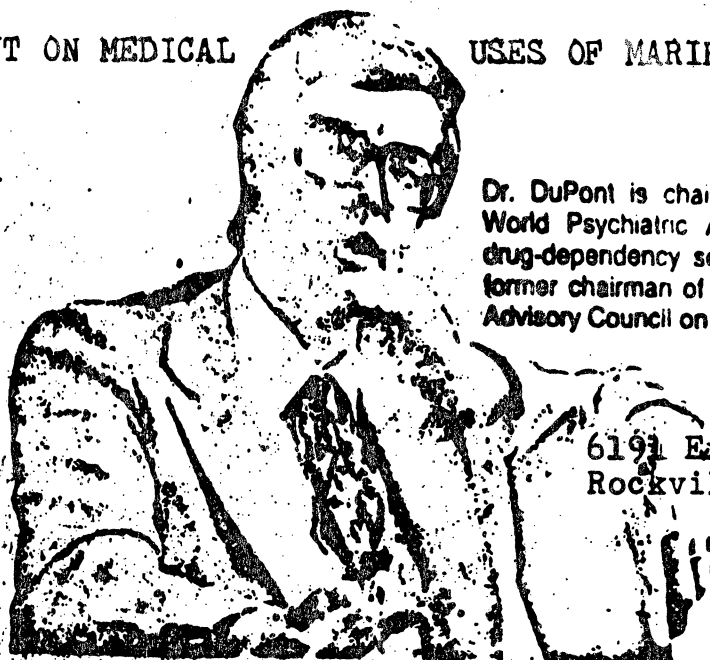
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# Is U.S. Becoming a Drug-Ridden Society?



Dr. DuPont is chairman of the World Psychiatric Association's drug-dependency section and a former chairman of the National Advisory Council on Drug Abuse.

6191 Executive Blvd  
Rockville, Maryland  
20852

For years "decriminalization" was the stalking horse for the marihuana lobby. Today "medical uses" has become the symbol behind which the pro-pot activists are marching. Their target is state legislatures.

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I urge state legislators to oppose bills to make marihuana available as a "medicine". Such laws are not needed and passage of such laws are widely interpreted by the public, especially by youth as a signal that pot is "okay" or even worse that it is "healthy".

*Robert L. DuPont MD*  
Robert L. DuPont, MD

301-468-8980

Comm. from James A. McGrath, Exec. Office of  
Human Services, Div. of Food & Drugs Re: Senate  
Bill 570 entitled "An Act Providing For The Use  
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