PROPOSITION 215: UPDATE #2

People v. Martinez and Miller Sonoma County Chief Deputy District Attorney Kathy DeLoe (707) 527-2311

This case presented the issue whether Health and Safety Code section 11362.5 provided an affirmative defense or was a bar to criminal prosecution. It also raised certain issues regarding whether the recommending physician's identity had to be revealed. The trial court ruled that the section does provide an affirmative defense and that the physician's identity must be revealed.

The defendants have filed a request for writ of mandamus seeking review of all of the trial court rulings. They also requested a stay of the proceedings. As of the date of this update the court of appeals has denied the request for a stay, but has not yet acted on the request for the writ.

People v. Dennis Peron, Beth Moore, et al. Alamada County Senior Assistant Attorney General Ron Bass (415) 356-6185 Deputy Attorney General Mark Howell (415) 356-6238

In this case the management of the Cannabis Buyers' Club are being prosecuted for sale related offenses. This case arose before passage of Proposition 215.

Scheduled hearings on the indictment (a 995 and discriminatory prosecution motion) were continued until April. No trial date has yet been scheduled.

People v. Dennis Peron and Beth Moore San Francisco City and County Senior Assistant Attorney General John Gordnier (916) 324-5169 Deputy Attorney General Jane Zack Simon (415) 356-6286 Deputy Attorney General Larry Mercer (415) 356-6259

The People had successfully enjoined the operation of a buyers' club prior to the passage of Proposition 215. In January, 1997, the trial judge modified the injunction to permit the club to operate provided it made no net profit.

The people filed a request for writ of mandamus from the superior court ruling modifying the injunction against operation of a buyers' club. This writ was filed February 14, 1997.

On March 3, 1997, the Court of Appeals denied the writ, but invited an appeal from the court's order of modification. Notice of appeal was filed March 7, 1997.

People v. Gibson, et al. Mariposa County Deputy District Attorney Quinn Baranski (209) 966-3626

This case involves charges of possession and possession for sale. A motion to remand for further proceedings in the municipal court was made and granted. The theory of the motion was that because the preliminary hearing had occurred before Proposition 215 the defendants had been deprived of their right to present the affirmative defense at that hearing. The motion was granted. When the parties appeared a dispute over the nature of the hearing arose between the court and defense counsel. The result was a motion to disqualify under C.C.P. 170.5. The matter is on calendar for further proceedings March 10, 1997.

People v. Elm Santa Cruz County Assistant District Attorney Paul Marigonda (408) 454-2568

Defendant was charged with violation of Health and Safety Code sections 11358 and 11359. She moved for dismissal of the cultivation charge on the basis of Health and Safety Code section 11362.5. In support of the motion, defendant offered a letter from her psychiatrist which asserted: (1) that defendant suffered from Dysthymia (depressive neurosis); (2) that defendant was using marijuana as treatment; and (3) that defendant had medical reasons for her use of marijuana. On the strength of these three assertions, defendant argued that she was not subject to any criminal prosecution or sanction.

The preliminary hearing judge denied the motion to dismiss. He found that section 11362.5 applied only to "seriously ill" California residents and that the court may determine: (1) whether a person is seriously ill; and (2) whether marijuana use is an appropriate medical use for that person. With those two determinations in mind, the court held that the psychiatrist's letter was insufficient evidence on both the illness and appropriateness issues. In his ruling the judge did suggest that if adequate evidence was presented a pretrial motion to dismiss could be granted.

Preliminary hearing is scheduled for March 14th. A request for writ of mandamus has been filed, but not yet acted upon by the Court of Appeals.

People v. Stockdale Nevada County Deputy District Attorney Katherine Kull (916) 265-1301

In this case a defendant on probation for violation of Health and Safety Code section 11359 seeks to modify a term of probation that prohibits consumption of or possession of marijuana. His reason, of course, is that his physician has recommended use of marijuana.

The matter is set for hearing on March 17, 1997.

People v. King Tulare County Deputy District Attorney Douglas Squires (209) 733-6411

Cultivation of a significant (thirty mature plants) controlled grow. A search warrant was served, the defendant was observed involved in acts consistent with cultivation. Defendant has cancer. This case arose before the passage of Proposition 215.

Attorney Logan has stated his intention to raise Health and Safety Code section 11362.5 as a bar to the prosecution. In the alternative he has stated that he will assert the affirmative defense.

The case is scheduled for preliminary hearing setting on April 1, 1997.

Conant, et al. v. McCaffrey, et al. United States District Court, Northern District Assistant United States Attorney Derrick Watson (415) 436-7073

In this class action seeking declaratory and injunctive relief several physicians have advanced a first amendment theory seeking to prevent the federal agencies from acting to discipline them for recommending use of marijuana. An amended complaint has been filed alleging lack of statutory authority. A hearing on the issues of preliminary injunction and the certification of the class is scheduled for April 11, 1997.

Of interest in connection with this suit which was filed on January 14, 1997, is the federal Health & Human Services letter to Dr. Lewin of C.M.A. (copy attached), dated February 27, 1997.

Legislation Introduced by State Senator John Vascancellos

This legislation is designed to see that Proposition 215: ". be implemented expediently and in a manner that is consistent with the understanding of the voters . . . of the purpose and intent of the measure". The bill, as introduced, contains an "urgency" clause which, if it were enacted and signed by the Governor, would make the law effective immediately.

A copy of the language of the proposed legislation is attached.

♦ Medical Board of California

The Medical Board of California met in Los Angeles on February 8, 1997. On the agenda for this meeting was the topic of the policy of that agency regarding physicians and Proposition 215. A copy of the agenda item presented to the board is attached, the board voted (with one dissenting vote) for the first option.

Essentially, the board concluded that it would evaluate any charges on a case-by-case basis. The agenda item notes, at pages 2 and 3, the advice board staff has been giving. This advice is consistent with the "intractable pain" guidelines which appeared in the April 1996 board publication (copy attached).

• <u>Table</u>

Finally, a copy of a table which appeared in the February 3, 1997, issue of Newsweek magazine is attached. As you can see, it compares "mainstream" treatments with marijuana.

If you have any items of general interest, please notify:

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Senior Assistant Attorney General
Department of Justice
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P.O. Box 944255
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THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. This act shall be known and may be cited as the Proposition 215 Implementation Act of 1997.

SEC. 2. (a) It is the intent of the Legislature that Proposition 215, as approved by the voters on November 5, 1996, be implemented expediently and in a manner that is consistent with the understanding of the voters of California of the purpose and intent of the measure.

This bill requires an urgency to ensure that we keep the faith and will of the people and address the immediate needs of Californians who have a legitimate medical use for marijuana.

- (b) The Legislature finds and declares that by their approval of Proposition 215, California voters affirmed all of the following:
- (1) Medical marijuana is a drug with appropriate uses for the treatment of thousands of Californians suffering from serious illnesses.
- (2) Physician-recommended use of medical marijuana is a health issue and not a criminal justice issue.
- (3) Patients who use medical marijuana in a manner consistent with the measure are not criminals and must not be treated as such.
- . (4) California should develop a method for the safe, affordable distribution of medical marijuana to all patients in need of it.
 - (c) The Legislature also finds and declares all of the following:

- (I) In order to ensure that patients who use medical marijuana in a manner consistent with the measure are not treated as criminals, the Legislature must clarify certain aspects of the measure, because the only alternative is to leave important terms of the measure undefined.
- (2) The greatest obstacle to patient access to medical marijuana in cases where it is medically appropriate is reticence on the part of some licensed physicians and surgeons to recommend it to seriously ill patients for the following reasons:
- (A) There is a need for more scientific research on the appropriate uses of medical marijuana.
- (B) Physicians fear federal or state retribution for recommending or approving patient use of medical marijuana.
- (3) The federal government has failed to conform its medical marijuana policy to the desires of the Legislature, as expressed in Resolution Chapter 70 of the Statutes of 1993, and, therefore, the implementation of Proposition 215 is an urgent issue for the health and safety of suffering Californians.

The Legislature agrees with the January article printed in the New England Journal of Medicine titled, "Federal Foolishness."

- (d) The Legislature hereby acts to resolve these impediments to the implementation of Proposition 215.
 - SEC. 3. Section 11362.51 is added to the Health and Safety Code, to read:
- 11362.51. For purposes of Section 11362.5, the following terms shall have the following meanings:
 - (a) "Physician" means a licensed physician and surgeon by the state.

- (b) "Not subject to criminal prosecution" means that a person charged with an offense under this Article shall have the right to have the claim of medicinal use of marijuana, pursuant to Section 11362.5, determined at a pretrial hearing, and shall retain the right to claim medicinal use of marijuana at any subsequent hearing.
 - SEC. 4. Section 11362.53 is added to the Health and Safety Code, to read:
- 11362.53. Section 11362.5 shall not be construed either to supersede or to conflict with state or local smoking laws in force prior to November 6, 1996.
 - SEC. 5. Section 11362.55 is added to the Health and Safety Code, to read:
- 11362.55. Section 11362.5 shall not be construed to supersede or to conflict with laws prohibiting persons from engaging in conduct that endangers others.
 - SEC. 6. Section 11362.57 is added to the Health and Safety Code, to read:
- 11362.57. For purposes of Section 11362.5, no physician shall recommend or approve use of medical marijuana by an unemancipated minor unless both of the following requirements are met:
- (a) The physician explains the possible risks and benefits of the use to the minor and to at least one of the minor's parents or guardians.
- (b) The parent or guardian has acknowledged in writing that he or she understands the possible risks and benefits.
- SEC. 7. Section 11352.59. (a) The University of California shall create a Medical Marijuana Research Center which shall develop and implement a medical marijuana study intended to ascertain the general medical safety and efficacy of marijuana and to develop medical guidelines for the use of marijuana.

- (b) The center may immediately solicit proposals for research projects to be included in the medical marijuana study.
- (c) The medical marijuana study shall include the greatest amount of new scientific research possible on the medical uses of marijuana. The center shall consult with analogous agencies in other states in an attempt to avoid duplicative research and the wasting of research dollars.
- (d) The medical marijuana study shall be designed to include the broadest variety of patients, physicians, and medical conditions as possible.
- (e) The center shall make every effort to recruit patients and physicians from throughout the state for the medical marijuana study.
 - (f) The medical marijuana study shall employ state-of-the-art research methodologies.
- (g) The center shall ensure that all medical marijuana used in the study is of the appropriate medical quality.
- (h) Within six months of the operative date of this section, the center shall report to the Legislature on the progress of the medical marijuana study.
- (I) Thereafter, the center shall issue a report to the Legislature every six months detailing the progress of the study. The interim reports shall include, but shall not be limited to, data on all of the following:
 - (1) The names and number of diseases or conditions under study.
 - (2) The number of patients enrolled in the study per disease.
 - (3) The patient dropout rate in each disease category.
 - (4) The reasons for patient withdrawal.

- (5) Any scientifically valid preliminary findings.
- (j) The center shall consist of three primary research and development components:
- (1) Clinical Trials Component. To enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent, it is proposed that the California Marijuana Research Center (CMRC) will conduct focused controlled clinical trials on the usefulness of marijuana in conditions such as chronic pain (including AIDS neuropathy), utility of marijuana in treatment of nausea related to chronic disease or antineoplastic chemotherapy, its utility as an anticonvulsant, usefulness in chronic inantition, in treatment of glaucoma, and other possible conditions. In particular, such trials should focus on comparisons between routes of delivery (e.g., inhalational vs. oral) and develop further information on pharmacokinetics.
- (2) Adverse Effects Component. This component of the CMRC would concern itself with (a) safety of medicinal marijuana in patients with various medical disorders, (b) long-term adverse consequences in long-term users be they medically sanctioned or "recreational".
- (3) Prevention and Intervention Component. Irrespective of whether medicinal marijuana is determined to be useful under certain circumstances, because it is a psychoactive drug society has a stake in preventing individuals, particularly children and adolescents, from experimenting with marijuana or becoming regular users. It is proposed that the CMRC develop new and more targeted approaches, whose efficacy can be established, and thereby provide a scientific basis for efforts at prevention. Additionally, it is envisioned that the CMRC will take the lead in developing new treatment techniques directed at those who have become regular marijuana users.

- (k) The Legislature hereby appropriates two million dollars (\$2,000,000) per year for three years, from the General Fund to the Medical Marijuana Research Center to conduct the medical marijuana study.
- (1) The center shall no longer receive funding for the medical marijuana study after three years.
- (m) In order to maximize the scope and size of the medical marijuana study, the California Research Advisory Center is hereby authorized to do all the following:
- (1) Solicit, apply for, and accept funds from foundations, private individuals, and all other funding sources which can be used to expand the scope or time frame of the medical marijuana study which is authorized under Section 11352,59(a).
- (A) In no case shall the California Research Center expend more than five percent (5%) of its allocated General Fund funding in efforts to obtain money from outside sources.
- (2) Include within the scope of the medical marijuana study other medical marijuana research projects that are independently funded and which meet the requirements set forth in 11352.59(a) above.

SEC. 8. Section 11352.62 is added to the Health and Safety Code, to read:

11352.62. (a) Pursuant to Sec. 1.(C) and in keeping faith with the will of the voters, the Legislature hereby creates the Medical Marijuana Distribution System Task Force, which is charged with the research and design of a statewide plan to provide for the safe and affordable testing and distribution of marijuana to all patients in medical need of marijuana.

- (b) In order to provide breadth of perspective and public credibility, the task force shall consist of 12 members broadly reflective of the general public of California, including ethnic minorities, women, and persons of varying economic levels.
- (c) The membership of the task force shall include all of the following, or his or her designee:
 - (1) The Chair of the School of Pharmacy at the University of California, San Francisco.
 - (2) The Chair of the University of California at Davis, School of Agriculture.
 - (3) The Chancellor of the University of California, San Francisco Medical School as chair
 - (d) The Chancellor of the UCSF Medical School shall serve as the chair of the task force.
- (e) The Senate Committee on Rules shall appoint 3 citizen members. The Speaker of the Assembly shall appoint 3 citizen members.
- (f) The Governor shall appoint the remaining 3 members and shall appoint the vice chair of the task force.
- (g) Each appointing authority shall make the required appointments within 30 days of the operative date of this section. The chair or his or her designee shall call the first meeting of the task force within 45 days of the operative date of this section.
- (h) In making the appointments to the task force, each appointing authority is encouraged to appoint persons from varying backgrounds to create a balanced task force. Each appointing authority shall appoint from the following categories, but shall appoint no more than one from any of the categories:
 - (1) Organized physicians' societies or groups.

- (2) Organized registered nurses' societies or groups.
- (3) The health care industry.
- (4) Medical marijuana patients (either past or present).
- (5) Medical marijuana patient advocates.
- (6) The judiciary.
- (7) Law enforcement.
- (I) All members shall be appointed for a term of two years and shall serve without compensation.
- (j) In the event of a resignation, the inability of a member to continue service, or other vacancy, a new member shall be appointed to the task force by the original appointing authority in accordance with the requirements applicable to an original appointment.
- (k) Task force members shall be reimbursed for normal travel and per diem expenses required to attend meetings.
- (l) The chairperson shall appoint a search committee reflective of the composition of the task force which shall, in turn, make recommendations concerning selection of appropriate staff.
- (m) The task force shall hold at least four public hearings per year to gather public input regarding a medical marijuana implementation system. The public hearings shall be held in different regions of the state in order to gather input from the largest number of citizens.
- (n) The task force shall complete its work and report to the Legislature within two years of the first meeting and shall provide the Legislature with an interim report of its progress within one year from that date.

- (o) The task force's report shall recommend to the Legislature a medical marijuana distribution system that meets the criteria outlined in Section 11362.5.
- (p) The sum of one hundred forty thousand dollars (\$140,000) is hereby appropriated from the General Fund to the Medical Marijuana Distribution Systems Task Force. It is the intention of the Legislature to appropriate a like amount through the budget process for the second year of the task force.

SEC. 9. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to ensure that we keep the faith and will of the people and address the immediate needs of Californians who have a legitimate medical use for marijuana, it is necessary that this act take effect immediately.

DEPARTMENT OF HEALTH & HUMAN SERVICES Washington, D.C. 2020!

DEPARTMENT OF JUSTICE Washington, D.C. 20530

February 27, 1997

John C. Lewin MD
Executive Vice President
California Medical Association
P.O. Box 7690
San Francisco, CA 94120

Dear Medical Leader:

On December 30, 1996, Barry R. McCaffrey, Director of the Office of National Drug Control Policy, Attorney General Janet Reno, and Donna E. Shaiala, Secretary of the Department of Health and Human Services (HHS), announced the Administration's position regarding the recent passage of California Proposition 215 and Arizona Proposition 200. Among other things, they stated that the Department of Justice and HHS would follow up with a letter to national, state, and local medical organizations such as yours with respect to the Administration's position.

We are concerned that several misperceptions have developed concerning the federal government's response to the two Propositions. Before their enactment, nothing in federal law prevented a physician, in the context of a legitimate physician-patient relationship, from merely discussing with a patient the risks and alleged benefits of the use of marijuana to relieve pain or alleviate symptoms. This continues to be true.

The federal government recognizes that patients look to their physicians as their primary source of knowledge about a wide variety of potential health hazards and treatments. Thus, physicians are encouraged to talk with patients about their concerns and answer inquiries about any procedure, treatment, substance, or device that may affect a patient's health. Physicians are also encouraged to share their knowledge and their professional expertise regarding the risks, benefits, and legality of any potential medical treatment or modality. No "gag rule" stops physicians from engaging in these discussions.

Such discussions, however, have their limits. Physicians may not intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law. Physicians who do so risk revocation of their DEA prescription authority, criminal prosecution, and exclusion from participation in the Medicare and Medicaid programs.

Federal law establishes specific criteria that every potential medication must meet before vican be sold to the public or prescribed by doctors. For decades, this process of federal drug approval has protected the American public from dangerous drugs and ineffective treatments, and has

Page 2

helped provide the public with a medical care system that is the envy of the world. This process must be preserved. What is, and what is not, a drug with an accepted medical use should continue to be determined through rigorous scientific testing.

To date, the scientific testing of marijuana has not demonstrated that marijuana is a safe and effective drug with an accepted medical use. We remain concerned that the weight of current scientific evidence shows that marijuana can significantly harm the central nervous, cardiovascular, respiratory, and immune systems, and can limit memory, perception, judgment, and the ability to drive a motor vehicle. In addition, marijuana smoke contains over 400 compounds, some of which are carcinogens and may be addictive.

The federal government is undertaking additional steps to analyze carefully the state of all available scientific knowledge about the risks and alleged benefits of marijuana for medicinal purposes. In January, the Office of National Drug Control Policy committed nearly \$1 million to fund a comprehensive review by the Institute of Medicine of the National Academy of Sciences of the existing clinical, medical, and scientific knowledge of the health effects and potential medical use of smoked marijuana. Moreover, on February 19 and 20, 1997, the National Institutes of Health held a two-day workshop at which non-government experts in fields such as cancer treatment, infectious diseases, neurology, and ophthalmology reviewed existing research about marijuana, assessed what is known about its possible therapeutic potential, and discussed the factors to be taken into account in undertaking clinical research of marijuana. If and when there is adequate scientific evidence to support a reclassification of marijuana under the Controlled Substances Act, rulemaking proceedings could be used to change marijuana's current classification as a Schedule I controlled substance. However, unless and until that occurs, current federal law remains in effect.

Sincerely yours,

Jo Tvey Boufford, M.D.

Acting Assistant Secretary for Health

Department of Health and Human Services

Mark M Richard, Esq.

Acting Assistant Attorney General

Criminal Division

Department of Justice



MEDICAL BOARD OF CALIFORNIA

1426 Howe Avenue Sacramento, CA 95825-3236 (916) 263-2389

January 17, 1997

AGENDA NO.

 $(\wp$

To: Members, Medical Board of California

From: Ron Joseph, Executive Director

Re: Proposition 215, Use of Marijuana for Medicinal Purposes

<u>Issue</u>

In view of Proposition 215, what is the Medical Board of California's appropriate position relative to application of the Medical Practice Act to physicians who recommend marijuana to their patients.

Background

On November 5, 1996 Californian's voted for passage of Proposition 215 (see Attachment A). Proposition 215, titled the "Compassionate Use Act of 1996," would seek to provide certain individuals with a defense against prosecution under existing laws which apply to the cultivation, possession, provision, or use of marijuana, when that substance is recommended or used for "medical purposes." One requirement of the law, which became effective immediately upon passage, is that the use of marijuana for the stated medical purpose "... be recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine or any other illnesses for which marijuana provides relief." (Health & Saf. Code § 11362.5(b)(1)(A).)

In order to effectuate that provision, the Act proceeds to declare that "... no physician ... shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes" (Health & Saf. Code §11362.5(c)) [emphasis added]. These are the primary aspects of the Act which would require the Medical Board of California to consider the impact of Proposition 215 on its role of enforcing the Medical Practice Act.

Prior to the passage of Proposition 215, there was no legally defensible basis for causing marijuana to be used. Insofar as doing so could have been determined to be a violation of xisting law, it may have led to a finding that the Medical Practice Act had been violated based on the violation of state or federal drug laws. (It should be noted that the Medical Board of California has never received a complaint related to the recommendation/

prescription of marijuana by a physician and, therefore, has no practical history which would serve as precedence in this area). While there has been no change in the status of marijuana as a Schedule I (no established medical use) drug, physicians are now provided with a defense to its recommendation under state law (see Attachment B for the Attorney General's analysis). Federal law was unchanged by Proposition 215 and will continue to be violated if a physician recommends the use of marijuana to a patient. Under section 2236 of the Business & Professions Code (see Attachment C), prosecution under federal Law for the recommendation of marijuana could give rise to disciplinary action by the Medical Board of California.

In summary, following the passage of proposition 215, a licensee of the Medical Board has little, if any legal certainty concerning his or her authority to recommend marijuana to a patient. The Act and provide a defense in those instances which it addresses (e.g., for seriously ill Calmornians within certain classes of illness), but perhaps not in other instances (e.g., for patients who are not from California); it would continue to violate federal law, but the enforcement of those laws are still uncertain. Attachment C contains the Federal Administration's response to the passage of Proposition 215 and suggests a very strong reaction which may include the criminal prosecution of physicians, revocation of their DEA registration and exclusion from participation in the Medicare and Medicaid program. However, the leading proponent of that policy was reported to have stated on January 14, 1997 that the Governor "will not go after physicians who might recommend this in the context of a established patient, if it's not being done indiscriminately." (Reported in the Sacramento Bee (1/15/97).) The foregoing suggests that there is little about the matter at this time. Policies are still evolving among the many agencies that have some responsibility for enforcement of the laws, and ultimately the courts will probably need to rule on a number of the conflicts and gaps which have resulted from the reasser in which this law was drafted.

Nevertheless, Medical Board staff continues to receive inquiries from concerned physicians asking the position the Medical Board will take regarding a physician's license if he or she is determined to have followed the dictates of Proposition 215. Aside from assuring that the inquiring party is aware of and understands the risks which result from the conflicting laws and multiple enforcement possibilities, there is little in the way of definitive advice which can be offered at this early point. In order to provide some reasoned guidance, staff has been advising callers that if they choose to recommend marijuana to their patients, then they must ensure:

- Their recommendation has been made consistent with a good faith, reasoned application of the spirit and intent of Proposition 215 (This is in contrast to the use of the new statute as a license to sanction the widespread, non-medical use of marijuana.)
- Treatment is for an established patient, or, if a new patient, there has been a history and physical examination performed
- Compliance with medical community standards (Scientifically supported medical standards have
 yet to be developed; while awaiting future studies, it is important that the physician be able to
 articulate the application of reasonable medical rationale in determining when and how the
 redicinal use of marijuana is indicated.)

- A treatment plan and objectives are developed and maintained for each patient
- Informed consent and appropriate disclosure is provided, including discussions of side effects and limitations (e.g., motor vehicle operation)
- Periodic review of the course of treatment occurs throughout the term of the management of the condition
- The physician complies with other drug laws
- Proper record keeping -- this is <u>very</u> important to document that all of the above steps have been taken.

Failure to clearly document these prudent steps, or, if other indications exist that the recommendation(s) made were for the purposes of marijuana distribution rather than for medical care, could result in discipline based on one or more violations of the Medical Practice Act. Inquirers are always cautioned to contact others who have legal responsibility for the enforcement of laws (e.g. DEA, local/state/federal law enforcement agencies ...) or their own private legal counsel. The foregoing was developed to provide a reasonable response to callers in the early period of uncertainty which followed passage of Proposition 215. The Medical Board of California should consider the position which should be taken during the coming period in which this issue will continue to be unsettled.

Alternatives:

1. Make no definitive statement at this time. Declare that with the existing uncertainty, the Medical Board will evaluate any charges brought to its attention on a case-by-case basis to determine whether violation of the Medical Practice Act exists.

<u>Pro</u>: Allows for the evolution of a policy concurrent with those of other affected agencies and as case law directs.

<u>Con</u>: Fails to provide clear guidance to those who are seeking to understand the risks and could lead to inconsistent responses.

2. Prosecute all cases when made aware of them. One expectation of physicians is that they will obey all laws substantially related to the practice of medicine. On the principle that violation of federal drug laws constitutes a violation of that expectation, the Medical Board could establish as its policy the intent to seek discipline in all such cases.

<u>Pro</u>: Establishes a clear, consistent standard and is supportive of espoused federal and state anti-drug efforts.

<u>Con</u>: May require that violation of federal statute be proven first and would probably lead to prolonged litigation.

3. Prosecute no cases in which action consistent with Proposition 215 is alleged as the defense.

Pro: Establishes a clear, consistent standard, and supports the decision of the voters.

Con: Overlooks the probability that some people may use Proposition 215 as a pretext for the distribution of marijuana, with or without medical rationale. The Medical Board's policy should not serve to facilitate that behavior.

4. Declare a set of standards which, if followed, would be accepted by the Medical Board of California as consistent with the principles of the Medical Practice Act and would not lead to disciplinary action. These standards would be consistent with those required in the application of sound medical judgment.

Pro: Would recognize that the Medical Board's authority is confined to physician conduct under the Medical Practice Act, and would serve to define the relationship of Proposition 215 with the Act.

Con: Could be perceived as an implicit approval of the medical use of marijuana and a minimization of the importance of the state and federal anti-drug effort.

Recommendation:

Alternative 4. It is recommended that the Medical Board establish specific standards which will be required of any licensee who chooses to recommend the use of marijuana to his or her patients. A starting point for these standards is found on page 2 of this document. These standards will be disseminated broadly to physicians along with any other information from other agencies as it becomes available.

It is further recommended that the Medical Board of California add its voice to those others, including the California Medical Association who have called on the Federal government to proceed with the necessary scientific research to establish or refute, through objective means, the medical value of marijuana.

Finally, it is recommended that the Medical Board of California commit to work cooperatively with responsible agencies of the federal government, if contacted by them and if that cooperation is consistent with the position taken by the Board.

11:39 ction Report

Medical Board of Californi

April 1996 Vol. 57 A Quarterly Publication

Where Is The Board Going This Үсэг?

₽60-11-1996

Policy Statement:

Medical Practitioners and Sexual Misconduct

Managed Care in California: A Policy Statement and a Statement of Concern 4

Medical Board to Table Fee Increase Legislation

Disciplinary Actions 7-11



The Medical Sourd's policy statement declaring that sexual

misconduct is anacceptable is published in its entirety.



The Medical Board has put off any action on a potential fee increase

pending staff's ongoing review of alternatives.

Viedical Board of California Meeting Dates/Locations

May 10-11 Sacramento July 26-27 San Francisco November 1-2 San Diego

Treatment Of Intractable Pain: A Guideline

The under treatment of intractable puth is often a more significant problem than over treatment, and one reason amon many is the physician's fear that a complaint for over prescribing may put his/her license in jeopardy. The Medical Board of California is aware of this difemma and encourages physicians to apply their best medical judgment when treating the patient, rather than basing their treatment on a fear of discipline by the MBC. To this end, the MBC adopted guidelines on prescribing in July 1994, which were intended to relieve that fear by clarifying the principles of professional practice that are endorself by the Board.

MBC created these requirements to complement legislation (SB 1802, Greene, B&P Code section 2241.5) which established California public policy as supportive of the responsible practice of pain management. Simply stated, the treatment of chronic pain, as is true with any medical treatment, must be consistent with established medical standard. which serve the patient's total well-being.

These guidelines are being republished to reinforce the MBC's position that the public is best served by a health care environment where physicians are free to exert their own best medical judgment consistent with accepted community standards of care.

1. HISTORY/PHYSICAL EXAMINATION A thorough medical history and physical examination must be accomplished. Prescribing controlled substances for intractable pain in Cafifornia also requires evaluation by one or more specialists.

2. TREATMENT PLAN, OBJECTIVES The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function. and indicate if any further diagnostic evaluations or other treatments are planned. Several treatment modalities or a rehabilitation program may be necessary

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian. (Cont. on.p. 6

Medical Board Of California Quality Of Care in A Managed Care Environment

After convening meetings and public forums statewide, the Board adopted two statements on managed care at its February 3, 1996 meeting in Los Angeles. One is a policy statement which focuses on the primacy of the relationship between physician and patient, while the second addresses a concern about the growing trend toward a corporate, business orientation to health care delivery. For nearly a year, the Board's Committee on Quality of Care in a Manager Care Environment heard numerous acquants of treatments denied or delayed, physicians threatened with loss of their contracts if they advocated for their patients, arbitration which was anything but impartial, and other problems. The committee studied current laws and regulations, bills being considered in the 1995 legislative session, and policies adopted by other states.

In addition to the two statements, the Board is pursuing two changes in law. One would require any person who has final decision-making authority over medical matters in a managed care plan to have a current California license. The other would define medical decisions made by plan employees as constituting the practice of medicine. For additional information about these issues, or about upcoming meetings of the Committee, please call Linda McCready at (916) 263-2522.

The full text of both statements are on pages 4 and 5.

THE MISSION OF THE MEDICAL BOARD OF CALIFORNIA

The mission of the Medical Board of California is to protect consumers through proper licensing of physicians and surgeons and certain allied health professions and through the vigorous, objective enforcement of the Medical Practice Act.

Medical Board to Table Fee Increase Legislation

t its November 1995 meeting, the Medical Board of alifornia voted to authorize staff's pursuit of legislation hich would inclease the cailing for biennial license pewal from \$600 to \$700. This action did not atomatically increase those fees, but made a future icrease possible if it were determined to be necessary for entinued program operations. However, at the same time. ic Board directed staff to aggressively review all existing sternal operations, as well as those services paid for by the IBC at the Office of the Attorney General and the Office f Administrative Hearings to determine if there were fficiency improvements available to make a fee increase nnecessary.

hat review was exhaustively pursued over the ensuing tree months and resulted in the identification of some neasures which have the potential to reduce operating costs or the MBC, while maintaining service levels.

Auch work needs to be done to determine if the early indings will lead to success, and MBC staff have already egun to draft the necessary new procedures. Nevertheless, while these options are as yet unproven, they have sufficient respect to have enabled the MBC to call for a delay in the sursuit of legislation which would have made possible a fee

increase in the coming year. As a result, the MBC voted at is February 1996 meeting to defer the pursuit of any increase until such time as staff could further assess the value of recent program improvements, the prospect for future efficiencies, and the resulting funding needs for future operation.

Executive Director Ron Joseph committed to bring back to the Board within the year a complete management plan which will provide a clear picture of the Board's current program responsibilities, and the most cost-efficient options for maintaining its achievement of those responsibilities. Additionally, he will present to the Board the costs of implementing any proposed changes to its consumer protection functions. "The MBC continues to be responsible for a critical public protection role which must be dequately funded. Therefore, the result of this ongoing eview will not guarantee that a fee increase will be innecessary, but it will enable clear decisions to be made concerning the appropriate program levels which that role equires and the cost of those decisions," said Joseph. Combined with our collective resolve to operate costeffectively, this ensures that responsible public policy will be established pursuant to a forthright, value-based model."

Freatment Of Intractable Pain (Cont. from p. 1)

1. PERIODIC REVIEW

The physician should periodically review the course of ppioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress and treatment objectives.

Physician Alert

New Regulation Affecting Faxing of Schedule II Drugs

The Drug Enforcement Administration has made the following interpretation of Title 21. Code of Federal Regulations, (21 CFR), Section 1306.11(d), regarding emergency prescriptions for Schedule II controlled substances: A physician may transmit an emergency Schedule II prescription by facsimile provided that a written prescription is presented to the dispensing pharmacy within 72 hours. All other provisions of 21 CFR. Section 1306.11(d), including the requirement that "Authorization for Emergency Dispensing" be written on the face of the prescription, must be followed.

For further information, please contact DEA's Liaison and Policy Section at (202) 307-7297.

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment to achieve treatment objectives. Physicians should give special attention to those pain patients who are at risk for misusing their medications. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction specialists, and may entail the use of agreements between the provider and the patient to specify rules for medication use.

6 RECORDS

The physician should keep accurate and complete records, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe substances, the physician must be appropriately licensed in California and comply with federal and state regulations for issuing controlled substances prescriptions. Documented adherence to these guidelines will substantially establish the physician's responsible treatment of patients with intractable pain and will serve to defend that treatment practice in the face of complaints which may be brought.

> Medical Board of California Action Report April 1996 Page 6



cine? Federal drug-enforcement officials say the drug is both useless and dangerous. They're challenging the new initiatives in court and vow to punish doctors who prescribe pot to their patients. But proponents claim marijuana can help control glaucoma. forestall AIDS-related wasting, ease the nausea brought on by cancer chemotherapy and counter the symptoms of epilepsy and multiple sclerosis. The claims are largely unproven, but they warrant some serious attention.

Marijuana's basic mode of action is well known. Several years ago, researchers discovered that the body makes a chemical closely resembling THC, the main active ingredient in cannabis, and that the brain has receptors designed specifically to receive it. The receptors are concentrated in the brain regions responsible for motor activity, concentration and short-term memory. As anyone who ever inhaled will attest, marijuana can disrupt all those functions.

The question is whether it can do anything else. For nearly three decades the government has listed marijuana as a "schedule I" drug, a designation reserved for substances with no apparent medical value and a high potential for abuse. Barry McCaffrey, director of the Office of National Drug Control Policy, stoutly defends that ruling, saying there is "no convincing scientific evidence" that marijuana offers benefits that a person can't get from approved prescription drugs.

Where glaucoma is concerned, McCaffrey has a point. It's well known that smoking marijuana can reduce pressure within the eye, a hallmark of the disease. But the drug may also reduce the blood supply to the optic nerve—the last thing a glaucoma sufferer needs—and it doesn't seem to prevent blindness. Even if marijuana could save eyes, smoking it enough would take extraordinary effort. "In order to substantially reduce eye pressure," says Dr. Harry Quigley of Johns Hopkins University's Wilmer Eye Institute, "you'd have to be stoned all the time." When researchers tried dissolving THC in eye drops, they succeeded only in irritating people's eyes, but other compounds proved more useful. As a result, glaucoma patients can now choose from a number of potent topical treatments. The latest, a once-a-day eye drop called Xalatan, is virtually free of major side effects.

Marijuana may not cure glaucoma, but it



The Medical Bottom I

Though largely illegal since 1937, marijuana may prove an effective alternative to more commonly prescribed drugs for some diseases. California, Arizona and Massachusetts are leading the fight to make marijuana more readily available. They aren't alone: 26 states and the District of Columbia have passed various laws and resolutions establishing therapeutic-research programs, allowing doctors to prescribe marijuana, or asking the federal government to lift the ban on medical use.

A PARTY IN	
States with medical-marijuana laws	

CONDITION MA	RIJUANA TREATMEN
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Cancer chemotherapy Often causes extreme nausea and vomiting

AIDS-related wasting Low appetite, loss of lean

 Active ingredient THC reduces vomiting and nausea, alleviates pretreatment anxiety

• Improves appetite

CONVENTIONAL TREATMENT

- Marinol (synthetic THC): Commonly used but can cause intoxication. Pill form only, hard to swallow if you're vomiting.
- Serotonin antagonists such as Zofran (ondansetron): Can be taken intravenously but more expensive than Marinol
- (muscle) mass
- Marinol: Boosts appetite, but smokable marijuana allows better dose control
- Megase (megestrol acetate): Stimulates appetite and may reduce y nausea. Currently being compared to Marinol for cancer patients.

Pain and muscle spasms Associated with epilepsy and multiple sclerosis

 Reduces muscle spasms; may ease incontinence of bladder and bowel and relieve depression

 Dantrium (dantrolene sodium): Capsules or injection can relax \(\frac{1}{12} \). nerves and muscles to calm spasms. Can cause liver damage.

 Lioresal (bectofen): Tablet alleviates spasticity but also causes | | | | | | | | sedation. Sudden withdrawal can cause ballucinations and seizures;

Glaucoma

A progressive form of blindness due to increased pressure inside the eyeball

- When smoked, it reduces pressure within the eye. But it may also reduce blood flow to the optic nerve, exacerbating the loss of vision.
- Xalatan (latanoprost): Once-a-day eye drop. Low rate of side effects. Changes eye color in some users.
- Beta-blocker eye drops: Can cause lethargy and trigger asthma at-
- Miotic eye drops: Allow eye to drain faster but constrict the pupil. dimming vision
- Carbonic anhydrase inhibitors: Decrease production of fluid in the eye, but can cause numbness and weight loss